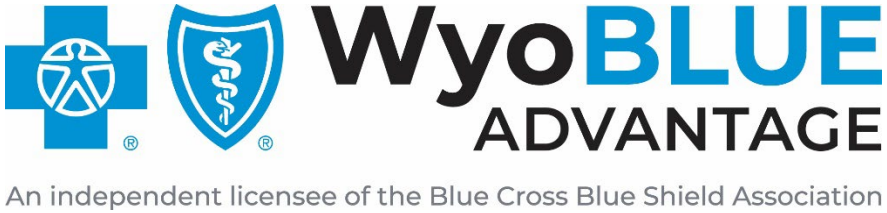
# Medicare Advantage Medical Drug Policy




## Description

This document contains information regarding **WyoBlue Advantage's** Medicare Part B (medical) drugs requiring prior authorization and/or step therapy. For medical procedures, refer to the Medicare Coverage Database and **WyoBlue Advantage's** medical policies for applicable coverage policies.

## Related Medical Coverage Policies

- This policy document is meant to be used alongside the following websites:
  - Medicare Coverage Database Search (website to search for National and Local Coverage Determinations and Coverage Articles [NCD, NCA, LCD, and LCAs]: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

## Policy Guidelines

WyoBlue Advantage adheres to guidance from the Centers for Medicare and Medicaid Services (CMS), including when performing organization determinations for Medicare Advantage Plan members. CMS Medicare statutes, regulations, manuals, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and other sub-regulatory guidance provide the clinical guidelines for coverage determinations, payment integrity functions, and all other uses by CMS regulations. When CMS Medicare guidance is not fully established, CMS permits the plan to utilize "internal coverage criteria", such as

independent criteria, health plan policy research, LCD/LCAs outside the services area or research from independent medical research repositories (i.e., Hayes) for coverage policies 42 CFR § 422.101. WyoBlue Advantage internal medical coverage policies are developed and based on current evidence in widely accepted treatment guidelines or clinical literature; in addition, they address how clinical benefits may or may not outweigh member harm.

**The following is applicable for this medical policy**:
After searching the Medicare Coverage Database and other sources of conditions of coverage, it was determined that CMS guidance is not fully developed, related to codes found in this medical policy. WyoBlue Advantage internal policy coverage criteria will be applied. This service may be medically necessary when the criteria are met.

The above information is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. Please refer to the Medicare Coverage Database website at https://www.cms.gov/medicare-coveragedatabase/search.aspx for the most current applicable NCD, LCD, LCA, and CMS Online Manual System Transmittals.

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## Important Reminder

WyoBlue Advantage follows CMS Medicare coverage guidance to limit coverage to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare Advantage Medical Policies list the criteria WyoBlue Advantage uses to decide which medical services are considered "reasonable and necessary" when Medicare coverage rules are not fully developed, or as otherwise may permitted by CMS Medicare regulations. Individual member benefit plan documents, such as the Evidence of Coverage and Annual Notice of Change, as well as

applicable laws govern benefit coverage, including any inclusion, exclusion, and/or other restrictions.

Medicare Advantage Medical policies are created when permitted by CMS Medicare regulations, reviewed regularly, and may be revised periodically. WyoBlue Advantage Medical Policies are proprietary and should not be copied or disseminated without the express, prior written approval of WyoBlue Advantage. All providers are required to review applicable WyoBlue Advantage reimbursement policies prior to claim submission and bill for covered services in accordance with those policies. Additionally, providers contracted with WyoBlue Advantage's Medicare Advantage network(s) should review the provider manual for any additional claim submission requirements. Providers not contracted with WyoBlue Advantage's Medicare Advantage network may be required to submit documentation to WyoBlue Advantage or its delegated entity supporting billed claims, including but not limited to applicable medical records.

**Note**: U.S. Food and Drug Administration (FDA) approval for a specific indication or the issuance of a CPT code is not sufficient for a procedure to be considered medically reasonable and necessary. Similarly, the presence of a procedure/device code or payment amount for the service in the Medicare fee schedule does not necessarily indicate coverage.

If a service is deemed not reasonable and necessary, to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), the procedure is considered not covered.

**Disclaimer:** This medical policy is not an authorization, certification, explanation of benefits, or a contract for the services, devices, or drugs that is referenced in the medical policy. Medical policies do not constitute medical advice and do not guarantee any results or outcomes or guarantee payment. The medical policy is not intended to replace independent medical judgment for treatment of individuals. Treating physicians and health care providers are solely responsible for determining what care to provide to their patients. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another.

Pursuant to Section 1557 and Section 504, WyoBlue Advantage does not discriminate on the basis of race, color, national origin, age, disability, or sex (including sex characteristics, intersex traits; pregnancy or related conditions; sexual orientation; gender identity, and sex stereotypes). This includes our rules, benefit designs and medical policies.

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| **Abecma**® (idecabtagene vicleucel)<br>**HCPCS:** Q2055 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indications<br>b. FDA approved age<br>c. Prescribed by or in consultation with an oncologist<br>d. Treatment of patients with relapsed or refractory multiple myeloma after at least 2 prior lines of therapy<br>e. Patients must have been treated with all of the following:<br>i. An immunomodulatory agent<br>ii. A proteasome inhibitor<br>iii. An anti-CD38 antibody<br>f. Must have active disease defined by at least one of the following:<br>i. Serum M-protein greater or equal to 1.0 g/dL<br>ii. Urine M-protein greater or equal to 200 mg/24 h<br>iii. Serum free light chain (FLC) assay greater or equal to 10 mg/dL provided the baseline serum FLC ratio is abnormal<br>g. Patients must meet all of the following<br>i. ECOG performance status of 0 - 2<br>ii. No known central nervous system involvement with myeloma<br>iii. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>iv. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>v. Creatinine clearance greater than 30 mL/min<br>vi. Alanine aminotransferase less than 5 times upper limit of normal<br>vii. Left ventricular ejection fraction greater than 40%<br>viii. Platelets greater than 50,000/$mm^3$<br>ix. No second malignancies in addition to myeloma if the second malignancy has required therapy in the last 3 years or is not in complete remission<br>x. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>xi. No thromboembolic events within 6 months<br>xii. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, |

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| | idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>xiii. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>h. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>i. Only to be administered at certified bone marrow/stem cell transplant centers<br>j. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list<br>k. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>l. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case-by-case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
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| **Adakveo®** (crizanlizumab-tmca)<br>**HCPCS:** J0791 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with a hematologist |

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| | d. Patient has experienced 2 or more sickle cell-related crises in the past 12 months<br>e. Trial and failure for at least 6 months, contraindication, OR intolerance to hydroxyurea<br>f. Must not be using long-term red blood cell transfusion therapy<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Patient has experienced a decrease in the number of sickle cell-related crises |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Adstiladrin®** (nadofaragene firadenovec-vncg)<br>**HCPCS:** J9029 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with an oncologist or urologist<br>d. Must be Bacillus Calmette-Guérin (BCG) unresponsive defined as:<br>i. Having received at least 2 previous courses of BCG within a 12-month period defined as<br>1. At least 5 of 6 induction BCG instillations and at least 2 out of 3 instillations of maintenance BCG<br>OR<br>2. At least two of six instillations of a second induction course where maintenance BCG is not given<br>AND<br>ii. Recurrence of high-grade Ta or T1 non-muscle-invasive bladder cancer within 6 months of disease-free state after BCG therapy<br>OR |

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| | iii. Recurrence of carcinoma in situ (CIS) within 12 months of disease-free state after BCG therapy OR<br>iv. Persistent high-grade Ta or CIS or progression to T1 disease after BCG therapy<br>e. ECOG performance score less than or equal to 2<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Continue until unacceptable toxicity or recurrent high-grade (HG) non-muscle invasive bladder cancer (NMIBC) |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Adzynma** (ADAMTS13, recombinant-krhn)<br>**HCPCS:** J7171 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmation of diagnosis by serum assay showing less than 10% of normal ADAMTS13 enzyme activity and genetic testing showing a mutation in the ADAMTS13 gene<br>d. Must not be used in combination with any other therapy for the treatment of congenital thrombotic thrombocytopenic purpura (cTTP)<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the pan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Aflibercept Products**<br>**Aflibercept-yszy** Q5153<br>**Ahzantive** (aflibercept-mrbb) Q5150<br>**Enzeevu** (aflibercept-abzv) Q5149<br>**Eydenzelt**® (aflibercept-boav) J3590<br>**Eylea**® (aflibercept) J0178<br>**Eylea**® **HD** (aflibercept) J0177<br>**Opuviz** (aflibercept-yszy) Q5153<br>**Pavblu** (aflibercept-ayyh) Q5147<br>**Yesafili (**aflibercept-jbvf) Q5155 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Treatment with bevacizumab or a bevacizumab biosimilar has been ineffective, not tolerated or contraindicated<br>i. Trial and failure of bevacizumab is NOT required for those with a diagnosis of diabetic macular edema when visual acuity in the affected eye(s) is less than or equal to 20/50<br>ii. Trial and failure of bevacizumab is not required for those with a diagnosis of retinopathy of prematurity (ROP)<br>d. Diagnosis of ROP<br>i. Must have a maximal gestational age of 32 weeks OR a maximum birth weight of 1,500 grams<br>ii. Must weigh greater than 800 grams on the day of treatment<br>iii. Must have one of the following retinal findings classified according to the International Classification for Retinopathy of Prematurity in the treatment eye(s):<br>1. ROP Zone I Stage 1+, 2+, 3 or 3+ |

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| | 2. ROP Zone II Stage 2+ or 3+<br>3. Aggressive posterior ROP<br>e. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | For at least 60 days and up to one year at a time |
| Renewal Criteria | i. ROP: Patient must meet criteria in sub-bullet A, d to be considered for retreatment<br>ii. All other indications: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Amtagvi™** (lifileucel)<br>**HCPCS:** J3590 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Must have progressive disease following at least one prior systemic therapy including a programmed cell death protein ligand-1 (PD-1) inhibitor and if BRAF V600 mutation-positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor<br>d. Must have at least one measurable, resectable lesion that is a minimum of 1.5 cm in diameter post-resection<br>e. Must not have any of the following: |

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| | i. ECOG performance status > 1<br>ii. Absolute neutrophil count (ANC) ≤ 1,000/$mm^3$<br>iii. Hemoglobin < 9.0 g/dL<br>iv. Platelets ≤ 100,000/$mm^3$<br>v. Alanine transaminase (ALT) and aspartate transaminase (AST) ≥ 5 time the upper limit of normal (ULN)<br>vi. Creatinine clearance < 40 mL/min<br>vii. Left ventricular ejection fraction (LVEF) < 45%<br>viii. Symptomatic and/or untreated brain metastases<br>ix. History of another primary malignancy that has not been in remission for at least 3 years prior to consideration of Amtagvi<br>x. Infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>xi. HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>xii. Any primary immunodeficiency<br>f. Have not received prior treatment with any tumor infiltrating lymphocyte (TIL) therapy despite indication or any other genetically-modified TIL therapy or are being considered for treatment with any other genetically-modified TIL therapy<br>g. Only to be administered at a certified TIL treatment center<br>h. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Amvuttra™®** (vutrisiran)<br>**HCPCS:** J0225 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy(formerly known as familial amyloid polyneuropathy or FAP) and ALL of the following:<br>i. Documentation of TTR gene mutation<br>ii. Signs and symptoms of ocular or cerebral area involvement (such as in ocular amyloidosis or primary/leptomeningeal amyloidosis), if present, must not predominate over polyneuropathy symptomology associated with hATTR<br>iii. Documentation of clinical signs and symptoms of peripheral neuropathy (such as: tingling or increased pain in the hands, feet and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)<br>*AND/OR*<br>Documentation of clinical signs and symptoms of autonomic neuropathy symptoms (such as: orthostasis, abnormal sweating, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])<br>iv. Must have a baseline polyneuropathy disability (PND) score ≤ IIIb and/or baseline FAP Stage 1 or 2<br>c. Diagnosis of wild-type or variant (hereditary) transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) and ALL of the following:<br>i. ATTR-CM diagnosis must be confirmed by ONE of the following:<br>1. A negative monoclonal light chain screen ruling out amyloid light chain cardiomyopathy AND technetium-labeled bone scintigraphy, OR<br>2. Endomyocardial biopsy with confirmatory transthyretin amyloid typing by mass spectrometry, immunoelectron microscopy, or immunohistochemistry<br>ii. For variant ATTR-CM, diagnosis must also be confirmed by documentation of TTR gene mutation<br>iii. Documentation of clinical signs and symptoms of ATTR-CM, including NYHA Class I, II, or III heart failure characterized by limited functional capacity and decline in quality of life |

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| | iv. Trial and failure, contraindication, or intolerance to a transthyretin stabilizer indicated for ATTR-CM, such as Vyndaqel®, Vyndamax®, or Attruby®<br>d. Amvuttra will not be used in combination with other therapies approved for transthyretin-mediated amyloidosis<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Anktiva®** (nogapendekin alfa inbakicept-pmln)<br>**HCPCS:** J9028 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with an oncologist or urologist<br>d. Must be Bacillus Calmette-Guérin (BCG) unresponsive defined as:<br>i. Persistent or recurrent CIS within 12 months of receiving adequate BCG defined as<br>1. At least five of six instillations of an initial BCG induction course plus either<br>- At least two of three instillations of maintenance therapy<br>OR |

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| | - At least two of six instillations of a second induction course<br>ii. Recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG defined as<br>1. At least five of six instillations of an initial BCG induction course plus either<br>- At least two of three instillations of maintenance therapy<br>OR<br>- At least two of six instillations of a second induction course<br>iii. T1 high-grade disease at the first evaluation following an induction BCG course alone defined as<br>1. At least five of six doses of an initial induction course<br>e. All visible papillary tumors must be resected and those with persistent T1 disease on transurethral resection of bladder tumor (TURBT) should undergo an additional re-TURBT within 14 to 60 days prior to beginning Anktiva<br>f. ECOG performance score less than 2<br>g. Must not have concomitant upper tract urothelial carcinoma or urothelial carcinoma within the prostatic urethra<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity up to a maximum of 37 months of therapy |
| Quantity Limitations | Align with FDA recommended dosing. |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Arcalyst®** (rilonacept)<br>**HCPCS:** J2793 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) with phenotypes of Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)<br>i. Laboratory evidence of a genetic mutation (such as in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1 – also referred to as the NLRP-3)) OR<br>ii. Elevated inflammatory markers (C-reactive protein [CRP] and serum amyloid A) plus at least two of six typical CAPS manifestations:<br>1. Urticaria-like rash<br>2. Cold-triggered episodes<br>3. Sensorineural hearing loss<br>4. Musculoskeletal symptoms<br>5. Chronic aseptic meningitis<br>6. Skeletal abnormalities<br>c. Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)<br>i. Laboratory evidence of homozygous genetic mutations of IL1RN<br>ii. Trial and failure, contraindication, or intolerance to Kineret<br>d. Diagnosis of recurrent pericarditis (RP)<br>i. Trial and failure, contraindication, OR intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs) in combination with colchicine<br>ii. Trial and failure, contraindication, OR intolerance to Kineret<br>e. Not to be used in combination with other biologics or targeted DMARDs for the same indication<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list.<br>*****Note: This policy pertains to Medicare Part B only***** |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |

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| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Atezolizumab Products**<br>**Tecentriq**® (atezolizumab) J9022<br>**Tecentriq Hybreza**™ (atezolizumab and hyaluronidase-tqjs) J9024 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Treatment must follow the FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation<br>i. Must be used with concomitant treatment according to FDA indication or NCCN category 1 or 2A recommendation<br>b. Must be prescribed by or in consultation with an oncologist<br>c. FDA approved age<br>d. No prior use or failure with Tecentriq or another program death receptor 1 (PD-L1) inhibitor<br>e. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant<br>f. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | i. Metastatic non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy<br>ii. All other indications: Treatment may be continued until unacceptable toxicity or disease progression |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Aucatzyl**® (obecabtagene autoleucel)<br>**HCPCS:** Q2058 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication[a,b]<br>b. FDA approved age<br>c. Prescribed by or in consultation with an oncologist<br>d. Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to, or have failed 2 lines of and tyrosine kinase inhibitor therapy (TKI), or have failed 1 line of a second generation TKI, or if TKI therapy is contraindicated<br>e. Patient must meet all of the following:<br>i. ECOG performance status 0 - 2<br>ii. No diagnosis of Burkitt's lymphoma<br>iii. No grade 2 to 4 graft-versus-host disease<br>iv. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal<br>v. Creatinine clearance greater than 30 mL/min<br>vi. Cardiac ejection fraction greater than 40%<br>vii. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>viii. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>ix. Has not received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to Aucatzyl infusion<br>x. No known active central nervous system malignancy<br>xi. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months |

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| | xii. No thromboembolic events within 6 months<br>xiii. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>xiv. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>f. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>g. Trial and failure, intolerance, or a contraindication to the preferred products as listed in plan's utilization management medical drug list<br>h. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan.<br>i. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case-by-case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee<br>[a] Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, ie, failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).<br>[b] Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic stem cell transplant |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Benlysta**® (belimumab)<br>**HCPCS:** J0490 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Patients have tested positive for serum antibodies at 2 independent time points<br>d. Patients must have active disease<br>e. If the patient has lupus nephritis ONLY and no other symptoms of system lupus erythematosus (SLE):<br>i. Must have active disease of the kidney confirmed on biopsy<br>f. Patient does not have active central nervous system lupus<br>g. Previous treatment courses of at least 12 weeks each with 2 or more of the following have been ineffective: chloroquine, hydroxychloroquine, methotrexate, azathioprine, cyclophosphamide, OR mycophenolate mofetil, unless all are contraindicated or not tolerated<br>h. Patient is currently receiving and will continue to receive a stable standard of care regimen. Standard of care treatment regimen comprised of any of the following drug classes, alone or in combination:<br>i. Antimalarials<br>ii. Corticosteroids<br>iii. Non-biologic immunosuppressants<br>i. Not to be used in combination with other biologics (ex. Humira®)<br>j. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents or the plan's medical utilization management drug list |
| Authorization Period | 1 year |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Beovu®** (brolucizumab-dbll)<br>**HCPCS:** J0179 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Treatment with bevacizumab or a bevacizumab biosimilar has been ineffective, not tolerated or contraindicated<br>d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | For at least 60 days and up to one year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Bevacizumab Policy**<br>Alymsys® (bevacizumab-maly) Q5126<br>Avastin® (bevacizumab) J9035<br>Avzivi® (bevacizumab-tnjn) J3590<br>Jobevne™ (bevacizumab-nwgd) J9035<br>Mvasi™ (bevacizumab-awwb) Q5107 | |

| Vegzelma® (bevacizumab-adcd) Q5129<br>Zirabev™ (bevacizumab-bvzr) Q5118 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>a. Prescribed by, or in consultation with a hematologist/oncologist<br>b. A diagnosis of persistent, recurrent, or metastatic cervical cancer, when given in combination with paclitaxel and cisplatin or paclitaxel and topotecan<br>c. A diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer<br>i. Platinum-resistant recurrent disease in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan<br>OR<br>ii. Platinum-sensitive recurrent disease in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by bevacizumab or a bevacizumab biosimilar as a single agent<br>OR<br>iii. Stage III or IV disease following initial surgical resection in combination with carboplatin and paclitaxel, followed by bevacizumab or a bevacizumab biosimilar as a single agent<br>d. A diagnosis of metastatic colorectal cancer (adenocarcinoma)<br>e. Recurrent glioblastoma<br>f. A diagnosis of unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer<br>i. Patient has had no prior chemotherapy<br>ii. Bevacizumab or a bevacizumab biosimilar is administered in combination with carboplatin and paclitaxel<br>g. A diagnosis of metastatic renal cell carcinoma<br>i. Bevacizumab or a bevacizumab biosimilar is administered in combination with interferon-alfa<br>h. A diagnosis of unresectable or metastatic hepatocellular carcinoma<br>i. Patient has had no prior chemotherapy |

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| | ii. Bevacizumab or a bevacizumab biosimilar is administered in combination with atezolizumab<br>i. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Continuation of therapy until disease progression or unacceptable toxicity |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Bimzelx®** (bimekizumab-bkzx)<br>**HCPCS:** J3590; C9399 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of psoriasis<br>i. Trial and failure, contraindication, or intolerance to one topical steroid<br>c. Diagnosis of non-radiographic axial spondyloarthritis<br>d. Diagnosis of ankylosing spondylitis<br>e. Diagnosis of psoriatic arthritis<br>f. Diagnosis of hidradenitis suppurativa<br>i. Previous 3-month trial of oral antibiotics<br>g. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic agents (DMARDs) for the same indication |

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| | h. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Botulinum Toxin Type A**<br>**Botox**® (onabotulinumtoxinA) J0585<br>**Daxxify**® (daxibotulinumtoxinA) J0589<br>**Dysport**® (abobotulinumtoxinA) J0586<br>**Xeomin**® (incobotulinumtoxinA) J0588 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided in patients with observed functional impairment originating from spasticity or dystonia (conditions of involuntary sustained muscle contraction) resulting from one of the following conditions:<br>a. Blepharospasm<br>b. Central demyelinating of corpus callosum<br>c. Cerebral Palsy<br>d. Cervical dystonia with documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures<br>e. Demyelinating diseases of CNS<br>f. Facial nerve VII disorders<br>g. Facial nerve disorders, other<br>i. Facial myokymia, Melkersson's syndrome, facial/hemifacial spasms<br>h. Hereditary spastic paraplegia |

i. Laryngeal spasm; laryngeal adductor spastic dysphonia, or stridulus
j. Leukodystrophy (CNS disease characterized by adrenal atrophy and diffuse cerebral demyelination)
k. Multiple sclerosis
l. Neuromyelitis optica
m. Organic writer's cramp
n. Orofacial dyskinesia (i.e., jaw closure dystonia), Meige syndrome
o. Orofacial/ormandibular dystonia with documentation of observed abnormal or repetitive movements of the jaw
p. Schilder's disease
q. Spasmodic dysphonia
r. Spastic hemiplegia
s. Spasticity related to stroke
t. Spasticity related to spinal cord injury
u. Strabismus
v. Torsion dystonia, idiopathic and symptomatic (also known as Oppenheim's dystonia)
w. Upper limb spasticity in adult and pediatric patients 2 years of age and older to decrease the severity of increased muscle tone in elbow flexors, wrist flexors, finger flexors, and thumb flexors
x. Lower limb spasticity in adults and pediatric patients 2 years of age and older to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus and flexor digitorum longus)

B. Botulinum toxin type A may be considered for approval in patients with functional impairment resulting from one of the following conditions when generally accepted treatments are not effective or not tolerated:
a. Anal fissures - patients will be assessed for trial and/or failure with other therapeutic alternatives, such as nitroglycerin ointment.
b. Achalasia/Cardiospasm - in patients who have not responded to dilation therapy or who are considered poor surgical candidates.
c. Primary axillary hyperhidrosis - Botulinum toxin type A may be considered for approval when ALL of the criteria are met:
i. Treatable primary medical conditions and contributing factors (including drugs) causing secondary hyperhidrosis are identified and addressed where possible.
ii. Documented adequate trial of available agents (e.g., Topical antiperspirants, anticholinergic drugs).
iii. Medical treatment of persistent hyperhidrosis is not considered for approval in the absence of significant medical complications associated with the condition.
d. Treatment of hyperhidrosis, including gustatory or palmar hyperhidrosis, may be considered for approval only when the hyperhidrosis is persistent and severe and has resulted in significant medical complications such as skin maceration with secondary infection.
e. Chronic migraine headache - Botulinum toxin type A may be considered for approval when all ALL THREE (3) of the criteria in a, b, and c, below are met:

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| | i. There is a persistent history of recurring debilitating headaches (15 or more days per month with migraine headache lasting for 4 hours per day or longer).<br>AND<br>ii. Adequate trials (at least 6 weeks) of prophylactic therapy from at least TWO different therapy classes listed in Appendix 3 unless all were not effective, contraindicated, or not tolerated.<br>AND<br>iii. Other conditions or aggravating factors that are contributing to the development of chronic migraine headaches are being treated. Possible examples: dental or jaw problems, muscle tension, depression, fibromyalgia, sleep disorders and smoking.<br>f. Urinary incontinence, either idiopathic or due to neurogenic causes (e.g., spinal cord injury, multiple sclerosis), when therapy with two anticholinergics or other agents indicated for the treatment of idiopathic or neurogenic incontinence are not effective or not tolerated.<br>g. Overactive bladder with symptoms of urge incontinence, urgency, and frequency in adults who have an inadequate response to, or are intolerant of two agents for the treatment of overactive bladder (e.g. anticholinergics or beta-3 receptor agonists).<br>h. Chronic sialorrhea (drooling).<br>i. Pelvic floor spasms - patients will be assessed on a case by case basis after trial and failure with at least 2 other therapeutic alternatives, such as muscle relaxants and benzodiazepines.<br>j. Complex and large or recurrent ventral/abdominal hernia repair prior to abdominal wall reconstructions (AWR)<br>k. Trial and failure of the preferred products as listed in the plan's utilization management medical drug list. |
| Authorization Period | a) 6 months for initial therapy<br>b) 1 year for continuation of therapy<br>c) Authorization will be reviewed for objective clinical response to confirm the medication is effective<br>i. For chronic migraine, the frequency or duration for chronic migraines will be reduced from the time of initial presentation with treatment by at least:<br>a) 7 days/month (frequency)<br>b) 100 hours/month (duration) |
| Renewal Criteria | Continuation of therapy requires documented positive clinical response |
| Quantity Limitations | Align with FDA recommended dosing. Any requests greater than this may require supporting documentation |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33646 |
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**Botulinum Toxin Type B Injection**
**Myobloc®** (rimabotulinumtoxinB)
**HCPCS:** J0587

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. A confirmed diagnosis of cervical dystonia or spasmodic torticollis with documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures. Documentation of functional impairment from cervical dystonia or spasmodic torticollis will be required.<br>OR<br>b. Chronic sialorrhea (excessive saliva) in adults.<br>c. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents.<br>d. Botulinum toxin type B is not covered for skin wrinkles or other cosmetic indications<br>e. Botulinum toxin type B is considered investigational when used for all other conditions, including but not limited to:<br>i. Axillary hyperhidrosis<br>ii. Carpal tunnel syndrome<br>iii. Cerebral palsy<br>iv. Palmar hyperhidrosis<br>v. Refractory detrusor overactivity<br>vi. Spasmodic dystonia |

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| | vii. Spastic movement disorders in children<br>viii. Upper limb spasticity following stroke |
| Authorization Period | Initial: 6 months<br>Renewal: Annually |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35172&ver=68&= |
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| **Breyanzi**® (lisocabtagene maraleucel)<br>**HCPCS:** Q2054 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indications<br>b. FDA approved age<br>c. Prescribed by on in consultation with an oncologist<br>d. Diagnosis of relapsed or refractory Non-Hodgkin's lymphoma<br>i. Treatment of patients with relapsed or refractory Non-Hodgkin's lymphoma of the following subtypes:<br>1. Diffuse large B-cell lymphoma (DLBCL)<br>2. Primary mediastinal B-cell lymphoma (PMBCL)<br>3. Follicular lymphoma, grade 3B<br>ii. Received ≥ 2 lines of chemotherapy, including rituximab and anthracycline<br>OR<br>iii. Refractory disease or relapse within 12 months of first-line anti-CD20 and anthracycline therapy |

OR

iv. Refractory disease to first-line chemoimmunotherapy or relapse after first-line therapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age

v. Patients must meet all of the following
   1. ECOG performance status of 0 - 2
   2. Creatinine clearance greater than 30 mL/min
   3. Alanine aminotransferase less than 5 times the upper limit of normal
   4. Left ventricular ejection fraction greater than 40%
   5. No known active CNS involvement by primary malignancy (secondary CNS involvement is allowed)
   6. No history of another primary malignancy that has not been in remission for at least 2 years prior to consideration of CAR-T therapy
   7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
   8. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
   9. No presence of graft-vs-host disease (GVHD)
   10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
   11. No thromboembolic events within 6 months
   12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
   13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis

e. Diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

vi. Must have received at least 2 prior lines of therapy including all of the following
   1. A Bruton tyrosine kinase (BTK) inhibitor
   2. A B-cell lymphoma 2 (BCL-2) inhibitor

vii. Patients must meet all of the following
   1. ECOG performance status of 0 - 2
   2. No known active central nervous system malignancy
   3. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
   4. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
   5. Creatinine clearance greater than 30 mL/min
   6. Alanine aminotransferase less than 5 times upper limit of normal
   7. Left ventricular ejection fraction greater than 40%
   8. Platelets greater than 50,000/$mm^3$

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| | 9. No second malignancies in addition to CLL or SLL if the second malignancy has required therapy in the last 2 years or is not in complete remission<br>10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>11. No thromboembolic events within 6 months<br>12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>f. Diagnosis of relapsed or refractory follicular lymphoma (FL)<br>2. Subjects must have received at least 2 prior lines of therapy including an anti-CD20 monoclonal antibody and an alkylating agent<br>3. Must have measurable disease<br>4. Patient must meet all of the following:<br>1. No prior allogeneic HSCT<br>2. No known active central nervous system malignancy<br>3. ECOG performance status 0 - 2<br>4. No transformed FL<br>5. No histological grade 3b FL<br>6. Creatinine clearance greater than 30 mL/min<br>7. Hepatic transaminases less than 5 times the upper limit of normal<br>8. Cardiac ejection fraction greater than 40%<br>9. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>10. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>11. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>12. No thromboembolic events within 6 months<br>13. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>14. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>g. Diagnosis of relapsed or refractory mantle cell lymphoma (MCL) |

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| | i. Subjects must have received at least two prior line of therapy including all the following:<br>1. An anthracycline or bendamustine-containing chemotherapy<br>2. An anti-CD20 monoclonal antibody therapy<br>3. A Bruton's tyrosine kinase (BTK) inhibitor<br>ii. Must have 1 measurable lesion<br>iii. Patient must meet all of the following:<br>1. No known active central nervous system malignancy<br>2. ECOG performance status 0 - 2<br>3. Creatinine clearance greater than 30 mL/min<br>4. Hepatic transaminases less than 5 times the upper limit of normal<br>5. Cardiac ejection fraction greater than 40%<br>6. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>8. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>9. No thromboembolic events within 6 months<br>10. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>11. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>h. Diagnosis of relapsed or refractory marginal zone lymphoma (MZL)<br>i. Subjects must have received at least 2 prior lines of therapy including an anti-CD20 monoclonal antibody and an alkylating agent OR relapsed after hematopoietic stem cell transplant (HSCT)<br>ii. Must have measurable disease<br>iii. Patient must meet all of the following:<br>1. No known active central nervous system malignancy<br>2. ECOG performance status 0 - 2<br>3. Creatinine clearance greater than 30 mL/min<br>4. Hepatic transaminases less than 5 times the upper limit of normal<br>5. Cardiac ejection fraction greater than 40%<br>6. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>8. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>9. No thromboembolic events within 6 months |

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| | 10. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>11. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>i. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>j. Only to be administered at certified bone marrow/stem cell transplant centers<br>k. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list<br>l. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>m. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the Pharmacy and Therapeutics Committee |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
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| **Calcitonin Gene Related Peptide (CGRP) Antagonists**<br>**Vyepti®** (eptinezumab-jjmr)<br>**HCPCS:** J3032 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.* |

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| | A. Coverage of the requested drug is provided when all the following are met:<br>a. Migraine Prevention:<br>i. FDA approved age<br>ii. Medication is being used for preventive treatment of migraine headaches.<br>iii. Adequate trials (at least 2 month trial) of prophylactic therapy from at least TWO different therapy classes listed in Appendix 1 were not effective, contraindicated, or not tolerated.<br>1. For pediatric patients refer to Appendix 2<br>iv. Not to be used in combination with other CGRP antagonists for migraine prevention<br>b. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | i. 6 months for initial therapy<br>ii. 1 year for continuation of therapy |
| Renewal Criteria | Documentation of at least a 50% or greater reduction in monthly migraine days (MMDs) from baseline |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Carvykti™** (ciltacabtagene autoleucel)<br>**HCPCS:** Q2056 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. FDA approved indication<br>c. Prescribed by an oncologist<br>d. Treatment of patients with relapsed or refractory multiple myeloma after at least 1 prior lines of therapy<br>e. Patients must have been treated with all of the following: |

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| | i. An immunomodulatory agent<br>ii. A proteasome inhibitor<br>f. Must have active disease defined by at least one of the following:<br>i. Serum M-protein greater or equal to 1.0 g/dL<br>ii. Urine M-protein greater or equal to 200 mg/24 h<br>iii. Serum free light chain (FLC) assay greater or equal to 10 mg/dL provided the serum FLC ratio is abnormal<br>g. Must be refractory to lenalidomide defined as failure to achieve minimal response or progression on or within 60 days of completing lenalidomide therapy<br>h. Patients must meet all of the following<br>i. ECOG performance status of 0 - 2<br>ii. No known central nervous system involvement with myeloma as determined by appropriate testing<br>iii. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>iv. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>v. Creatinine clearance greater than 30 mL/min<br>vi. Alanine aminotransferase less than 5 times upper limit of normal<br>vii. Left ventricular ejection fraction greater than 40%<br>viii. Platelets greater than 50,000/$mm^3$<br>ix. No second malignancies in addition to myeloma if the second malignancy has required therapy in the last 3 years or is not in complete remission<br>x. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>xi. No thromboembolic events within 6 months<br>xii. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>xiii. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis |

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| | i. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>j. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>k. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee<br>l. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374 |
| | |
| **Casgevy™** (exagamglogene autotemcel)<br>**HCPCS:** J3392 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with a hematologist<br>d. Sickle cell disease<br>i. Diagnosis of sickle cell disease (SCD) confirmed either via genetic testing or electrophoresis |

ii. Trial and failure, contraindication, or intolerance to hydroxyurea
iii. Must have experienced at least 4 severe vaso-occlusive crises in the past 24 months
iv. Must not have any of the following:
    1. Active infection with HIV-1 or HIV-2, hepatitis B, or hepatitis C
    2. White blood cell count less than $3 \times 10^9$/L or platelet count less than $50 \times 10^9$/L not related to hypersplenism
    3. Advanced liver disease defined as alanine transferase greater than 3 times the upper limit of normal, total bilirubin greater than 2 times the upper limit of normal, baseline prothrombin time 1.5 times the upper limit of normal, or history of cirrhosis, any evidence of bridging fibrosis, or active hepatitis
    4. Prior treatment with an allogenic stem cell transplant
    5. Prior or current malignancy or immunodeficiency disorder
    6. Must not have received prior treatment with any gene therapy for sickle cell disease or are being considered for treatment with any other gene therapy for sickle cell disease

e. β-Thalassemia
    i. Genetic testing confirming diagnosis of β-thalassemia
    ii. Must not have α-thalassemia
    iii. Must be considered transfusion dependent with a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the previous two years OR be managed under standard thalassemia guidelines with ≥ 8 transfusions of pRBCs per year in the previous two years
    iv. Must not have
        1. A prior hematopoietic stem cell transplant (HSCT) or currently be eligible for a HSCT with an HLA matched family donor
        2. Active infection with HIV-1 or HIV-2 infection
        3. Active immunodeficiency disorder or malignancy
        4. Uncorrected bleeding disorder
        5. Advanced liver disease defined as
            a) Alanine transferases greater than 3 times the upper limit of normal (ULN) OR
            b) Direct bilirubin greater than 2.5 times the ULN OR
            c) Baseline prothrombin time or partial thromboplastin time greater than 1.5 times the ULN suspected of arising from liver disease OR

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| | d) Magnetic resonance imaging (MRI) of the liver demonstrating clear evidence of cirrhosis<br>v. Have not received prior treatment with any gene therapy or are being considered for treatment with any other gene therapy for beta-thalassemia<br>f. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan.<br>g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 12 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Cimzia**® (certolizumab pegol)<br>**HCPCS:** J0717 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age.<br>b. Diagnosis of rheumatoid arthritis (RA)<br>i. Trial and failure of at least 3 months of one disease-modifying anti-rheumatic agent (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine<br>c. Diagnosis of psoriatic arthritis (PsA)<br>d. Diagnosis of ankylosing spondylitis (AS) |

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| | e. Diagnosis of Crohn's disease (CD)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>f. Diagnosis of psoriasis (PsO)<br>i. Trial and failure, contraindication, or intolerance to one topical corticosteroid<br>g. Diagnosis of Non-Radiographic Axial Spondyloarthritis (NRAS)<br>h. Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)<br>i. Trial and failure of at least 3 months of one DMARD unless contraindicated or not tolerated. Examples include methotrexate and leflunomide<br>i. The member will self-administer Cimzia unless clinically unable to do so<br>j. Not to be used in combination with other biologics or targeted DMARDs for the same indication<br>k. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or as listed in the plan's prior authorization and step therapy documents. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Cinqair®** (reslizumab)<br>**HCPCS:** J2786 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.* |

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| | A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. FDA approved indication<br>c. Patient is currently receiving, and will continue to receive standard of care regimen<br>d. Severe eosinophilic asthma identified by:<br>i. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment<br>e. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with<br>i. Long acting inhaled β2 agonist modifier for at least 3 months fails to maintain adequate control<br>OR<br>ii. leukotriene modifier for at least 3 months fails to maintain adequate control<br>OR<br>iii. LAMA (long acting muscarininc antagonists) in adults and children ≥ 12 years old for at least 3 months fails to maintain adequate control<br>f. History of treatment failure, intolerance or contraindication to at least a 4 month trial of Fasenra® or Nucala®<br>g. History of treatment failure, intolerance or contraindication to at least a 4 month trial of Dupixent®<br>h. Not to be used in combination with other biologics or targeted DMARDs immunosuppressants for the same indication<br>i. Trial and failure, contraindication, OR intolerance to the preferred products as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time. |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Colony Stimulating Factors (CSFs)**<br>**Armlupeg™** (pegfilgrastim-unne) J3590<br>**Filkri®** (filgrastim-laha) J3590<br>**Fulphila™** (pegfilgrastim-jmbd) Q5108<br>**Fylnetra®** (pegfilgrastim-pbbk) Q5130<br>**Granix®** (tbo-filgrastim) J1447<br>**Leukine®** (sargramostim) J2820<br>**Neulasta®** (pegfilgrastim) J2506<br>**Neulasta On-Pro®** (pegfilgrastim) J2506<br>**Neupogen®** (filgrastim) J1442<br>**Nivestym™** (filgrastim-aafi) Q5110<br>**Nypozi™** (filgrastim-txid) Q5148<br>**Nyvepria™** (pegfilgrastim-apgf) Q5122<br>**Releuko™** (filgrastim-ayow) Q5125<br>**Rolvedon™** (eflapegrastim-xnsxt) J1449<br>**Ryzneuta®** (efbemalenograstim alfa-vuxw) J9361<br>**Stimufend®** (pegfilgrastim-fpgk) Q5127<br>**Udenyca™** (pegfilgrastim-cbqv) Q5111<br>**Udenyca Onbody™** (pegfilgrastim-cbqv) Q5111<br>**Zarxio®** (filgrastim-sndz) Q5101<br>**Ziextenzo™** (pegfilgrastim-bmez) Q5120 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Primary prophylaxis of chemotherapy-induced febrile neutropenia is considered clinically appropriate when ALL of the following are met:<br>i. The individual has a non-myeloid malignancy<br>ii. The individual falls into one of the following risk categories for febrile neutropenia:<br>1. High risk of febrile neutropenia (≥ 20%) based on chemotherapy regimen; OR |

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| | 2. Intermediate risk of febrile neutropenia (≥ 10% but < 20%) based on chemotherapy regimen, and at least ONE of the following significant risk factors:<br>- Age > 65<br>- Poor performance status (ECOG 3 or 4, but chemotherapy still indicated)<br>- Preexisting neutropenia, for example resulting from bone marrow damage or tumor infiltration (ANC < 1500 $mm^3$)<br>- Previous febrile neutropenia episode from a prior treatment regimen<br>- Liver dysfunction, with bilirubin ≥ 1.0 or liver enzymes ≥ 2x upper limit of normal<br>- Presence of open wounds or active infections, when chemotherapy cannot be delayed to accommodate recovery<br>- Renal dysfunction with creatinine clearance of less than 50 mL/min<br>- Poor nutritional status (baseline albumin less ≤ 3.5 g/dL or BMI less than 20)<br>- HIV infection<br>- Advanced cancer (i.e. metastatic or stage IV, unresectable disease).<br>- Multiple (5 or more) chronic conditions or at least two serious comorbidities<br>3. Low risk of febrile neutropenia (>10%) based on chemotherapy regimen, and<br>- Dose reduction is not clinically appropriate<br>- Member has at least TWO of the following significant risk factors:<br>1) Age > 65<br>2) Poor performance status (ECOG 3 or 4, but chemotherapy still indicated)<br>3) Preexisting neutropenia, for example resulting from bone marrow damage or tumor infiltration (ANC < 1,500 $mm^3$)<br>4) Previous febrile neutropenia episode from a prior treatment regimen<br>5) Liver dysfunction, with bilirubin ≥ 1.0 or liver enzymes ≥ 2x upper limit of normal<br>6) Presence of open wounds or active infections, when chemotherapy cannot be delayed to accommodate recovery<br>7) Renal dysfunction with creatinine clearance of less than 50 mL/min<br>8) Poor nutritional status (baseline albumin less ≤ 3.5 g/dL or BMI less than 20) |

9) HIV infection
10) Advanced cancer (i.e. metastatic or stage IV, unresectable disease).
11) Multiple (5 or more) chronic conditions or at least two serious comorbidities

b. Secondary Prophylaxis of febrile neutropenia is considered clinically appropriate when there has been a previous neutropenic complication (in the absence of primary prophylaxis), and a change to the regimen (including dose reduction, schedule change, or change in therapy) would be expected to compromise patient outcome, particularly in the setting of curative intent.
c. Adjunctive treatment of febrile neutropenia is considered clinically appropriate when any of the following risk factors are present:
    i. Age > 65
    ii. Neutrophil recovery is expected to be delayed (greater than 10 days)
    iii. Neutropenia is profound (less than $0.1 \times 10^9$)
    iv. Active pneumonia
    v. Sepsis syndrome (hypotension and/or multi-organ damage/dysfunction noted)
    vi. Invasive fungal or opportunistic infection
    vii. Onset of fever during inpatient stay
d. The following indications by growth factor type are also considered clinically appropriate when the requirements below are met:
    i. Filgrastim and filgrastim biosimilars
        1. Acute lymphocytic leukemia (ALL)
            - After start of induction or first post-remission chemotherapy course; OR
            - As an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
        2. Acute myeloid leukemia (AML)
            - After induction, reinduction, or consolidation; OR
            - As an alternate or adjunct to donor leukocyte infusions (DLI) for relapsed disease after transplant
        3. Aplastic anemia, moderate or severe
        4. To treat severe neutropenia in hairy cell leukemia
        5. Hematopoietic stem cell transplant

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| | - To promote bone marrow myeloid recovery; OR<br>- To treat delayed or failed engraftment; OR<br>- To mobilize stem cells for collection by pheresis<br>6. Myelodysplastic syndrome (MDS)<br>- To treat recurrent infection; OR<br>- To treat neutrophil count < 500 $mm^3$<br>7. Radiation exposure<br>- Following radiation therapy in the absence of chemotherapy, if prolonged delays are expected; OR<br>- After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome)<br>8. Support for dose dense or dose intensive chemotherapy in any of the following scenarios:<br>- Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel; OR<br>- High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; OR<br>- Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma<br>ii. Peg-filgrastim and peg-filgrastim biosimilars<br>1. Acute lymphocytic leukemia (ALL) after the start of induction of first post-remission chemotherapy course<br>2. Hematopoietic stem cell transplant<br>- To promote bone marrow myeloid recovery; OR<br>- To treat delayed or failed engraftment<br>3. Myelodysplastic syndrome (MDS)<br>- To treat recurrent infection; OR<br>- To treat neutrophil count < 500 $mm^3$<br>4. After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome)<br>5. Support for dose dense chemotherapy in any of the following scenarios: |

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| | - Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel; OR<br>- High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; OR<br>- Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma<br>iii. Sargramostim<br>1. Acute lymphocytic leukemia (ALL) after the start of induction or first post-remission chemotherapy course<br>2. Acute myeloid leukemia (AML) after induction, reinduction, for individuals over 55 years of age<br>3. Hematopoietic stem cell transplant<br>- To promote bone marrow myeloid recovery; OR<br>- To treat delayed or failed engraftment; OR<br>- To mobilize stem cells for collection by pheresis<br>4. Myelodysplastic syndrome (MDS)<br>- To treat recurrent infection; OR<br>- To treat neutrophil count < 500 $mm^3$<br>5. Radiation exposure<br>- After radiation therapy in the absence of chemotherapy, if prolonged delays are expected; OR<br>- After accidental or intentional body irradiation of doses greater than 2 Gy (hematopoietic syndrome of acute radiation syndrome)<br>6. Support for dose dense chemotherapy in any of the following scenarios:<br>- Adjuvant treatment of high-risk breast cancer with combination therapy that includes anthracycline (doxorubicin or epirubicin)/cyclophosphamide followed by paclitaxel; OR<br>- High-dose intensity methotrexate, vinblastine, doxorubicin, and cisplatin (HD-M-VAC) in urothelial cancer; OR<br>- Chemotherapy intensification for newly diagnosed, localized Ewing sarcoma |

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| | 7. In combination with naxitamab for pediatric patients one year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy<br>8. In combination with dinutuximab, interleukin-2, and 13-cis-retinoic acid for the pediatric patients with high risk neuroblastoma who achieve at least a partial response to prior first line multiagent, multimodal therapy<br>iv. Tbo-filgrastim for use in hematopoietic stem cell transplant in any of the following scenarios:<br>1. To promote bone marrow myeloid recovery; OR<br>2. To treat delayed or failed engraftment; OR<br>3. To mobilize stem cells for collection by pheresis<br>e. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days up to 6 months at a time |
| Renewal Criteria | a. Authorization may be reviewed at least annually to confirm that current criteria are met and that the medication is effective as demonstrated by a decrease in the interruption of chemotherapy cycles and reduced incidence of febrile neutropenia<br>b. Renewal Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days up to 6 months at a time |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=37176 |
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| **Cosentyx® IV** (secukinumab)<br>**HCPCS:** C9166 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>j. FDA approved indications<br>k. FDA approved age<br>l. Diagnosis of psoriatic arthritis (PsA)<br>m. Diagnosis of ankylosing spondylitis (AS)<br>e. Diagnosis of non-radiographic axial spondyloarthritis (NRAS)<br>f. The member will self-administer Cosentyx unless clinically unable to do so<br>e. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication<br>f. Trial and failure, contraindication, or intolerance to the preferred drugs as listed the plan's prior authorization and step therapy documents and/or the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Crysvita®** (burosumab-twza)<br>**HCPCS:** J0584 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |

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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br><br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of X-linked hypophosphatemia (XLH) confirmed by:<br>i. Genetic testing OR elevated serum fibroblast growth factor 23 (FGF23) level based on the normal range for age AND<br>ii. Low serum phosphate level based on the normal range for age AND<br>iii. Presence of clinical signs and symptoms of the disease (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures)<br>iv. Adults only: trial and failure, contraindication, or intolerance to active vitamin D and phosphate supplements<br>c. Diagnosis of FGF23-related hypophosphatemia in tumor induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be resected or localized confirmed by:<br>i. Elevated FGF23 level based on the normal range for age AND<br>ii. Low serum phosphate level based on the normal range for age AND<br>iii. Low ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) based on the normal range for age AND<br>iv. Presence of clinical signs and symptoms of the disease (e.g. bone pain, fractures, difficulty walking, muscle weakness and fatigue) AND<br>v. Trial and failure, contraindication, or intolerance to active vitamin D and phosphate supplements<br>d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 6 months initially and annually thereafter |
| Renewal Criteria | Clinical documentation showing improvement on therapy such as experienced normalization of serum phosphate and experienced a positive clinical response to burosumab (e.g., enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain) |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Denosumab Products**<br>**Aukelso™** (denosumab-kyqq) J3590<br>**Bildyos®** (denosumab nxxp) J3590<br>**Bilprevda®** (denosumab-nxxp) J3590<br>**Bomyntra®** (denosumab-bnht) Q5158<br>**Bosaya™** (denosumab-kyqq) J3590<br>**Boncresa™** (denosumab-mobz) J3590<br>**Conexxence®** (denosumab-bnht) Q5158<br>**Denosumab-bbdz** J3590<br>**Denosumab-bmwo** J3590<br>**Denousmab-bnht** Q5158<br>**Denosumab-dssb** J Q5159<br>**Enoby™** (denosumab- qbde) J3590<br>**Jubbonti®** (denosumab-bbdz) Q5136<br>**Jubereq®** (denosumab-desu) J3590<br>**Osenvelt® (**denosumab-bmwo) Q5157<br>**Ospomyv™** (denosumab-dssb) Q5159<br>**Osvyrti®** (denosumab-desu) J3590<br>**Oziltus™** (denosumab-mobz) J3590<br>**Prolia®** (denosumab) J0897<br>**Stoboclo®** (denosumab-bmwo) Q5157<br>**Wyost®** (denosumab-bbdz) Q5136<br>**Xgeva®** (denosumab) J0897<br>**Xbryk™** (denosumab-dssb) Q5159 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. For the prevention of skeletal-related events in patients with multiple myeloma or with bone metastases from solid tumors (Xgeva or Xgeva biosimilar only) when the criteria below are met:<br>i. Documentation that at least one IV bisphosphonate has been ineffective, not tolerated or contraindicated<br>OR |

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| | ii. National Comprehensive Cancer Network (NCCN) supported category 1 preferred agent for prevention of skeletal related events in patients with bone metastases for the specific oncological diagnosis<br>b. For the treatment of adults and skeletally mature adolescents with giant cell tumor of bone (Xgeva or Xgeva biosimilar only) when all of the criteria below are met:<br>i. Documentation of confirmed giant cell tumor of bone and radiologic evidence of measurable disease (via CT scan or MRI)<br>ii. Bone is unresectable or surgical resection is likely to result in severe morbidity<br>c. For the treatment of hypercalcemia of malignancy (HCM) refractory to bisphosphonate therapy (Xgeva or Xgeva biosimilar only) when all of the criteria below are met:<br>i. Diagnosis of hypercalcemia secondary to a malignancy (including hematologic malignancies)<br>ii. Albumin corrected serum calcium (CSC) ≥ 12mg/dL (3.0mmol/L)<br>iii. Documentation that at least one IV bisphosphonate has been ineffective, not tolerated or contraindicated<br>d. For the treatment of osteoporosis (Prolia or Prolia biosimilar only) when all of the criteria below are met:<br>i. FDA approved diagnosis<br>ii. At least one bisphosphonate (if patient has intolerance to oral administration, IV administration will be required) is not effective (such as reduction of T-score or fracture) except if:<br>1. Treatment with bisphosphonates (oral and intravenous formulations) are not tolerated or contraindicated<br>e. To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer OR women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer (Prolia or Prolia biosimilar only) when all of the criteria below are met:<br>i. When the 10-year probability of hip fracture is ≥ 3% or the 10-year probability of a major osteoporosis-related fracture is ≥ 20%<br>ii. At least one bisphosphonate (if patient has intolerance to oral administration, IV administration will be required) is not effective (such as reduction of T-score or fracture) except if:<br>1. Treatment with bisphosphonates (oral and intravenous formulations) are not tolerated or contraindicated<br>f. Will NOT be used in combination with any anabolic bone modifying agent or bisphosphonate |

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| | g. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met.<br>h. Trial and failure of the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | 6 months for initial approval and one year at a time for renewal |
| Renewal Criteria | i. Xgeva or Xgeva biosimilar (multiple myeloma or bone metastases from solid tumors and breast cancer): If more than 1 fracture in the last 6 months alternative therapy is recommended<br>ii. Xgeva or Xgeva biosimilar (giant cell tumor of the bone): Goals of therapy have been met<br>iii. Xgeva or Xgeva biosimilar (hypercalcemia of malignancy): Decrease in albumin CSC levels from baseline<br>iv. Prolia or Prolia biosimilar: Documentation of improved or stable T-scores while on Prolia |
| Quantity Limitations | Aligns with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Eculizumab Products**<br>**Bkemv™** (eculizumab-aeeb) Q5139<br>**Epysqli®** (eculizumab-aagh) Q5151<br>**Soliris®** (eculizumab) J1300 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)<br>i. Flow cytometric confirmation of PNH type III red cells<br>ii. Had at least 1 transfusion in 24 months preceding eculizumab<br>OR |

iii. Documented history of major adverse thrombotic vascular events from thromboembolism

OR

iv. Patient has high disease activity defined as a lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms:

1. Weakness
2. Fatigue
3. Hemoglobinuria
4. Abdominal pain
5. Dyspnea
6. Hemoglobin < 10 g/dL
7. A major vascular event
8. Dysphagia
9. Erectile dysfunction

v. Trial and failure, contraindication, or intolerance to Empaveli™

vi. Must not be used in combination with Ultomiris®, Empaveli™, or other medications to treat PNH

c. For a diagnosis of atypical hemolytic uremic syndrome (aHUS)

i. Common causes of typical hemolytic uremic syndrome have been ruled out, including infectious causes of HUS and thrombotic thrombocytopenic purpura (TTP)

ii. Must present with the following symptoms:

1. Hemoglobin < 10 g/dL
2. Platelets < 150,000/$mm^3$
3. Documented evidence of hemolysis, such as, elevated lactate dehydrogenase levels, decreased haptoglobin level, or schistocytosis
4. Increased serum creatinine OR currently undergoing dialysis

iii. Must not be used in combination with Ultomiris or other medications to treat aHUS

d. Diagnosis of refractory generalized myasthenia gravis (MG)

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| | i. Documented diagnosis of refractory, anti-acetylcholine receptor (AChR) antibody positive MG identified by:<br>1. Lab record or chart notes identifying the patient is positive for anti-AChR antibodies<br>AND<br>2. One of the following confirmatory tests:<br>a) Positive edrophonium test<br>b) History of clinical response to oral cholinesterase inhibitors (for example: pyridostigmine)<br>c) Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>ii. Patients must NOT have a history of:<br>1. Thymectomy within 12 months<br>2. Current thymoma<br>3. Other neoplasms of the thymus<br>iii. Must have class II – IV disease<br>iv. Previous treatment courses of at least 12 weeks with one of the following standards of care have been ineffective: methotrexate, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, or tacrolimus unless all are contraindicated or not tolerated<br>v. Patient is currently receiving, and will continue to receive, a stable standard of care regimen<br>vi. Must not be used with other biologic therapies for myasthenia gravis or immunoglobulin therapy<br>e. Diagnosis of aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD)<br>i. FDA approved age<br>ii. Must not be used in combination with Uplizna™, Enspryng™, or other medications to treat neuromyelitis optica spectrum disorder (NMOSD)<br>iii. Adequate trial and failure of an adequate trial of, contraindication, or intolerance to Uplizna, and Enspryng<br>f. Diagnosis of CHAPLE disease<br>i. Confirmed biallelic CD55 loss-of-function mutation |

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| | ii. Must not be used in combination with Veopoz™ or any other C5 complement inhibitor to treat CHAPLE disease<br>g. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Efgartigimod Products**<br>**Vyvgart®** (efgartigimod alfa-fcab) J9332<br>**Vyvgart® Hytrulo** (efgartigimod alfa and hyaluronidase-qvfc) J9334 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Diagnosis of myasthenia gravis<br>i. Documented anti-acetylcholine receptor (AChR) antibody positive myasthenia gravis (MG) identified by:<br>1. Lab record or chart notes identifying the patient is positive for anti-AChR antibodies |

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| | AND<br>2. One of the following confirmatory tests:<br>a) Positive edrophonium test<br>b) History of clinical response to oral cholinesterase inhibitors (for example: pyridostigmine)<br>c) Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>i. Patients must NOT have a history of:<br>1. Thymectomy within 3 months<br>2. Current thymoma<br>3. Other neoplasms of the thymus:<br>ii. Previous treatment courses of at least 12 weeks with one of the following standards of care have been ineffective: methotrexate, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, or tacrolimus unless all are contraindicated or not tolerated<br>iii. Patient is currently receiving, and will continue to receive, a stable standard of care regimen<br>iv. Must not be used with other biologic therapies or immunoglobulin therapy for myasthenia gravis<br>d. Diagnosis of chronic idiopathic demyelinating polyneuropathy (CIDP) (Vyvgart Hytrulo Only)<br>i. Significant functional disability<br>ii. Definitive diagnosis based on the electrodiagnostic criterion from the Joint Task Force of the European Federation of Neurological Societies (EFNS)/Peripheral Nerve Society (PNS)<br>iii. If probable CIDP based on the electrodiagnostic criteria from the Joint Task Force of the EFNS/PNS, then documentation of elevated spinal fluid protein on lumbar puncture or an MRI showing enlarged or enhancing nerves confirming the diagnosis<br>iv. Trail and failure, contraindication, or intolerance to generic corticosteroids or immunoglobulin therapy |

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| | v. Must not be used in combination with other biologic therapies or immunoglobulin therapy for CIDP<br>e. The member will self-administer Vyvgart Hytrulo unless clinically unable to do so<br>f. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Elevidys™** (delandistrogene moxeparvovec-rokl)<br>**HCPCS:** J1413 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Coverage of the requested drug is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit<br>i. The plan is awaiting the results of ongoing clinical trials to provide evidence of a clinical benefit |
| Authorization Period | N/A |
| Renewal Criteria | N/A |

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| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Empaveli™** (pegcetacoplan)<br>**HCPCS:** J3490 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. For the treatment of paroxysmal nocturnal hemoglobinuria (PNH):<br>i. Flow cytometric confirmation of PNH type III red cells<br>ii. Had at least 1 transfusion in 12 months preceding Empaveli<br>OR<br>iii. Documented history of major adverse thrombotic vascular events from thromboembolism<br>OR<br>iv. Patient has high disease activity defined as a lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms:<br>1. Weakness<br>2. Fatigue<br>3. Hemoglobinuria<br>4. Abdominal pain<br>5. Dyspnea<br>6. Hemoglobin < 10 g/dL<br>7. A major vascular event<br>8. Dysphagia<br>9. Erectile dysfunction<br>v. Must not be used in combination with Soliris®, Ultomiris®, or other medications to treat PNH<br>d. For reduction of proteinuria in members with complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN): |

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| | i. Diagnosis of C3G or IC-MPGN confirmed by renal biopsy<br>ii. Patient is currently being treated with a maximally tolerated dose of one of the following:<br>1. Angiotensin-converting enzyme inhibitor (ACE)<br>2. Angiotensin-receptor blocker (ARB)<br>3. Sodium-glucose cotransporter-2 inhibitor (SGLTi)<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Empliciti**® (elotuzumab)<br>**HCPCS:** J9176 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Prescribed by or in consultation with an oncologist or hematologist<br>b. Diagnosis of multiple myeloma<br>c. Used in combination with lenalidomide and dexamethasone after treatment failure with one to three prior lines of therapy; OR<br>d. Used in combination with pomalidomide and dexamethasone after treatment failure with two prior therapies, including lenalidomide and a proteasome inhibitor<br>e. Should not be used if prior treatment failure to Empliciti or another anti-SLAMF7 monoclonal antibody |

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| Authorization Period | Aligns with FDA recommended or guidelines supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Treatment may be continued until treatment failure, disease progression or until unacceptable toxicity occurs |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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**Encelto™** (revakinagene taroretcel-lwey)
**HCPCS:** J3590

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Must have an inner segment - outer segment junction line (IS/OS) photo receptor (PR) break and en face EZ (area of IS/OS loss) as measured by spectral-domain optical coherence tomography (SDOCT) between 0.16 $mm^2$ and 2.00 $mm^2$<br>d. Must have a best corrected visual acuity (BCVA) letter score of 54 or better (greater than or equal to 20/80) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart<br>e. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | 3 months with the allowance of only one dose per eye per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Enjaymo™** (sutimlimab)<br>**HCPCS:** J1302 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Diagnosis of cold agglutin disease confirmed by a cold agglutinin titer level of ≥ 64<br>b. FDA approved age<br>c. Hemoglobin level ≤ 10.0 g/dL<br>d. Prescence of one or more symptoms associated with CAD (including but not limited to symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria)<br>e. Trial and failure, contraindication, OR intolerance to:<br>i. Rituximab in combination with bendamustine<br>OR<br>ii. Rituximab monotherapy if the patient is not a candidate for bendamustine<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing. |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Entyvio® IV** (vedolizumab)<br>**HCPCS:** J3380 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Diagnosis of Crohn's Disease (CD)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>d. Diagnosis of Ulcerative Colitis (UC)<br>1. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>e. The member will self-administer Entyvio unless clinically unable to do so<br>f. Not to be used in combination with other biologics or targeted disease modifying anti-rheumatic drugs (DMARDs) for the same indication<br>g. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Enzyme Replacement Therapy for Fabry Disease**<br>**Elfabrio**® (pegunigalsidase alfa-iwxj) J0180<br>**Fabrazyme**® (agalsidase beta) J2508 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with a geneticist or metabolic specialist<br>d. Confirmation of diagnosis as follows:<br>i. Males: Serum assay of enzyme α- galactosidase showing decreased activity followed by genetic testing showing a mutation in the GLA gene<br>ii. Females: Genetic testing showing a mutation in the GLA gene<br>e. Initiation of therapy should begin as follows:<br>i. Males with classic disease: At time of diagnosis<br>ii. Females and males with atypical disease: Once patient is showing symptoms of Fabry's disease<br>f. Must not be used in combination or with any other enzyme replacement therapy or molecular chaperone for Fabry's disease<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | 1 year at a time |

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| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Enzyme Replacement Therapy for Gaucher's Disease**<br>**Cerezyme**® (imiglucerase) J1786<br>**Elelyso**® (taliglucerase) J3060<br>**Vpriv**® (velaglucerase alfa) J3385 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmation of diagnosis by biochemical assay showing decreased glucocerebrosidase activity in white blood cells or skin fibroblasts AND genotyping revealing two pathogenic mutations of the glucocerebrosidase gene<br>d. Two symptomatic manifestations of the disease are present, such as anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 1 year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |

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| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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**Enzyme Replacement Therapy for Mucopolysaccharidosis (MPS)**
**Aldurazyme**® (laronidase) J1931
**Elaprase**® (idursulfase) J1743
**Mepsevii™** (vestronidase alfa-vjbk) J3397
**Naglazyme**® (galsulfase) J1458
**Vimizim™** (elosulfase alfa) J1322

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Aldurazyme<br>i. FDA approved indications<br>ii. FDA approved age<br>iii. Confirmation of diagnosis by serum assay showing a decrease of α-L-iduronidase activity followed by genetic testing showing a mutation in the IDUA gene<br>b. Elaprase<br>i. FDA approved indication<br>ii. FDA approved age<br>iii. Confirmation of diagnosis by serum assay showing a decrease of iduronate sulfatase activity followed by genetic testing showing a mutation in the I2S gene<br>c. Vimizim<br>i. FDA approved indication<br>ii. FDA approved age |

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| | iii. Confirmation of diagnosis by serum assay showing a decrease in N-acetly-galactosamine-6-sulfatase followed by genetic testing showing a mutation in the GALNS gene<br>d. Naglazyme<br>i. FDA approved indication<br>ii. FDA approved age<br>iii. Confirmation of diagnosis by serum assay of enzyme deficiency of N-acetylgalactosamine-4-sulfatase activity followed by genetic testing showing a mutation in the ARSB gene<br>e. Mepsevii<br>i. FDA approved indication<br>ii. FDA approved age<br>iii. Confirmation of diagnosis by serum assay showing a decrease in β-glucoronidase activity followed by genetic testing showing a mutation in the GUSB gene<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | 1 year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Enzyme Replacement Therapy for Pompe Disease**<br>**Lumizyme**® (alglucosidase alfa) J0221 | |

| **Nexviazyme**® (avalglucosidase alfa-ngpt) J0219<br>**Pombiliti**™ (cipaglucosidase alfa-atga) J1202 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmation of diagnosis by serum assay showing a decrease of acid α-glucosidase activity followed by genetic testing showing a mutation in the GAA gene<br>d. In late-onset disease, symptomatic manifestations of the disease must be present, including but not limited to, progressive muscle weakness, respiratory failure, frequent upper airway infections, orthopnea, sleep apnea, and/or morning headaches (must not present with only cardiac hypertrophy)<br>e. Must not be used in combination or with any other enzyme replacement therapy for Pompe disease<br>f. For Pombiliti only:<br>i. Trial and failure, contraindication, or intolerance to at least one other enzyme replacement therapy for the treatment of Pompe disease<br>ii. Must be used in combination with Opfolda™<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 1 year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Epkinly™** (epcoritamab-bysp)<br>**HCPCS:** J9321 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Treatment of patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high grade B-cell lymphoma after at least 2 prior lines of therapy, one of which is an anti-CD20 antibody containing regimen<br>d. In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have been treated with an anti-CD20 antibody containing regimen<br>e. Treatment of patients with relapsed or refractory FL as monotherapy after two or more prior lines of systemic therapy one of which is an anti-CD20 antibody containing regimen<br>f. Have not received prior treatment with Epkinly or any other bispecific CD20-directed CD3 T-cell engager therapy<br>g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Treatment may be continued until disease progression or until unacceptable toxicity occurs |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Evenity®** (romosozumab-aqqg)<br>**HCPCS:** J3111 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Diagnosis of osteoporosis with a T-score of less than or equal to -2.5, history of a fragility fracture, or high FRAX fracture probability (defined as a 10-year major osteoporotic fracture risk greater than or equal to 20% or hip fracture risk greater than or equal to 3%)<br>b. If member has very high risk osteoporosis: Trial and failure (such as reduction of T-score or fracture) of zoledronate OR if zoledronate is contraindicated a preferred denosumab product<br>i. Very high risk meets ONE of the following criteria:<br>a) Recent fracture (e.g., within the past 12 months)<br>b) Fractures while on approved osteoporosis therapy<br>c) Multiple fractures<br>d) Fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)<br>e) Very low T-score (e.g., less than − 3.0)<br>f) High risk for falls or history of injurious falls<br>g) Very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture > 30%, hip fracture > 4.5%) or other validated fracture risk algorithm<br>c. If member is high risk: Trial and failure (such as reduction of T-score or fracture) of oral or IV bisphosphonates AND preferred denosumab product unless contraindicated<br>d. Will not be used in combination with bisphosphonates, another anabolic bone-modifying agent or denosumab<br>e. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's prior |
| Authorization Period | 12 months |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Evkeeza™** (evinacumab-dgnb)<br>**HCPCS:** J1305 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Trial and therapeutic failure of one high-intensity statin<br>OR<br>d. History of statin-associated side effects or intolerance (e.g., skeletal muscle related symptoms) after a trial of two generic statins<br>OR<br>e. History of rhabdomyolysis after a trial of one statin<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Exdensur™** (depemokimab-ulaa)<br>**HCPCS:** J3590 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment or greater than or equal to 300 cells/microliter within the past 12 months<br>d. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with<br>i. Long-acting inhaled β2 agonist (LABA) for at least 3 months fails to maintain adequate control<br>OR<br>ii. Leukotriene modifier for at least 3 months fails to maintain adequate control<br>OR<br>iii. Long-acting muscarinic antagonists (LAMA) in adults and children ≥ 12 years old for at least 3 months fails to maintain adequate control<br>e. Must be used as add-on maintenance treatment with severe uncontrolled eosinophilic asthma<br>f. Patient is currently receiving, and will continue to receive, standard of care regimen<br>g. Not to be used in combination with other biologics or targeted DMARDs for the same indication.<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Fasenra™** (benralizumab)<br>**HCPCS:** J0517 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. FDA approved indication<br>c. For the diagnosis of severe eosinophilic asthma:<br>i. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment<br>ii. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with<br>1. Long-acting inhaled β2 agonist (LABA) for at least 3 months fails to maintain adequate control<br>OR<br>2. Leukotriene modifier for at least 3 months fails to maintain adequate control<br>OR<br>3. Long-acting muscarinic antagonists (LAMA) in adults and children ≥ 12 years old for at least 3 months fails to maintain adequate control<br>iii. Must be used as add on maintenance treatment with severe uncontrolled eosinophilic asthma<br>iv. Patient is currently receiving, and will continue to receive standard of care regimen<br>d. For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)<br>i. Documentation of a consult with an allergist/immunologist or pulmonologist prior to initiation of Fasenra therapy<br>ii. History or presence of asthma<br>iii. At least 2 of the following criteria that are typical of EGPA<br>1. Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation<br>2. Neuropathy<br>3. Pulmonary infiltrates |

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| | 4. Allergic rhinitis and nasal polyps<br>5. Cardiomyopathy<br>6. Glomerulonephritis<br>7. Alveolar hemorrhage<br>8. Palpable purpura<br>9. Antineutrophil cytoplasmic antibody (ANCA) positivity<br>e. The member will self-administer Fasenra unless clinically unable to do so<br>f. Not to be used in combination with other biologics or targeted disease-modifying antirheumatic drugs (DMARDs) for the same indication<br>g. Trial and failure, contraindication, OR intolerance to the preferred products as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **General Drug Utilization Management Policy**<br>**FDA Approved Drugs**<br>**Unapproved Drugs**<br>**Not Otherwise Classified (NOC) Drugs**<br>**HCPCS:** N/A | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.* |

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| | A. Coverage of the requested drug is provided when all the following are met:<br>a. Drug is used in accordance with the FDA approved prescribing information.<br>b. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents.<br>c. For Part D drugs:<br>i. All medically accepted indications not otherwise excluded from Part D<br>ii. Subject to part B vs part D review |
| Authorization Period | For at least 60 days and up to one year at a time<br>i. For Oncology Vendor Managed Medications Managed via General UM (i.e., supportive care and non-chemotherapy agents): Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time. |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing. Quantity limits may align with recommended maintenance dosing. Use of maximum recommended doses may require review to assess appropriateness (for example, member has been adherent to a lower recommended dose and the dose is deemed ineffective) |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Givlaari**® (givosiran)<br>**HCPCS:** J0223 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of Acute Hepatic Porphyria (AHP) which includes: ALA-Dehydratase Deficiency Porphyria (ADP), Acute Intermittent Porphyria (AIP), Hereditary Coproporphyria (HCP), or Variegate Porphyria (VP) |

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| | c. Documentation of elevated urinary aminolevulinic acid (ALA) OR porphobilinogen (PBG) levels above the lab test upper limit of normal obtained during an acute attack AND/OR genetic testing positive for a mutation consistent with ADP, AIP, HCP, or VP<br>d. Have active disease with at least 2 documented porphyria attacks in the last 6 months OR chronic baseline disease activity with symptoms such as:<br>i. Pain in the abdomen, back, and/or chest<br>ii. Cardiovascular conditions including hypertension and tachycardia<br>iii. Gastrointestinal involvement including nausea, vomiting, and constipation<br>iv. Neurological involvement including neuropathic pain, sensory loss, muscle weakness, paralysis, confusion, anxiety, depression, memory loss, fatigue, hallucinations, seizures<br>v. Other system involvement including respiratory failure, skin lesions, hyponatremia<br>e. Have taken the appropriate lifestyle modifications to prevent acute attacks including, but not limited to: dietary modifications, quitting smoking, stopping alcohol use, and removing medications known to cause acute attacks when possible<br>f. Must not have had a previous liver transplant or have a scheduled liver transplant<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Hemgenix®** (etranacogene dezaparvovec-drlb)<br>**HCPCS:** J1411 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |

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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of moderate to severe hemophilia B<br>c. Prescribed by or in consultation with a hematologist providing attestation of knowledge the patient is suitable for treatment, including the AAV5 viral vector antibody titer<br>d. Must currently be on factor IX therapy with greater than 150 prior exposure days to treatment<br>e. Must not have a history of inhibitors to factor IX or a positive inhibitor screen defined as greater than or equal to 0.3 Bethesda units prior to administration of Hemgenix<br>f. Must not have received prior treatment with any gene therapy for hemophilia B or are being considered for treatment with any other gene therapy for hemophilia B<br>g. Must be being treated at a federally recognized hemophilia treatment center site<br>h. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>i. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 3 months |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Hemophilia Class Policy**<br>**HCPCS:** See Appendix A below | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |

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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Factor VIII products<br>i. Diagnosis of hemophilia A, established by or in consultation with a hematologist<br>AND<br>ii. The requested dose and frequency are within the limits reflecting FDA labeled dosing OR the provider has documented clinical reasoning for higher dosing<br>AND<br>iii. Patient weight, age, history of bleeds (both spontaneous and trauma) and inhibitor status-testing has been completed within the last 12 months and provided to plan<br>AND<br>iv. Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)<br>b. Factor IX products<br>i. Diagnosis of hemophilia B, established by or in consultation with a hematologist<br>AND<br>ii. The requested dose and frequency are within the limits detailed in reflecting FDA labeled dosing OR the provider has documented clinical reasoning for higher dosing<br>AND<br>iii. Patient weight, age, history of bleeds (both spontaneous and trauma) and inhibitor status-testing has been completed within the last 12 months and provided to plan<br>AND<br>iv. Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)<br>c. Hemlibra<br>i. For prophylaxis of bleeding episodes in patients diagnosed with congenital hemophilia A with inhibitors<br>1. Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>2. Documentation of a historical or current high titer for factor VIII inhibitors measuring > 5 Bethesda Units per milliliter (BU/mL) |

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| | 3. Will not be used in combination with Immune Tolerance Induction (ITI)<br>4. Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)<br>ii. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophilia A without inhibitors<br>1. Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>2. Documentation of severe hemophilia A with factor VIII level <1% OR moderate hemophilia A with factor VIII level between 1%-5%<br>3. Documentation of optimally dosed prophylactic factor VIII product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)<br>4. Documentation of the number of bleeds experienced within the past 12 months<br>5. Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)<br>d. Hympavzi<br>ii. Hemophilia A<br>1. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophila A without inhibitors<br>2. Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>3. Documentation of severe hemophilia A with factor VIII level <1% OR moderate hemophilia A with factor VIII level between 1%-5%<br>4. Documentation of optimally dosed prophylactic factor VIII product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)<br>5. Documentation of the number of bleeds experienced within the past 12 months<br>6. Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers) |

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| | 7. Trial and failure, intolerance, or contraindication to Hemlibra<br>iii. Hemophilia B<br>1. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophilia B without inhibitors<br>2. Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>3. Documentation of severe hemophilia B with factor IX level <1% OR moderate hemophilia B with factor IX level between 1%-5%<br>4. Documentation of optimally dosed prophylactic factor IX product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)<br>5. Documentation of the number of bleeds experienced within the past 12 months<br>6. Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome-based results (i.e.: hemophilia treatment centers)<br>e. Alhemo<br>i. Hemophilia A<br>1. For prophylaxis of bleeding episodes in patients diagnosed with congenital hemophilia A with inhibitors<br>a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>b) Documentation of a historical or current high titer for factor VIII inhibitors measuring greater than 5 BU/mL. For those with inhibitors less than 5 BU/mL, a trial and failure of additional higher doses of factor is required.<br>c) Will not be used in combination with Immune Tolerance Induction (ITI)<br>d) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcomes based results (ie: hemophilia treatment centers)<br>e) Trial and failure, intolerance, or contraindication to Hemlibra<br>2. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophilia A without inhibitors<br>a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center |

b) Documentation of severe hemophilia A with factor VIII level <1% OR moderate hemophilia A with factor VIII level between 1%-5%
c) Documentation of optimally dosed prophylactic factor VIII product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)
d) Documentation of the number of bleeds experienced within the past 12 months
e) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome- based results (ie: hemophilia treatment centers)
f) Trial and failure, intolerance, or contraindication to Hemlibra

ii. Hemophilia B

1. For prophylaxis of bleeding episodes in patients diagnosed with congenital hemophilia B with inhibitors
   a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center
   b) Documentation of a historical or current high titer for factor IX inhibitors measuring greater than 5 BU/mL. For those with inhibitors less than 5 BU/mL, a trial and failure of additional higher doses of factor is required.
   c) Will not be used in combination with Immune Tolerance Induction (ITI)
   d) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)
2. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophilia B without inhibitors
   a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center
   b) Documentation of severe hemophilia B with a factor IX level < 1% OR moderate hemophilia B with factor IX level between 1% - 5%
   c) Documentation of optimally dosed prophylactic factor IX product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)
   d) Documentation of the number of bleeds experienced within the past 12 months

e) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers

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i. Hemophilia A

1. For prophylaxis of bleeding episodes in patients diagnosed with congenital hemophilia A with inhibitors

a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center

b) Documentation of a historical or current high titer for factor VIII inhibitors measuring > 5 Bethesda units per milliliter (BU/mL). For those with inhibitors less than 5 BU/mL, a trial and failure of additional higher doses of factor is required.

c) Will not be used in combination with Immune Tolerance Induction (ITI)

d) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)

e) Trial and failure, intolerance, or contraindication to Hemlibra

2. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophilia A without inhibitors

a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center

b) Documentation of severe hemophilia A with factor VIII level <1% OR moderate hemophilia A with factor VIII level between 1%-5%

c) Documentation of optimally dosed prophylactic factor VIII product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)

d) Documentation of the number of bleeds experienced within the past 12 months

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| | e) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)<br>f) Trial and failure, intolerance, or contraindication to Hemlibra<br>ii. Hemophilia B<br>1. For prophylaxis of bleeding episodes in patients diagnosed with congenital hemophilia B with inhibitors<br>a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>b) Documentation of a historical or current high titer for factor IX inhibitors measuring > 5 Bethesda units per milliliter (BU/mL). For those with inhibitors less than 5 BU/mL, a trial and failure of additional higher doses of factor is required.<br>c) Will not be used in combination with Immune Tolerance Induction (ITI)<br>d) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers)<br>2. For prophylaxis of spontaneous bleeding episodes in patients diagnosed with congenital hemophilia B without inhibitors<br>a) Prescribed and dispensed by a specialist that works in a hemophilia treatment center<br>b) Documentation of severe hemophilia B with a factor IX level < 1% OR moderate hemophilia B with factor IX level between 1% - 5%<br>c) Documentation of optimally dosed prophylactic factor IX product is ineffective for the prevention of spontaneous bleeding events (such as: continuing to have bleeding events or arthroscopic changes within a target joint)<br>d) Documentation of the number of bleeds experienced within the past 12 months<br>e) Medication is dispensed by a treatment center associated with hemophilia that provides high quality hemophilia care with outcome based results (ie: hemophilia treatment centers) |

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| | g. For all hemophilia products, the member will be required to self administer unless clinically unable to do so<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list or the plan's prior authorization and step therapy documents |
| Authorization Period | A. Initial Authorization Period: 6 months<br>B. Renewal Authorization Period: 1 year |
| Renewal Criteria | A. Continuation of coverage will be provided when treatment has been proven successful through a decrease in the number of bleeds<br>B. If requesting doses above the standard FDA recommended dosing regimen, documentation that the patient has not developed anti-drug antibodies that impact the clearance or efficacy (Hemlibra only) |
| Quantity Limitations | A. Align with FDA recommended dosing or the quantities listed below with a maximum 30 day supply<br>a. Hympavzi Only: 150 mg weekly. If requesting doses greater than 150 mg weekly, consultation with a Blue Cross Blue Shield medical director is required to discuss if the patient is a candidate for gene therapy |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=150 |
| | |

**Hyaluronic Acid Intra-Articular Injections**

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| **Durolane** | J7318 |
| **Euflexxa** | J7323 |
| **Gel-One** | J7326 |
| **Gelsyn-3** | J7328 |
| **GenVisc 850** | J7320 |
| **Hyalgan** | J7321 |
| **Hymovis** | J7322 |
| **Monovisc** | J7327 |
| **Orthovisc** | J7324 |

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| **Supartz, FX** J7321<br>**Synojoynt** J7331<br>**Synvisc** J7325<br>**Synvisc–One** J7325<br>**Triluron** J7332<br>**TriVisc** J7329<br>**Visco-3** J7321 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Medicare Benefit<br>a. Treatment of osteoarthritis of the knee<br>b. Trial and failure of the preferred products as specified in the plan's utilization management medical drug list |
| Authorization Period | FDA recommended duration of treatment |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39260&ver=5 |
| | |
| **Ilumya™** (tildrakizumab-asmn)<br>**HCPCS:** J3245 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met: |

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| | a. FDA approved age<br>b. Diagnosis of psoriasis (PsO)<br>i. Trial and failure, contraindication, or intolerance to one topical corticosteroid<br>c. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication<br>d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Imaavy™** (nipocalimab-aahu)<br>**HCPCS:** J9256 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Documented anti-acetylcholine receptor (AChR) antibody positive myasthenia gravis (MG) identified by:<br>i. Lab record or chart notes identifying the patient is positive for anti-AChR antibodies AND<br>ii. One of the following confirmatory tests: |

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| | 1. Positive edrophonium test<br>2. History of clinical response to oral cholinesterase inhibitors (for example: pyridostigmine)<br>3. Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>OR<br>d. Documented anti-muscle-specific tyrosine kinase (MuSK) antibody positive MG identified by:<br>i. Lab record or chart notes identifying the patient is positive for anti-MuSK antibodies<br>AND<br>ii. Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>e. Patients must NOT have a history of:<br>i. Thymectomy within 6 months<br>ii. Current thymoma<br>iii. Other neoplasms of the thymus<br>f. Previous treatment courses of at least 12 weeks with one of the following standards of care have been ineffective: methotrexate, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, or tacrolimus unless all are contraindicated or not tolerated<br>g. Patient is currently receiving, and will continue to receive, a stable standard of care regimen<br>h. Must not be used with other biologic therapies for myasthenia gravis or immunoglobulin therapy<br>i. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the the plan's medical utilization management drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Imdelltra™** (tarlatamab-dlle)<br>**HCPCS:** J9026 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with an oncologist<br>d. Treatment of extensive-stage small cell lung cancer with disease progression on or after platinum-based chemotherapy<br>i. Being used as second line therapy for patients whose chemotherapy treatment free interval (CTFI) is less than 6 months<br>OR<br>ii. Patient has documented intolerance or contraindication to platinum based therapy<br>OR<br>iii. Being used as third line or later therapy<br>e. Patient must meet all of the following:<br>i. ECOG performance status 0 - 2<br>ii. Platelet count greater than 100,000/µL<br>iii. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal<br>iv. Creatinine clearance greater than 30 mL/min<br>v. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>vi. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>vii. No untreated or symptomatic brain metastases and leptomeningeal disease |

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| | viii. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 12 months<br>ix. No thromboembolic events within 12 months<br>x. No pulmonary disease requiring oxygen dependence<br>f. Have not received prior treatment with any bispecific delta-like ligand 3 (DLL3)-directed T-cell engager therapy<br>g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time up to the maximum FDA approved duration of treatment |
| Renewal Criteria | Treatment may be continued until disease progression or until unacceptable toxicity occurs |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Imfinzi™** (durvalumab)<br>**HCPCS:** J9173 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Treatment must follow the FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation<br>i. Must be used with concomitant treatment according to FDA indication or NCCN category 1 or 2A recommendation<br>b. Must be prescribed by or in consultation with an oncologist<br>c. FDA approved age<br>d. No prior use or failure with Imfinzi or another program death receptor 1 (PD-L1) inhibitor |

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| | e. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant<br>f. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | i. Unresectable stage III non-small cell lung cancer: Treatment may be continued until disease progression or until unacceptable toxicity occurs, up to maximum of 12 months<br>ii. Extensive stage small cell lung cancer: Treatment may be continued until disease progression or until unacceptable toxicity occurs<br>iii. Locally advanced or metastatic biliary tract cancer: Treatment may be continued until disease progression or until unacceptable toxicity occurs<br>iv. Unresectable hepatocellular carcinoma: Treatment may be continued until disease progression or unacceptable toxicity occurs<br>v. Metastatic non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |

**Immune Globulin Replacement Therapy Medication Use Guidelines**

**Alyglo™** J1552
**Asceniv™** J1599, J1554
**Bivigam®** J1556
**Carimune® NF** J1566
**Cutaquig®** J1599
**Cuvitru™ (SC only)** J1555
**Flebogamma® DIF** J1572
**GamaSTAN® S/D (IM)** J1460/J1560 CPT /90281

**Gammagard® Liquid (IV & SC)** J1569
**Gammagard Liquid ERC®** J1599
**Gammagard® S/D** J1566
**GammakedTM (IV & SC)** J1561
**Gammaplex®** J1557
**Gamunex®-C (IV & SC)** J1561
**Hizentra® (SC only)** J1559
**HyQvia® (SC only)** J1575
**Octagam®** J1568
**Panzyga®** J1576
**Privigen®** J1459
**Qivigy®** (immune globulin (human-kthm) 10%) J1599
**Xembify®** J1558
**Yimmugo®** J3590

| PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br><br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Acquired hemophilia A (acquired factor VIII inhibitor)<br>iv. Confirmation of diagnosis with ALL of the following:<br>1. Factor VIII activity level of greater than 50% of normal for the reference range of the laboratory<br>2. Anti-human factor VIII inhibitor level greater than 0.6 BU/mL<br>v. Trial and failure of ONE of the following:<br>1. Corticosteroids<br>2. Corticosteroids + cyclophosphamide<br>3. Corticosteroids + rituximab or a rituximab biosimilar<br>b. Allogeneic bone marrow transplant (BMT) recipients or patients treated with an anti-CD19 directed chimeric antigen receptor T-cell therapy (CAR-T)<br>vi. Patients with moderate hypogammaglobulinemia evidenced by IgG laboratory findings or an inability to produce an antibody response to protein or carbohydrate antigens, receiving adequate prophylactic antibiotic therapy, and are still have recurrent infections<br>OR<br>vii. Patients with severe hypogammaglobulinemia evidenced by IgG laboratory findings<br>c. Autoimmune encephalitis<br>i. Patient has completed ALL of the following testing:<br>1. Cerebral spinal fluid (CSF) antibody testing |

2. Electroencephalography (EEG) testing to exclude nonconvulsive seizures. Autoimmune encephalitis findings include but are not limited to: focal or generalized slowing, epileptiform activity, or periodic lateralized epileptiform discharges (PLEDs)
3. Brain magnetic resonance imaging (MRI) to exclude a cerebrovascular event or metastatic disease. Autoimmune encephalitis findings include but are not limited to: signal hyperintensities on fluid-attenuated inversion recovery (FLAIR) or T2-weighted images in affected brain regoins

ii. Other conditions have been ruled out

d. Autoimmune hemolytic anemia (AIHA)

viii. Diagnosis of warm-type AIHA confirmed with ALL of the following:
1. Hemoglobin < 10 g/dL
2. Documented evidence of hemolysis, such as, elevated lactate dehydrogenase levels, decreased haptoglobin level, or schistocytosis
3. A direct agglutination (Coombs) test positive for IgG autoantibodies

ix. Trial and failure of TWO of the following:
1. Corticosteroids
2. Rituximab or a rituximab biosimilar
3. Azathioprine
4. Cyclosporin
5. Danazol
6. Mycophenolate mofetil
7. Splenectomy

e. Dermatomyositis

x. Adults
1. Both muscle and cutaneous symptoms are present
1. Trial and failure, contraindication, or intolerance to corticosteroids used in combination with either methotrexate or azathioprine
2. Only cutaneous symptoms are present (examples include: Gottron's sign, Gottron's papules, heliotrope eruption)
1. Failure of a three-month trial of each of the following unless contraindicated or not tolerated:
i. Hydroxychloroquine
ii. Methotrexate
iii. Mycophenolate mofetil

xi. Pediatrics
1. Trial and failure, contraindication, or intolerance to corticosteroids used in combination with either methotrexate or cyclosporine

f. Drug induced secondary hypogammaglobuliemia

xii. Patient has a history of recurrent or persistent severe bacterial infections

xiii. Patients with severe hypogammaglobulinemia evidenced by one of the following

1. A serum IgG less than 700 mg/dL with an inability to produce an antibody response to protein or carbohydrate antigens on vaccination and on prophylactic antibiotic therapy
2. A serum IgG level less than 400 mg/dL and on prophylactic antibiotic therapy
3. A serum IgG level less than 150 mg/dL

g. Fetal alloimmune thrombocytopenia
   xiv. For patients with a previous infant with thrombocytopenia but no intracranial hemorrhage, therapy should be initiated at 20 weeks gestation
   xv. For patients with a previous fetus or neonate with intracranial hemorrhage, therapy should be initiated at 12 weeks gestation
h. HIV infected children
   xvi. Less than 13 years of age
   xvii. Hypogammaglobulinemia evidenced by laboratory findings of low serum IgG
i. Hypogammaglobulinemia associated with either chronic lymphocytic leukemia (CLL), multiple myeloma, or anti-CD-20 monoclonal antibody B-cell lymphoma
   i. Patient is receiving adequate prophylactic antibiotic therapy supported by NCCN guidelines
   ii. Patient has a history of recurrent or persistent severe bacterial infections despite adequate treatment
   iii. Patients with severe hypogammaglobulinemia evidenced by IgG laboratory findings
   OR
   Patients with an inability to produce an antibody response to protein or carbohydrate antigens
j. Hypogammaglobulinemic neonates
   xviii. Patients with low birth weight of less than 1500 g
   xix. Patients less than 30 days of age
k. Inflammatory demyelinating polyneuropathy (acute)
   xx. Significant functional disability, including but not limited to:
      1. Deteriorating pulmonary function tests
      2. Rapid deterioration with symptoms for less than 2 weeks
      3. Rapidly deteriorating ability to ambulate
      4. Inability to walk independently for 10 meters
   xxi. Documentation of elevated spinal fluid protein on lumbar puncture
      1. If lumbar puncture is non-confirmatory:
         1. Documentation of slowing of nerve conduction velocity on EMG/NCS; or
         2. An MRI showing enlarged or enhancing nerves confirming the diagnosis
l. Inflammatory demyelinating polyneuropathy (chronic, CIDP)
   xxii. Significant functional disability
   xxiii. Definitive diagnosis based on the electrodiagnostic criterion from the Joint Task Force of the European Federation of Neurological Societies (EFNS)/Peripheral Nerve Society (PNS)
   xxiv. If probable CIDP based on the electrodiagnostic criteria from the Joint Task Force of the EFNS/PNS, then documentation of elevated spinal fluid protein on lumbar puncture or an MRI showing enlarged or enhancing nerves confirming the diagnosis
   xxv. Must not be used in combination with biologic therapies for CIDP

m. Idiopathic thrombocytopenia purpura (ITP, acute)
   xxvi. Current platelet count < 20,000/µL
   OR
   xxvii. Current platelet count < 30,000/µL and symptoms of active bleeding
n. Idiopathic thrombocytopenia purpura (ITP, chronic)
   xxviii. Thrombocytopenia with a platelet count < 100,000/µL for at least 12 months
   AND
   xxix. The patient's platelet count is currently dangerously low defined as, platelet count < 30,000/µL in children or < 20,000/µL in adults, for patients concurrently receiving corticosteroids or other 2nd line chronic ITP therapies
o. Idiopathic thrombocytopenia purpura in pregnancy
   xxx. Platelet count < 10,000/µL in the 3rd trimester
   OR
   xxxi. Platelet count < 30,000/µL and bleeding
   OR
   xxxii. After steroid failure and ONE of the following:
      1. Platelet count < 10,000/µL in the 1st or 2nd trimester
      2. Platelet count < 30,000/µL, asymptomatic
      OR
   xxxiii. Platelet count < 50,000/µL and patient requires a higher platelet count for an invasive procedure; i.e. planned cesarean delivery
p. Kawasaki syndrome during the first 10 days of diagnosis
q. Lambert-Eaton myasthenic syndrome
   xxxiv. Treatment with at least one oral immunosuppressant is ineffective or not tolerated. Examples of oral immunosuppressants include prednisone, azathioprine, mycophenolate mofetil, and cyclosporine
r. Multifocal motor neuropathy (MMN)
   xxxv. Patient has nerve conduction studies demonstrating focal demyelination and conduction block in the motor nerves and normal sensory nerves
   xxxvi. Documentation of slowly progressive, focal, asymmetric limb weakness; that is, motor involvement in the motor nerve distribution of at least two nerves for more than one month
   xxxvii. Patient does not have objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs
s. Myasthenia gravis (MG)
   xxxviii. Patient is experiencing an acute decompensation presenting as dyspnea or dysphagia
   OR
   xxxix. Patient has refractory disease defined as
      1. Must demonstrate profound muscle weakness throughout the body resulting in one or more of the following:
         a) Slurred speech
         b) Impaired swallowing and choking
         c) Double vision

d) Upper and lower extremity weakness
e) Disabling fatigue
f) Shortness of breath due to respiratory muscle weakness
g) Episodes of respiratory failure

2. Failure of corticosteroids and at least 2 or more immunosuppressive agents (for example: azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, and tacrolimus)

OR

xl. Using preoperatively as a bridge to thymectomy in patients with persistent respiratory impairment or dysphagia despite treatment with pyridostigmine or immunosuppression

xli. Must not be using with other biologic therapies for myasthenia gravis

t. Pediatric intractable epilepsy

xlii. Patient is NOT a candidate for surgical resection

OR

xliii. Other interventions are ineffective or not tolerated, including but are not limited to, anticonvulsant medications, ketogenic diets, vagus nerve stimulation, and steroids

u. Polymyositis (PM)

xliv. Trial and failure, contraindication, or intolerance to corticosteroids used in combination with either methotrexate or azathioprine

v. Post-transfusion purpura

i. History of transfusion of platelet-containing blood products occurring within 14 days prior to symptom onset
ii. Severe thrombocytopenia defined as less than 10,000 platelets/µL
iii. Presence of mucocutaneous bleeding; common sites of bleeding include, but are not limited to, mucous membranes, the gastrointestinal tract, and the urinary tract
iv. Identification of platelet antibodies in the patient's serum against one of the following human platelet antigens (HPA): HPA-2a, HPA-2b, HPA-3a, HPA-3b, HPA-4a, HPA-5a, HPA-5b, HPA-15b, or CD36/GPIV

w. Primary humoral immunodeficiency diseases

xlv. Transient hypogammaglobulinemia of infancy

1. Patients is 24 months of age or under at the time of symptom onset
2. Patients with severe hypogammaglobulinemia evidenced by IgG laboratory
3. Patient has a history of recurrent or persistent severe bacterial infections despite adequate treatment

xlvi. X-linked agammaglobulinemia (congenital agammaglobulinemia)

1. Patients with severe hypogammaglobulinemia evidenced by IgG laboratory
2. Patient has less than 2% CD19+ B cells
3. Patient has a mutation in the BTX gene

OR

Patient has absent BTK mRNA on Northern blot analysis of neutrophils or monocytes

OR

Patient has absent BTK protein in monocytes or platelets

OR

Patient has maternal cousins, uncles, or nephews with less than 2% CD19+ B cells

xlvii. Common variable immunodeficiency (CVID)
1. Patients with severe hypogammaglobulinemia, evidenced by IgG laboratory findings
2. Patients with an inability to produce an antibody response to protein or carbohydrate antigens

xlviii. Immunoglobulin subclass deficiency (e.g., X-Linked immunodeficiency with hyper-IgM)
1. Patients with an inability to produce an antibody response to protein or carbohydrate antigens
2. Patient has a history of recurrent or persistent severe bacterial infections despite adequate treatment
3. Patient has a deficiency of one or more IgG subclasses, assessed on two occasions
4. Patient has normal total serum IgG levels
5. Patient has aggressive management of other conditions predisposing to recurrent sinopulmonary infections

xlix. Combined immunodeficiency syndromes
1. Patients with a combined immunodeficiency confirmed by molecular genetic testing
OR
2. Patients with absent or below normal levels of both B- and T-lymphocytes AND an inability to produce an antibody response to protein or carbohydrate antigens

l. Idiopathic hypogammaglobulinemia
1. Patients without a diagnosed primary immunodeficiency
2. Patients with severe hypogammaglobulinemia evidenced by IgG laboratory findings
3. Patients with an inability to produce an antibody response to protein or carbohydrate antigens
4. Patient has a history of recurrent or persistent severe bacterial infections despite adequate treatment, including all of the following:
a) Aggressive management of other conditions predisposing to recurrent sinopulmonary infections
b) Prophylactic antibiotics

x. Prophylactic post exposure for hepatitis A, measles (rubeola), varicella, and rubella in early pregnancy (GammaSTAN only)

li. Hepatitis A within two weeks following exposure
1. Not to be administered if clinical manifestations of hepatitis A are present

lii. Measles (rubeola) within less than 6 days of exposure
1. Must be a susceptible person (one who has not been vaccinated and has not had measles previously) or a pregnant woman without evidence of immunity
2. Measles vaccine may not be co-administered with GamaSTAN

liii. Varicella in immunosuppressed patients when varicella zoster immune globulin (human) is unavailable

liv. Rubella in exposed pregnant women who will not consider a therapeutic abortion

y. Pure red cell aplasia (PRCA)

lv. Diagnosis of pure red cell aplasia confirmed with ALL of the following:
1. Normocytic, normochromatic red blood cells
2. Absolute reticulocyte count < 10,000/µL (< 1% reticulocytes)
3. Normal white blood cell and platelet counts in the absence of a concurrent disorder such as chronic lymphocytic leukemia (CLL)
4. Less than 1% erythroblasts on bone marrow differential count
5. No significant abnormalities in the myeloid, lymphocytic, or megakaryocyte lineages, unless the patient has a concurrent diagnosis of CLL or chronic myeloid leukemia (CML)

lvi. Postive test for parvovirus B19

z. Refractory pemphigus foliaceus

lvii. Diagnosis of pemphigus foliaceus as supported by ALL the following:

1. Cutaneous lesions, including superficial blisters and/or scaly, crusted erosions, in seborrheic skin areas (i.e. chest, scalp, face, interscapular region)
2. Subcorneal or granular layer acantholysis found on biopsy
3. Demonstration of intercellular deposition of immunoglobulin G (IgG) and/or C3 on direct immunofluorescence (DIF) OR demonstration of IgG antibodies to desmoglein 1 on enzyme-linked immunosorbent assay (ELISA)

lviii. Trial and failure of systemic corticosteroids and at least one of the following after 6 - 8 weeks of treatment unless contraindicated or not tolerated: azathioprine, mycophenolate mofetil, mycophenolate sodium, or rituximab/rituximab biosimilar

aa. Solid organ transplant

lix. For the prevention of antibody mediated rejection prior to solid organ transplant when patient is at high risk for antibody-mediated rejection OR

lx. Following solid organ transplant for the treatment of antibody-mediated rejection

bb. Stiff-Person Syndrome

lxi. Trial and failure, contraindication, or intolerance to maximally tolerated doses of oral diazepam or oral clonazepam

lxii. Trial and failure, contraindication, or intolerance to maximally tolerated doses of oral baclofen

cc. Systemic lupus erythematosus

lxiii. Diagnosis of lupus thrombocytopenia requiring acute treatment with platelets less than 30,000/$mm^3$

lxiv. Trial and failure of, contraindication, or intolerance to high-dose glucocorticoids

dd. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents

ee. BCBSM/BCN does not consider intravenous immune globulins to be self-administered medications and they are covered under the medical benefit. Subcutaneously administered immune globulin may be considered under the pharmacy benefit

ff. Subcutaneous and intravenous immune globulin products are not to be used in combination

B. Investigational Uses Including But Not Limited to:

a. Acute lymphocytic leukemia
b. Acute renal failure
c. Adrenoleukodystrophy
d. Adult HIV infection
e. Alzheimer's disease
f. Aplastic anemia
g. Asthma
h. Atopic dermatitis
i. Autism
j. Behçet's syndrome (Behçet's disease)

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| | k. Cardiomyopathy, recent-onset dilated<br>l. Chronic fatigue syndrome<br>m. Clostridium difficile, recurrent<br>n. Cystic fibrosis<br>o. Diabetes<br>p. Diamond-Blackfan anemia<br>q. Endotoxemia<br>r. Heart block, congenital<br>s. Hemolytic anemia<br>t. Hemolytic transfusion reaction<br>u. Hemophagocytic syndrome<br>v. Human T-lymphocyte virus-1 myelopathy<br>w. Hyper IgE syndrome<br>x. Immune mediated neutropenia<br>y. Inclusion body myositis<br>z. Infectious disease in high risk neonates and adults following surgery or trauma<br>aa. Lumbosacral plexopathy<br>bb. Miller-Fisher syndrome<br>cc. Motor neuron syndromes<br>dd. Multiple sclerosis<br>ee. Narcolepsy/cataplexy<br>ff. Neonatal hemochromatosis<br>gg. Neonatal hemolytic disease<br>hh. Nephropathy, membranous<br>ii. Nephrotic syndrome<br>jj. Neuromyelitis optica<br>kk. Nonimmune thrombocytopenia<br>ll. Ophthalmopathy, euthyroid<br>mm. Opsoclonus myoclonus<br>nn. Otitis media, recurrent<br>oo. Paraproteinemic neuropathy<br>pp. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)<br>qq. Polyneuritis<br>rr. Post-polio syndrome<br>ss. Recurrent spontaneous pregnancy loss/abortion<br>tt. Rheumatoid arthritis<br>uu. Sinusitis, chronic<br>vv. Stevens-Johnson Syndrome<br>ww. Still's Disease<br>xx. Surgery or trauma |

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| | yy. Thrombotic Thrombocytopenic Purpura/Hemolytic Uremic Syndrome (TTP/HUS)<br>zz. Thrombotic Thrombocytopenic Purpura, neonatal autoimmune – severe thrombocytopenia (TTP)<br>aaa. Thrombotic Thrombocytopenic Purpura, refractory to platelet transfusions. (TTP)<br>bbb. Tic disorder (DSM-IV)<br>ccc. Toxic epidermal necrolysis<br>ddd. Urticaria, delayed pressure<br>eee. Uveitis<br>fff. Vasculitic syndromes, systemic<br>ggg. Von Willebrand's syndrome<br>hhh. Wegener's granulomatosis |
| Authorization Period | Please refer to table 2 |
| Renewal Criteria | Please refer to table 2 |
| Quantity Limitations | Align with FDA recommended dosing. Please refer to table 1 for intravenous products. For subcutaneous products, quantity limits align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

**Table 1. Dosing per Indication (shown below)**

| Indication | Dose** |
|---|---|
| Acquired Factor VIII inhibitor | 1000 mg/kg for 2 days OR 400 mg/kg for 5 days |
| Allogeneic bone marrow transplant | 500 mg/kg on day 7 and day 2 prior to transplantation and then once weekly thereafter for 90 days after transplantation |
| Autoimmune encephalitis | 400 mg/kg/day for 5 days |
| Autoimmune hemolytic anemia | 400 mg/kg/day for 5 days |
| Dermatomyositis | 2000 mg/kg every month |
| Fetal alloimmune thrombocytopenia | 1000 mg/kg every week, 2 g/kg/week in refractory cases |
| HIV + children (< 13 years) | 400 mg/kg every 4 weeks |
| Hypogammaglobulinemia associated with chronic lymphocytic leukemia or multiple myeloma | 400 mg/kg IV every 4 weeks |

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| Hypogammaglobulinemic neonates | 400 – 600 mg/kg/month, administered as a single dose, or up to several months in duration |
| Inflammatory demyelinating polyneuropathy (acute), including Guillain-Barré syndrome | 400 mg/kg/day for 5 days |
| Inflammatory demyelinating polyneuropathy (chronic; CIDP) | Loading dose: 2000 mg/kg, given in divided doses over 2 - 4 consecutive days<br>Maintenance dose: 1000 mg/kg every 3 weeks OR 500 mg/kg/day, for 2 consecutive days every 3 weeks 400 mg/kg/5 days, repeated every 6 weeks |
| ITP (acute) | 1000 mg/kg/day for 2 consecutive days OR 400 mg/kg once daily for 2 - 5 consecutive days |
| ITP (chronic) | 1 – 2 g/kg as a single dose or divided into equal amounts and given over 2 - 5 days |
| ITP in pregnancy | 400 mg/kg/day for 5 days |
| Kawasaki syndrome | 2000 mg/kg as a single dose OR 400 mg/kg/day for 4 days |
| Lambert-Eaton myasthenic syndrome | 2000 mg/kg administered over 2 - 5 days |
| Multifocal motor neuropathy | 2000 mg/kg/month administered over 2 - 5 days |
| Myasthenia gravis | 1 - 2 g/kg/month IV given over 2 - 5 days |
| Pediatric intractable epilepsy | 2000 mg/kg over 4 days followed by 1000 mg/kg over 2 days every month for 6 months |
| Polymyositis | 2000 mg/kg/month given over 2 - 5 days |
| Post-transfusion purpura | 500 mg/kg/day for 2 consecutive days |
| Primary humoral immunodeficiency diseases | 100 – 800 mg/kg/month |
| Pure red cell aplasia | 400 mg/kg/day for 5 - 10 days OR 2000 mg/kg/day for 5 days |
| Refractory pemphigus foliaceus | 1 - 2 g/kg over 3 days every 4 weeks |
| Solid organ transplant | 2000 mg/kg/month for 4 months |
| Stiff-Person Syndrome | 400 mg/kg/day for 3 - 5 days |
| Systemic lupus erythematosus | 400 mg/kg/day for 5 days |

* Dosing must be based on ideal body weight (IBW) unless the patient's BMI is ≥ 30 kg/m$^2$ or actual body weight is greater than ideal body weight (IBW)

by 20% or more, then adjusted body weight (adjBW) must be used.

** Initial dosing will be approved at the lower end of the dose range. Increase in dose and dosing interval will be authorized based on indication and literature support of the dose/dosing interval

**Table 2. Authorization Period and Renewal Criteria (shown below)**

| Indications | Frequency | Authorization Duration | | | | Reauthorization | |
|---|---|---|---|---|---|---|---|
| | IVIG may be given no more frequently than: | 60 days | 3 months | 6 months | 1 year | Yes/ No | Criteria |
| Acquired Factor VIII inhibitor | One treatment per month | | | X | | Yes | Documented initial response to IVIG and presence of factor VIII inhibitor |
| Allogeneic bone marrow transplant | On days 7 and 2 prior to transplant, then once weekly for up to 90 days (total therapy duration of 97 days) | | | X | | Yes | Reauthorization may be considered under hypogammaglobulinemia criteria |
| Autoimmune encephalitis | One treatment per month | | | X | | | Documentation of clinical improvement |
| Autoimmune hemolytic anemia | One treatment per month | | | X | | Yes | Documented initial response to IVIG and recurrence of clinically significant, symptomatic anemia |
| Dermatomyositis | One treatment per month | | X | | | Yes | Objective evidence of efficacy of initial three-month treatment, such as improvement in muscle strength or decreased CPK levels |
| Fetal alloimmune thrombocytopenia (FAIT) | One treatment per month | | | X | | Yes | Documented previous history of FAIT. Treatment not to exceed the duration of pregnancy |
| HIV + children | One treatment per month | | | | X | Yes | Documentation of clinical improvement |

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|---|---|---|---|---|---|---|---|
| Hypogammaglobulinemia associated with chronic lymphocytic leukemia or multiple myeloma | One treatment per month | | | | X | Yes | Documentation of clinical improvement and current IgG levels that are in the low to normal range. |
| Hypogammaglobulinemic neonates | One treatment per month | | | X | | Yes | Documentation of clinical improvement and current IgG levels that are in the low to normal range |
| Inflammatory demyelinating polyneuropathy (acute) | One treatment per month | | X | | | No | N/A |
| Inflammatory demyelinating polyneuropathy (chronic; CIDP) | One treatment per month | | | X | | Yes | Documented initial response to IVIG and evidence of functional improvement |
| ITP (acute) | Up to 4 doses given every other day | | | X | | No | N/A |

**Table 2 Continued - Authorization Period and Renewal Criteria (shown below)**

| Indication | Frequency | Authorization Duration | | | | Reauthorization | |
|---|---|---|---|---|---|---|---|
| | IVIG may be given no more frequently than: | 60 days | 3 months | 6 months | 1 year | Yes/ No | Criteria |
| ITP (chronic) | One treatment per month | | | X | | Yes | Platelet count equal to or greater than 30,000/ $mm^3$ but no more than 150,000/$mm^3$, OR less than 30,000/$mm^3$ but platelets have increased from base-line accompanied by resolution of previous bleeding. IVIG treatment only covered until conventional therapy takes effect |
| ITP in pregnancy | One treatment per month | | X | | | Yes | Platelet count (see policy criteria). Treatment is not to exceed the duration of pregnancy |
| Kawasaki syndrome | One treatment given within 10 days of symptom onset | X | | | | No | N/A |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Lambert-Eaton myasthenic syndrome | One treatment per month | | | X | | Yes | Documented initial response to IVIG and measurable improvement in muscle function/strength |
| Multifocal motor neuropathy | One treatment per month | | | X | | Yes | Documented initial response to IVIG and measurable improvement in muscle function/strength |
| Myasthenia gravis (acute and chronic) | One treatment per month | | | X | | Yes | Documented initial response to IVIG and measurable improvement in muscle function/strength. |
| Pediatric intractable epilepsy | One treatment per month | | | X | | Yes | Documented initial response to IVIG and significantly reduced frequency and/or duration of seizures |
| Polymyositis | One treatment per month | | X | | | Yes | Objective evidence of the efficacy of initial 3-month treatment, such as improvement in muscle strength and/or decreased CPK levels |
| Post-transfusion purpura | One or two treatments | X | | | | No | N/A |
| Primary humoral immunodeficiency diseases | One treatment per month | | | | X | Yes | Documented initial response to IVIG, current IgG levels that are in the low to normal range, and evidence of clinical improvement |
| Pure red cell aplasia | One treatment per month | | | X | | Yes | Documentation of initial response to IVIG, parvovirus, and recurrence of significant anemia |
| Refractory pemphigus foliaceus | One treatment per month | | | X | | No | N/A |

**Table 2 Continued - Authorization Period and Renewal Criteria (shown below)**

| Indication | Frequency | Authorization Duration | Reauthorization |
|---|---|---|---|

| | IVIG may be given no more frequently than: | 60 days | 3 months | 6 months | 1 year | Yes/ No | Criteria |
|---|---|---|---|---|---|---|---|
| Solid organ transplant | Up to 4 doses pre-transplant, then 1 dose weekly for 4 weeks post-transplant | | X | | | No | N/A |
| Stiff-Person Syndrome | One treatment per month | | X | | | Yes | Objective evidence of the efficacy of initial 3-month treatment, such as improvement in mobility, ability to perform work-related or household tasks, and decreased fall frequency |
| Systemic lupus erythematosus | One treatment per month | | | X | | Yes | Documentation of initial response to IVIG and evidence of clinical improvement |
| **GamaSTAN Only-Prophylactic Post Exposure - Medicare Only** | | | | | | | |
| Hepatitis A | Once for < 3 month stay in endemic region. Repeat every 4 to 6 months for > 3 month stay in endemic region | | | | X | Yes | Recommended for persons who plan to travel in areas where hepatitis A is common |
| Measles (Rubeola) | Once post suspected exposure if fewer than 6 days previously | | | | X | Yes | Prevention or to modify measles in a susceptible person exposed fewer than 6 days previously |
| Varicella | Once immediately post exposure | | | | X | Yes | When VZIG is unavailable, given promptly post exposure |
| Rubella | Once | | | | X | Yes | Exposed women who will not consider a therapeutic abortion |

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| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34314<br>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34771&ver=49& |
| | |

**Infliximab Policy**

**Avsola**™ (infliximab-axxq) Q5121
**Inflectra**® (infliximab-dyyb) Q5103
**Ixifi**™ (infliximab-qbtx) Q5109

| **Infliximab** (Remicade) J1745<br>**Infliximab-abda** J3590<br>**Renflexis**® (infliximab-abda) Q5104<br>**Zymfentra**® (infliximab-dyyb) J1748 | |
|---|---|
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Diagnosis of Crohn's disease<br>i. Active Crohn's disease:<br>1. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>ii. Fistulizing Crohn's disease<br>d. Diagnosis of ulcerative colitis:<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>e. Diagnosis of rheumatoid arthritis:<br>i. Trial and failure of at least 3 months of one disease-modifying anti-rheumatic drug (DMARD) unless contraindicated or not tolerated. Examples include methotrexate, hydroxychloroquine, leflunomide, sulfasalazine<br>ii. Administered in combination with methotrexate<br>f. Diagnosis of psoriatic arthritis<br>g. Diagnosis of plaque psoriasis<br>i. Trial and failure, contraindication, or intolerance to one topical corticosteroid<br>h. Diagnosis of ankylosing spondylitis<br>i. Diagnosis of generalized pustular psoriasis as defined by the European Rare and Severe Psoriasis Expert Network |

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| | j. Not to be used in combination with other biologics or targeted DMARDs for the same indication<br>k. Trial and failure of the preferred product despite dose optimization<br>l. A credible explanation must be provided as to why the requested product is expected to work when the preferred product did not<br>m. Trial and failure, contraindication, OR intolerance to the preferred products as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35677&ver=88&keyword=Infliximab&keywordType=starts&areaId=all&docType=F&contractOption=all&sortBy=relevance&bc=1 |
| | |

**Intravenous Iron Replacement**
**Feraheme**® (ferumoxytol) Q0138 / Q0139
**Generic Ferrlect**® (sodium ferric gluconate complex) J2916
**INFeD** (iron dextran) J1750
**Injectafer**® (ferric carboxymaltose) J1439
**Monoferric**® (ferric derisomaltose) J1437
**Triferic**®**/Triferic AVNU**® (ferric pyrophosphate citrate) J1445
**Venofer**® (iron sucrose) J1756

| PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>*****Note: This policy pertains to Medicare Part B only***** |

| | |
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| | A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. Trial and failure, contraindication, OR intolerance to oral iron and the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Izervay™** (avacincaptad pegol)<br>**HCPCS:** J2782 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Must not have geographic atrophy (GA) secondary to a condition other than dry AMD<br>d. Must have a visual acuity in the affected eye(s) of 20/320 or better<br>e. Must not be used in combination with Syfovre™ or any other medication for GA<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time and align with FDA recommended duration of treatment |

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| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |

| **Kanuma™** (sebelipase alfa)<br>**HCPCS:** J2840 | |
|---|---|
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmation of diagnosis by serum assay showing a decrease of lysosomal acid lipase (LAL) activity followed by genetic testing showing a mutation in the LIPA gene<br>d. Symptomatic manifestations of the disease are present, such as, elevated liver enzymes, microvesicular steatosis, elevated low-density lipoprotein, low high-density lipoprotein, or coronary artery disease<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 1 year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Kebilidi™** (eladocagene exuparvovec-tneq)<br>**HCPCS:** J3590 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Coverage of the requested drug is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit<br>i. The plan is awaiting the results of ongoing clinical trials to provide evidence of a clinical benefit |
| Authorization Period | Not applicable |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Not applicable |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Keytruda®** (pembrolizumab)<br>**HCPCS:** J9271 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Treatment must follow the FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation |

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| | i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation<br>b. Prescribed by or in consultation with an oncologist or hematologist<br>c. No prior failure of a programmed death receptor-1 (PD-1) inhibitor<br>d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant<br>e. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guidelines supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | i. Treatment continued until unacceptable toxicity or disease progression occurs<br>ii. Renewal beyond 24 months of total therapy will be considered according to FDA approved drug labelling<br>iii. Metastatic non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Kisunla™** (donanemab-azbt)<br>**HCPCS:** J0175 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | Coverage of the requested drug will be provided when all of the criteria are met. Coverage requests must be supported by submission of chart notes and patient specific documentation.<br>a. Diagnosis of early symptomatic Alzheimer's disease (AD) defined as mild cognitive impairment (MCI) or mild AD dementia as confirmed by ALL of the following:<br>i. Confirmed amyloid-beta pathology based on at least one of the following: |

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| | 1. The presence of amyloid beta pathology consistent with AD confirmed by amyloid positron emission tomography (PET) scan, OR<br>2. Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation in the brain (e.g., Aβ42: 40 ratio, p-tau/Aβ42)<br>ii. Other differential diagnoses have been ruled out and/or adequately managed by their respective specialists including:<br>1. Other types of dementia (e.g. vascular dementia, Lewy body dementia)<br>2. Other medical and neurological causes of cognitive impairment (e.g. medications, infections, vitamin B12 deficiency, folate deficiency)<br>3. Psychiatric diagnoses or symptoms (e.g. hallucinations, anxiety, major depression, or delusions)<br>iii. Mildly impaired cognition as evidenced by Mini Mental State Exam (MMSE) score and/or Montreal Cognitive Assessment (MoCA) score results within the past two months<br>iv. Global CDR score of 0.5 to 1.0 and a CDR Memory Box score of 0.5 or greater within the past two months.<br>b. Brain magnetic resonance imaging (MRI) completed within at most the past 12 months without findings that indicate an increased risk for amyloid-related imaging abnormalities (ARIA) and/or intracerebral hemorrhage, including:<br>v. Findings suggestive of ARIA and/or cerebral amyloid angiopathy (prior cerebral hemorrhage greater than 1 cm at greatest diameter, more than 4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage.<br>c. Member is not currently taking an anticoagulant (e.g. warfarin, apixaban)<br>i. If the member is currently taking an anticoagulant, the prescriber must attest that education has been provided that the use of anti-amyloid therapy with anticoagulant therapy may increase the risk of intracerebral hemorrhage<br>d. Testing for ApoE ε4 status has been completed and the prescriber attests that education has been provided on test results including the risk of ARIA associated with ApoE ε4 status if applicable<br>i. If the member has opted out of testing, the prescriber must attest that the patient understands the risk versus benefit of treatment, including an increased risk of ARIA if positive for ApoE ε4<br>e. No documented history of any of the following:<br>vi. Transient ischemic attacks (TIA), stroke, or seizures within 12 months<br>vii. Evidence of other clinically significant lesions on brain MRI at Screening that could indicate a dementia diagnosis other than AD<br>viii. Presence of a bleeding disorder that is not under adequate control (including a platelet count <50,000 or International normalized ratio [INR] >1.5)<br>f. Member must be enrolled in an approved study/registry that meets the Centers for Medicare and Medicaid Services (CMS) Coverage with Evidence Development (CED) criteria and is listed on the 'Monoclonal |

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| | Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)' page of the CMS CED website<br>g. Not to be used in combination with other anti-amyloid therapy |
| Authorization Period | Six months |
| Renewal Criteria | a. For continuation of therapy, all of the following requirements must be met:<br>i. Diagnosis of MCI or mild AD dementia as evidenced by Mini Mental State Exam (MMSE) score and/or Montreal Cognitive Assessment (MoCA) score results within the past three months<br>ii. Follow up MRIs have been completed at the intervals indicated in the FDA package insert and either:<br>a) ARIA has not been observed on MRI, OR<br>b) ARIA has been observed on MRI and all of the following:<br>• The prescriber attests that continuation of therapy is appropriate based on the severity of the patient's clinical symptoms, AND<br>• Follow-up MRI demonstrates radiographic resolution and/or stabilization, OR the prescriber attests that continuation of therapy is appropriate based on the radiographic severity of ARIA |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375 |
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| **Krystexxa**® (pegloticase)<br>**HCPCS:** J2507 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage will be provided if ALL of the following are met:<br>a. FDA approved age<br>b. Diagnosis of chronic gout<br>c. Patient has at least one of the following:<br>i. Two or more gouty flares in previous 12 months<br>ii. Presence of one or more tophi<br>iii. Chronic gouty arthritis (defined clinically or radiographically as joint damage due to gout)<br>d. Serum uric acid > 6 mg/ dL<br>e. Member has undertaken appropriate lifestyle modifications, (i.e. limiting alcohol consumption, discontinuing or changing other medications known to precipitate gout attacks when possible)<br>f. Treatment with maximally titrated or maximally tolerated dose of a xanthine oxidase inhibitor (i.e. allopurinol or febuxostat) has been ineffective or is contraindicated.<br>g. Treatment with an uricosuric agent (example: probenecid) in combination with a xanthine oxidase inhibitor unless contraindicated, not tolerated, or has been ineffective.<br>i. If xanthine oxidase inhibitor therapy is contraindicated or not tolerated, probenecid can be used unless contraindicated itself<br>h. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies (examples: allopurinol, febuxostat, probenecid)<br>i. Coverage will NOT be provided for the following indications:<br>i. Hyperuricemia not associated with gout<br>ii. Asymptomatic hyperuricemia<br>j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |

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| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Kymriah™** (tisagenlecleucel)<br>**HCPCS:** Q2042 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Prescribed by or in consultation with an oncologist<br>b. Diagnosis of pediatric and young adult with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory[a] or in second or later relapse[b]:<br>i. FDA approved age<br>ii. Primary refractory as defined by not achieving a complete response after 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a complete response after 1 cycle of standard chemotherapy for relapsed leukemia<br>iii. Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to or have failed 2 lines of tyrosine kinase inhibitor therapy (TKI), or if TKI therapy is contraindicated<br>iv. Any bone marrow (BM) relapse after allogenic SCT<br>v. Patient must meet all of the following:<br>1. No Burkitt's lymphoma |

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| | 2. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>3. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>4. No grade 2 to 4 graft-versus-host disease<br>5. No concomitant genetic syndrome with the exception of Down's syndrome<br>6. Must not have received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to Tisagenlecleucel infusion<br>7. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>8. No thromboembolic events within 6 months<br>9. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>10. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>c. Treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma:<br>i. FDA approved age<br>ii. Received ≥ 2 lines of chemotherapy, including rituximab and anthracycline<br>OR<br>iii. Relapsed following autologous hematopoietic stem cell transplantation (HSCT)<br>iv. Patient must meet all of the following:<br>1. No known active central nervous system malignancy<br>2. No prior allogenic HSCT<br>3. ECOG performance status 0 - 2<br>4. Creatinine clearance greater than 30 mL/min |

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| | 5. Alanine aminotransferase less than 5 times normal<br>6. Cardiac ejection fraction greater than 40%<br>7. Absolute lymphocyte concentration greater than 300/μL<br>8. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>9. No active infection including hepatitis B, hepatitis C, HIV, or systemic fungal, bacterial, or viral infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>11. No thromboembolic events within 6 months<br>12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>d. Treatment of adult patients with relapsed or refractory follicular lymphoma (FL)<br>i. Subjects must have received at least 2 prior lines of therapy<br>ii. Must have measurable disease<br>iii. Patient must meet all of the following:<br>1. No prior allogeneic HSCT<br>2. No known active central nervous system malignancy<br>3. ECOG performance status 0 - 2<br>4. No transformed FL<br>5. No histological grade 3b FL<br>6. Creatinine clearance greater than 30 mL/min<br>7. Hepatic transaminases less than 5 times the upper limit of normal<br>8. Cardiac ejection fraction greater than 40% |

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| | 9. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>10. No active infection including hepatitis B, hepatitis C, HIV, or systemic fungal, bacterial, or viral infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>11. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>12. No thromboembolic events within 6 months<br>13. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>14. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>e. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>f. Only to be administered at certified bone marrow/stem cell transplant centers<br>g. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list<br>h. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan.<br>i. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case-by-case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee<br><br>[a] *Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, i.e., failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).* |

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| | [b] *Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic stem cell transplant* |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=291 |
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| **Lamzede**® (velmanase alfa-tycv)<br>**HCPCS:** J0217 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with a geneticist or metabolic specialist<br>d. Confirmation of diagnosis by biochemical assay showing decreased alpha-mannosidase activity in white blood cells or skin fibroblasts less than 10% of normal AND genotyping revealing two pathogenic mutations of the MAN2B1 gene<br>e. Must not have a history of hematopoietic stem cell transplant (HSCT) |

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| | f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Lantidra™** (donislecel-jujn)<br>**HCPCS:** J3590 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of Type 1 diabetes for ≥ 5 years<br>c. Unable to reach target HbA1c despite intensive diabetes education and insulin management due to experiencing at least ONE of the following:<br>i. Current repeated episodes of severe hypoglycemia, as defined by:<br>1. The presence of hypoglycemia symptoms which required assistance of another person for intervention, AND<br>2. Either a blood glucose level < 50 mg/dL or prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration<br>ii. Hypoglycemia unawareness, as defined by the absence of adequate autonomic symptoms at glucose levels < 54 mg/dL, as reported by the patient |

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| | d. Episodes of severe hypoglycemia and/or hypoglycemia unawareness persist despite intensive diabetes management that includes appropriate use of all modalities to reduce hypoglycemia, including continuous subcutaneous insulin infusion (i.e., an insulin pump) and continuous glucose monitoring<br>i. Members who have failed to control hypoglycemia episodes and/or hypoglycemia unawareness utilizing non-integrated (i.e., self-managed) diabetes technologies must attempt management with an integrated system (i.e., automated insulin delivery system)<br>e. Must be taken in combination with concomitant immunosuppressants<br>f. Must not have had previous transplant<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 60 days |
| Renewal Criteria | Independence from exogenous insulin has not been achieved within one year of infusion OR within one year after losing independence from exogenous insulin after a previous infusion |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Leqembi™** (lecanemab-irmb)<br>**HCPCS:** J0174 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br><br>Coverage of the requested drug will be provided when all of the criteria are met. Coverage requests must be supported by submission of chart notes and patient specific documentation. |

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| | a. Diagnosis of early symptomatic Alzheimer's disease (AD) defined as mild cognitive impairment (MCI) or mild AD dementia as confirmed by ALL of the following:<br>i. Confirmed amyloid-beta pathology based on at least one of the following:<br>a) The presence of amyloid beta pathology consistent with AD confirmed by amyloid positron emission tomography (PET) scan, OR<br>b) Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation in the brain (e.g., Aβ42: 40 ratio, p-tau/Aβ42)<br>ii. Other differential diagnoses have been ruled out and/or adequately managed by their respective specialists including:<br>a) Other types of dementia (e.g. vascular dementia, Lewy body dementia)<br>b) Other medical and neurological causes of cognitive impairment (e.g. medications, infections, vitamin B12 deficiency, folate deficiency)<br>c) Psychiatric diagnoses or symptoms (e.g. hallucinations, anxiety, major depression, or delusions)<br>iii. Mildly impaired cognition as evidenced by Mini Mental State Exam (MMSE) score and/or Montreal Cognitive Assessment (MoCA) score results within the past two months<br>iv. Global CDR score of 0.5 to 1.0 and a CDR Memory Box score of 0.5 or greater within the past two months.<br>b. Brain magnetic resonance imaging (MRI) completed within at most the past 12 months without findings that indicate an increased risk for amyloid-related imaging abnormalities (ARIA) and/or intracerebral hemorrhage, including:<br>i. Findings suggestive of ARIA and/or cerebral amyloid angiopathy (prior cerebral hemorrhage greater than 1 cm at greatest diameter, more than 4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage.<br>c. Member is not currently taking an anticoagulant (e.g. warfarin, apixaban)<br>i. If the member is currently taking an anticoagulant, the prescriber must attest that education has been provided that the use of anti-amyloid therapy with anticoagulant therapy may increase the risk of intracerebral hemorrhage<br>d. Testing for ApoE ε4 status has been completed and the prescriber attests that education has been provided on test results including the risk of ARIA associated with ApoE ε4 status if applicable |

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| | i. If the member has opted out of testing, the prescriber must attest that the patient understands the risk versus benefit of treatment, including an increased risk of ARIA if positive for ApoE ε4<br>e. No documented history of any of the following:<br>i. Transient ischemic attacks (TIA), stroke, or seizures within 12 months<br>ii. Evidence of other clinically significant lesions on brain MRI at Screening that could indicate a dementia diagnosis other than AD<br>iii. Presence of a bleeding disorder that is not under adequate control (including a platelet count <50,000 or International normalized ratio [INR] >1.5)<br>f. Member must be enrolled in an approved study/registry that meets the Centers for Medicare and Medicaid Services (CMS) Coverage with Evidence Development (CED) criteria and is listed on the 'Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)' page of the CMS CED website<br>g. Not to be used in combination with other anti-amyloid therapy |
| Authorization Period | Six months |
| Renewal Criteria | a. For continuation of therapy, all of the following requirements must be met:<br>iii. Diagnosis of MCI or mild AD dementia as evidenced by Mini Mental State Exam (MMSE) score and/or Montreal Cognitive Assessment (MoCA) score results within the past three months<br>iv. Follow up MRIs have been completed at the intervals indicated in the FDA package insert and either:<br>a) ARIA has not been observed on MRI, OR<br>b) ARIA has been observed on MRI and all of the following:<br>• The prescriber attests that continuation of therapy is appropriate based on the severity of the patient's clinical symptoms, AND<br>• Follow-up MRI demonstrates radiographic resolution and/or stabilization, OR the prescriber attests that continuation of therapy is appropriate based on the radiographic severity of ARIA |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375 |
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| **Libtayo®** (cemiplimab-rwlc)<br>**HCPCS:** J9119 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Treatment must follow the Food and Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation<br>i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation<br>b. Must be prescribed by, or in consultation with, an oncologist or hematologist<br>c. No prior failure of a programmed death receptor-1 (PD-1 or PD-L1) inhibitor<br>d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant<br>e. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | i. Metastatic non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy<br>ii. All other indication: Treatment may be continued until unacceptable toxicity or disease progression |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Luxturna**® (voretigene neparvovec-rzyl)<br>**HCPCS:** J3398 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. Prescribed and administered by an ophthalmologist<br>c. Patient is 12 months of age or older<br>d. Documented biallelic RPE65 gene mutation<br>e. Retinal thickness greater than 100 microns within the posterior pole<br>f. Submission of baseline full field light sensitivity prior to approval and full field light sensitivity one year after administration as a follow-up to the prior approval request |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37863&ver=25& |
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| **Lyfgenia**™ (lovotibeglogene autotemcel)<br>**HCPCS:** J3394 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |

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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribing by or in consultation with a hematologist<br>d. Diagnosis of sickle cell disease (SCD) confirmed via genetic testing or electrophoresis<br>e. Must not be diagnosed with sickle β-thalassemia<br>f. Must have experienced at least 4 severe vaso-occlusive crises in the past 24 months<br>g. Trial and failure, contraindication, or intolerance to hydroxyurea<br>h. Must not have any of the following:<br>i. Positive presence of HIV-1 or HIV-2, hepatitis B, or hepatitis C<br>ii. Inadequate bone marrow function, as defined by an absolute neutrophil count of less than 1000/μL or less than 500/μL for patient taking hydroxyurea or a platelet count less than 120,000/μL without hypersplenism<br>iii. Advanced liver disease defined as AST, ALT, or total bilirubin greater than 3 times the upper limit of normal<br>iv. Prior treatment with an allogenic stem cell transplant<br>v. Prior or current malignancy or immunodeficiency disorder<br>i. Must not have received prior treatment with any gene therapy for sickle cell disease or are being considered for treatment with any other gene therapy for sickle cell disease<br>j. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>k. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | 12 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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**Medical Benefit Oncology Drug Class Policy**

**Avgemsi**™ (gemcitabine) J9184
**Alimta** (pemetrexed) J9305
**Beizray**™ (docetaxel) J9174
**Bizengri** (zenocutuzumab-zbco) J9382
**Boruzu**® (bortezomib) J9054
**Danyelza** (naxitamab-gqgk) J9348
**Darzalex** (daratumumab) J9415
**Darzalex FasPro (**daratumumab and hyaluronidase-fihj) J9144
**Datroway** (datopotamab deruxtecan-dlnk) J9011
**Docivyx**® (docetaxel) J9172
**Elahere** (mirvetuximab soravtansine-gynx) J9063
**Elzonris** (tagraxofusp-erzs) J9269
**Emrelis** (telisotuzumab vedotin-tllv) J3590
**Erbitux** (cetuximab) J9055
**Fyarro** (sirolimus protein-bound particles) J9331
**Jelmyto** (mitomycin) J9281
**Kimmtrak** (tebentafusp-tebn) J9274
**Kyxata**™ (carboplatin) C9308
**Lymphir** (denileukin diftitox-cxdl) J9161
**Padcev** (enfortumab vedotin-ejfv) J9177
**Pemetrexed** J9296, J9294, J9297, J9314, J9323, J9322, J9292
**Pemfexy (**pemetrexed) J9304
**Pemrydi RTU** (pemetrexed) J9324
**Polivy** (polatuzumab vedotin-piiq) J9309
**Rybrevant** (amivantamab-vmjw) J9061
**Rybrevant Faspro**® (amivantamab and hyaluronidase-lpuj) J3590
**Sarclisa** (isatuximab-irfc) J9227
**Tivdak** (tisotumab vedotin-tftv) J9273

| **Trodelvy** (sacituzumab govitecan-hziy) J9317<br>**Vyloy** (zolbetuximab-clzb) J1326<br>**Yondelis** (trabectedin) J9352<br>**Ziihera** (zanidatamab-hrii) J9276<br>**Zusduri** (mitomycin) J3590<br>**Zynlonta** (loncastuximab tesirine-lpyl) J9359 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>a. Coverage of the requested drug is provided for FDA approved indications<br>OR<br>b. When use is aligned with NCCN guidelines category 1 or 2A<br>OR<br>c. When use is aligned with NCCN guidelines category 2B recommendations when there is not a higher-rated NCCN category recommendation available<br>AND<br>d. When ALL of the following criteria are met:<br>i. Prescriber is an oncologist/hematologist OR another board-certified prescriber with qualifications to treat the specified malignancy.<br>ii. Genetic testing results support use based on package labeling/FDA requirements. Consideration may also be given to genetic testing as recommended by NCCN guidelines.<br>iii. Trial of medications and treatments supported by the NCCN guidelines and/or package labeling as prior lines of therapy.<br>iv. If appropriate, trial and failure of the preferred products as specified in the plan's utilization management medical drug list<br>e. No prior failure based on efficacy of a drug with the same mechanism of action unless retrial with the same mechanism of action is guideline recommended or supported by a randomized, controlled clinical trial |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | No evidence of disease progression or unacceptable toxicity |

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| Quantity Limitations | Align with FDA recommended dosing. |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35396 |
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| **Niktimvo™** (axatilimab-csfr)<br>**HCPCS:** J3590 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Trial and failure of at least two prior lines of systemic therapy<br>d. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Nivolumab Products** | |

| **Opdivo**® (nivolumab) J9299<br>**Opdivo Qvantig**™ (nivolumab and hyaluronidase-nvhy) J9289 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Treatment must follow the Food and Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation<br>i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation<br>b. Must be prescribed by, or in consultation with, an oncologist or hematologist<br>c. No prior failure of a programmed death receptor-1 (PD-1 or PD-L1) inhibitor<br>d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant<br>e. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | i. Metastatic non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy<br>ii. All other indication: Treatment may be continued until unacceptable toxicity or disease progression |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| **Nplate**® (romiplostim)<br>**HCPCS:** J2802 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |

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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis confirmed by, or in consultation with, a hematologist<br>c. For immune thrombocytopenic purpura (ITP)<br>i. Diagnosis of ITP defined by the following:<br>1. Thrombocytopenia (platelet count < 100,000/mcL)<br>- Current platelet count < 20,000/mcL<br>OR<br>- Current platelet count < 30,000/mcL AND symptoms of active bleeding<br>ii. Inadequate response to therapy with corticosteroids, immunoglobulins, or splenectomy<br>iii. Dose is ≤ 10 mcg/kg/week<br>OR<br>d. A diagnosis of hematopoetic syndrome of acute radiation syndrome (HS-ARS)<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | i. For ITP: Three months initially. Continuation of therapy to be reviewed annually<br>ii. For HS-ARS: 60 days approval to allow for one time administration |
| Renewal Criteria | i. For ITP:<br>a. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit<br>b. Recent platelet count of 30,000-150,000/mcL<br>c. Dose is ≤ 10 mcg/kg/week<br>ii. For HS-ARS:<br>a. Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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|---|---|
| **Nucala®** (mepolizumab)<br>**HCPCS:** J2182 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. For the diagnosis of severe uncontrolled eosinophilic asthma<br>i. Patient is currently receiving, and will continue to receive standard of care regimen<br>ii. Must be used as add on maintenance treatment with severe uncontrolled eosinophilic asthma<br>iii. Severe eosinophilic asthma identified by:<br>1. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment<br>iv. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with<br>1. Long acting inhaled β2 agonist for at least 3 months fails to maintain adequate control<br>OR<br>2. Leukotriene modifier for at least 3 months fails to maintain adequate control<br>OR<br>3. LAMA (long acting muscarinic antagonists) in adults and children ≥ 12 years old for at least 3 months fails to maintain adequate control<br>OR<br>c. Diagnosis of uncontrolled, moderate to severe chronic obstructive pulmonary disease (COPD)<br>i. Patient is currently receiving, and will continue to receive standard of care regimen including LABA + LAMA + ICS, unless contraindicated<br>ii. Evidence of type 2 inflammation (current eosinophils ≥ 150/μL OR eosinophils ≥ 300/μL within the past 12 months) |

OR

d. A diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), and
    i. Documentation of a consult with an allergist/immunologist or pulmonologist prior to initiation of Nucala therapy
    ii. History or presence of asthma
    iii. At least 2 of the following criteria that are typical of EGPA
        1. Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
        2. Neuropathy
        3. Pulmonary infiltrates
        4. Allergic rhinitis and nasal polyps
        5. Cardiomyopathy
        6. Glomerulonephritis
        7. Alveolar hemorrhage
        8. Palpable purpura
        9. Antineutrophil cytoplasmic antibody (ANCA) positivity

        OR

e. A diagnosis of hypereosinophilic syndrome (HES), and
    i. At least 2 HES flares within the past 12 months
        1. Defined as documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy
    ii. Stable on HES therapy for at least 4 weeks
        1. Examples include oral corticosteroids, immunosuppressive or cytotoxic therapy
    iii. Eosinophil counts of 1,000 cells/microL or higher at initiation of therapy
    iv. Member does not have eosinophilia of unknown clinical significance, non-hematologic secondary HES (drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy), or FIP1L1-PDGFRα kinase-positive HES

    OR

f. A diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)
    i. Patient is currently receiving, and will continue to receive standard of care regimen
    ii. Recurring severe CRSwNP despite previous treatment with intranasal corticosteroids

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| | g. Not to be used in combination with other biologics or targeted disease-modifying antirheumatic drugs (DMARDs) for the same indication.<br>h. The member will self-administer Nucala unless clinically unable to do so<br>i. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Nulibry®** (fosdenopterin)<br>**HCPCS:** J3490, C9399 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmed genetic diagnosis of molybdenum cofactor deficiency (MoCD) Type A (MOCS1 mutation) and/or biochemical profile consistent with MoCD Type A<br>i. Examples: elevated urinary sulfite and/or S-sulfocysteine (SSC), elevated xanthine in urine or blood, or low or absent uric acid in the urine or blood<br>d. Documentation of clinical presentation consistent with MoCD Type A |

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| | i. Examples: intractable seizures, exaggerated startle response, high-pitched cry, axial hypotonia, limb hypertonia, feeding difficulties<br>e. No current or planned treatment for MoCD Type A with another investigational drug or device<br>i. Exception: Recombinant Escherichia coli-derived cyclic pyranopterin monophosphate (rcPMP) through day 1<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | A. Initial Authorization Period: Two months<br>B. Renewal Authorization Period: Six months |
| Renewal Criteria | If not provided on initial approval, genetic confirmation of MoCD Type A (MOCS1 mutation) is required. Additionally, clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Omalizumab Products**<br>**Omalizumab-igec J3590**<br>**Omlyclo® (omalizumab-igec) J3590**<br>**Xolair® (omalizumab) J2357** | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. overage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of uncontrolled moderate to severe allergic asthma<br>i. Positive skin test or in-vitro reactivity to a perennial aeroallergen |

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| | ii. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with<br>1. Long acting inhaled β2 agonist (LABA) modifier for at least 3 months fails to maintain adequate control<br>OR<br>2. Leukotriene modifier for at least 3 months fails to maintain adequate control<br>OR<br>3. Long acting muscarinic antagonists (LAMA) in adults and children 12 years of age and older for at least 3 months fails to maintain adequate control<br>iii. IgE level greater than 30 but less than 700 IU/mL for patients 12 years of age and older<br>OR<br>IgE level greater than 30 but less than 1,300 IU/mL for patients 6 years to less than 12 years of age<br>c. Diagnosis of chronic idiopathic urticaria (CIU)<br>i. Must have occurrence of almost daily hives and itching for at least 6 weeks<br>ii. Past trial and failure of all of the following for at least 2 months:<br>1. Trial and failure of a second-generation antihistamine at the maximal tolerated dose<br>AND<br>2. Trial and failure of one of the following at maximal dosing:<br>a) Another second-generation antihistamine<br>b) H2 antagonist<br>c) Leukotriene receptor antagonist<br>d) First generation antihistamine given at bedtime<br>e) Hydroxyzine<br>f) Doxepin<br>iii. Other diagnoses have been ruled out<br>d. Diagnosis of nasal polyps<br>i. Patient is currently receiving and will continue to receive the standard of care regimen<br>ii. Inadequate response to treatment with intranasal corticosteroids |

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| | iii. Baseline serum total IgE level of 30 IU/mL to 1,500 IU/mL prior to initiating treatment with omalizumab<br>e. Diagnosis of IgE-mediated food allergy<br>i. Documentation of clinical history of allergic reaction following consumption of at least one of the following: peanuts, milk, eggs, wheat, cashews, hazelnuts, and walnuts<br>ii. Documentation of a confirmed diagnosis of an allergy to either peanuts, milk, eggs, wheat, cashews, hazelnuts, or walnuts confirmed by one of the following:<br>1. IgE specific antibodies greater than or equal to 6 $kU_A/L$<br>2. Food-specific skin prick test (SPT)<br>iii. Provider attestation that the member will be on an allergen avoidant diet while on omalizumab therapy<br>iv. Must have a current prescription for epinephrine and access to an epinephrine autoinjector while using omalizumab<br>v. Serum total IgE level greater than 30 but less than or equal to 1850 IU/mL<br>vi. Must not be used in combination with any other food allergy desensitization therapy<br>f. Not to be used in combination with other biologics or targeted DMARDs for the same indication<br>g. For self-administration of omalizumab prefilled syringe: the patient has received the first 3 doses under the guidance of a health care provider<br>i. After the first 3 doses under the guidance of a health care provider, the member will self-administer omalizumab unless clinically unable to do so<br>h. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met.<br>i. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing. |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| **Omvoh™ IV** (mirikizumab-mrkz)<br>**HCPCS:** J2267 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Diagnosis of ulcerative colitis (UC)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>d. Diagnosis of Crohn's disease (CD)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>e. The member will self-administer Omvoh unless clinically unable to so<br>f. Not to be used in combination with biologic therapies or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |

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| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Onasemnogene abeparvovec Products**<br>**Itvisma®** (onasemnogene abeparvovec-brve) J3590<br>**Zolgensma®** (onasemnogene abeparvovec) J3399 | |
|---|---|
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Prescribed by or in consultation with a neurologist or neuromuscular specialist with expertise in treating spinal muscle atrophy (SMA)<br>c. Diagnosis of spinal muscle atrophy with genetically-confirmed double-deletion of spinal motor neuron 1 (SMN1) gene and less than or equal to four copies of the SMN2 gene<br>d. Must not have antibodies against the viral vector, adeno-associated virus serotype 9 vector (AAV9), > 1:50<br>e. Must receive oral corticosteroids daily starting at least 24 hours prior to therapy and continuing 30 days after therapy with Zolgensma<br>f. The patient does not have advanced SMA (for example: complete paralysis of limbs, permanent ventilator dependence)<br>g. The member will not be taking concurrently with Spinraza® or Evrysdi™<br>h. The member has not received prior treatment with any gene therapy or are being considered for treatment with any other gene therapy for SMA<br>i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 3 months |

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| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Onpattro**® (patisiran)<br>**HCPCS:** J0222 | |
|---|---|
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (formerly known as familial amyloid polyneuropathy, or FAP)<br>i. Signs and symptoms of ocular or cerebral area involvement (such as in ocular amyloidosis or primary/leptomeningeal amyloidosis), if present, must not predominate over polyneuropathy symptomology associated with hATTR<br>c. Documentation of TTR gene mutation<br>d. Documentation of clinical signs and symptoms of peripheral neuropathy (such as: tingling or increased pain in the hands, feet and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)<br>AND/OR<br>e. Documentation of clinical signs and symptoms of autonomic neuropathy symptoms (such as: orthostasis, abnormal sweating, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety]) |

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| | f. Must have a baseline polyneuropathy disability (PND) score ≤ IIIb and/or baseline FAP Stage 1 or 2<br>g. Onpattro will not be used in combination with other therapies approved for transthyretin-mediated amyloidosis<br>h. Must not have New York Heart Association (NYHA) heart failure classification >2<br>i. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Orencia**® (abatacept)<br>**HCPCS:** J0129 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of rheumatoid arthritis (RA)<br>b) Trial and failure of at least a 3-month trial of one disease-modifying anti-rheumatic drug (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine<br>c. Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) |

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| | c) Trial and failure of at least a 3-month trial of one DMARD unless contraindicated or not tolerated. Examples include: methotrexate and leflunomide<br>d. Diagnosis of psoriatic arthritis (PsA)<br>e. For prophylaxis of acute graft versus host disease (aGVHD)<br>d) Used in combination with a calcineurin inhibitor and methotrexate<br>e) Undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor<br>f. The member will self-administer Orencia unless clinically unable to do so<br>g. Not to be used in combination with other biologics or targeted DMARDs for the same indication<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Oxlumo**® (lumasiran)<br>**HCPCS:** J0224 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation |

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| | b. Patient is not on peritoneal dialysis (PD)<br>c. Patient does not have a history of kidney or liver transplant<br>d. Trial and failure to at least 3 months, contraindication, OR intolerance to a course of high-dose vitamin B-6 therapy.<br>e. Will not be used in combination with Rivfloza<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**<br>**Leqvio®** (inclisiran)<br>**HCPCS:** J1306 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indications<br>b. FDA approved age<br>c. Trial and therapeutic failure with one high-intensity statin<br>OR |

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| | d. History of statin-associated side effects or intolerance (e.g., skeletal muscle related symptoms) after a trial of two generic statins<br>OR<br>e. History of rhabdomyolysis after a trial of one statin<br>f. Not to be used in combination with other PCSK9 inhibitors<br>g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **PiaSky®** (crovalimab-akkz)<br>**HCPCS:** J1307 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Flow cytometric confirmation of paroxysmal nocturnal hemoglobinuria (PNH) type III red cells<br>d. Had at least 1 transfusion in 12 months preceding Piasky<br>OR |

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| | e. Documented history of major adverse thrombotic vascular events from thromboembolism<br>OR<br>f. Patient has high disease activity defined as a lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms:<br>i. Weakness<br>ii. Fatigue<br>iii. Hemoglobinuria<br>iv. Abdominal pain<br>v. Dyspnea<br>vi. Hemoglobin < 10 g/dL<br>vii. A major vascular event<br>viii. Dysphagia<br>ix. Erectile dysfunction<br>g. Must not be used in combination with Soliris®, Ultomiris®, or other medications to treat PNH<br>h. Trial and failure, contraindication, or intolerance to Empaveli™<br>i. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Pulmonary Arterial Hypertension Products**<br>**Flolan®** (epoprostenol) J1325<br>**Remodulin®** (treprostinil) J3285 | |

**Tyvaso®** (treprostinil) J7686
**Uptravi®** (selexipag) J3490
**Veletri®** (epoprostenol) J1325
**Winrevair™** (sotatercept-csrk) J3590

| PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. If the requested drug is listed below, the member must meet the additional criteria listed: |

| Drug(s) | Criteria |
|---|---|
| Tyvaso | • For pulmonary hypertension associated with interstitial lung disease (PH-ILD; World Health Organization (WHO) Group 3) - no further criteria are required.<br>• Pulmonary Arterial Hypertension (PAH) WHO Group 1 - trial and failure, intolerance or contraindication to all of the following<br>○ Generic sildenafil or tadalafil<br>○ Generic ambrisentan or bosentan |
| Uptravi injection | • Trial and failure, intolerance or contraindication to all of the following:<br>○ Generic sildenafil or tadalafil<br>○ Generic ambrisentan or bosentan |

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<ul>
<li>Adempas</li>
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• Currently stable on oral Uptravi therapy<br>
• Will be used as short-term bridging therapy in those patients temporarily unable to take oral therapy
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<tr><td>Winrevair injection</td><td>
• Trial and failure, intolerance or contraindication to all of the following:
<ul>
<li>Generic sildenafil or tadalafil AND</li>
<li>A generic or preferred endothelin receptor antagonist (ERA)</li>
</ul>
• The member will self-administer Winrevair unless clinically unable to do so
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<br>
d. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents and/or the plan's utilization management medical drug list<br>
***Note: This policy pertains to Medicare Part B only**
</td></tr>
<tr><td>Authorization Period</td><td>One year at a time unless specified below<br>i. Uptravi injection: 60 days</td></tr>
<tr><td>Renewal Criteria</td><td>Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit unless specified below.<br>i. Uptravi injection: Not applicable as no further authorization will be provided</td></tr>
<tr><td>Quantity Limitations</td><td>Align with FDA recommended dosing</td></tr>
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|---|---|
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34149&ver=51&= |
| | |
| **Qalsody™** (tofersen)<br>**HCPCS:** J1304 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmed superoxide dismutase 1 (SOD1) mutation<br>d. Vital capacity greater than 50% predicted<br>e. Currently receiving treatment and will continue to receive treatment with riluzole, if tolerated<br>f. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Radicava®** (edaravone) | |

| **HCPCS:** J1301 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with a neurologist<br>d. Start of treatment is within 2 years of diagnosis with amyotrophic lateral sclerosis (ALS)<br>OR<br>After 2 years of diagnosis, with a percent predicted vital capacity value of ≥ 80 %.<br>e. Currently receiving treatment and will continue to receive treatment with riluzole, if tolerated<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | 6 months |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| | |
| **Ranibizumab Policy**<br>**Byooviz™** (ranibizumab-nuna) Q5124<br>**Cimerli™** (ranibizumab-eqrn) Q5128<br>**Lucentis®** (ranibizumab) J2778<br>**Nufymco®** (ranibizumab-leyk) J3590 | |

| **Ranibizumab-nuna** Q5124<br>**Susvimo™** (ranibizumab) J2779 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Treatment with bevacizumab or a bevacizumab biosimilar has been ineffective, not tolerated or contraindicated<br>d. For Susvimo only<br>f) Must have experienced disease stability or improvement following at least 2 injections in the same eye of either Beovu®, Eylea™, or Lucentis prior to Susvimo therapy<br>g) Supplemental treatment is allowed only with Lucentis if ONE of the following are met:<br>1. A decrease in visual acuity by half from the baseline visual acuity<br>2. Increase of 150 µm or more in retinal thickness<br>e. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | a. For at least 60 days and up to one year at a time<br>i. For Susvimo only: Up to 2 supplemental Lucentis injections per affected eye allowed per 6 month refill |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Reblozyl®** (luspatercept-aamt)<br>**HCPCS:** J0896 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of anemia in adult patients with beta-thalassemia who require regular red blood cell (RBC) transfusions<br>i. Genetic testing confirming diagnosis of β-thalassemia<br>ii. Must not have hemoglobin S/β-thalassemia or α-thalassemia<br>iii. Must be considered transfusion dependent with a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the previous two years OR be managed under standard thalassemia guidelines with ≥ 8 transfusions of pRBCs per year in the previous two years<br>c. Diagnosis of myelodysplastic syndrome (MDS)<br>i. Must have anemia requiring at least 2 units of red blood cells over 8 weeks (about 2 months)<br>ii. World Health Organization (WHO)/French American British (FAB) classification that meets IPSS-R classification of very low, low, or intermediate risk disease<br>iii. Less than 5% blasts in the bone marrow<br>iv. Must be refractory, intolerant, or ineligible to receive an erythropoietin stimulating agents (ESA) unless serum epopoietin is greater than 500 mU/mL or for those with IPSS-R very low, low, or intermediate disease without a del(5q) mutation with ring sideroblasts (RS) greater than or equal to 15% or RS greater than or equal to 5% with an SF3B1 mutation defined as at least one of the following:<br>1. Documentation of non-response or response that is no longer maintained to prior ESA-containing regimen of either recombinant human erythropoietin > 40,000 IU/week for at least 8 doses or equivalent OR darbepoetin alpha > 500 µg every 3 weeks for at least 4 doses or equivalent<br>2. Documentation of discontinuation of prior ESA-containing regimen at any time after introduction due to intolerance or an adverse event |

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| | 3. A low chance of response to an ESA based on endogenous serum erythropoietin level > 200 U/L for subjects not previously treated with ESA's<br>v. Must not have MDS associated with del 5q cytogenetic abnormality<br>vi. Must not have secondary MDS known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases<br>d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Continuation of therapy is provided based on documentation of clinical response demonstrated through a reduction in transfusions for transfusion dependent (TD) patients or increase in hemoglobin in non-transfusion dependent (NTD) patients |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Rebyota**® (fecal microbiota, live-jslm)<br>**HCPCS:** J1440 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Had at least 1 recurrence after a primary episode of *Clostridioides difficile* infection (CDI) and completion of one or more round(s) of standard-of-care antibiotic therapy (ex: metronidazole, vancomycin, fidaxomicin) OR two or more episodes of severe CDI resulting in hospitalization within the past year |

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| | d. A *C. difficile* stool test with toxin A/B positive results within the previous 30 days<br>e. Not to be used in combination with Zinplava™ or Vowst™<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 60 days |
| Renewal Criteria | Not applicable as no further authorization will be provided. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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**Rituximab Class Policy**
**Riabni™** (rituximab-arrx) Q5123
**Rituxan®** (rituximab) J9310; J9312
**Rituxan Hycela®** (rituximab and hyaluronidase human) J9311
**Ruxience™** (rituximab-pvvr) Q5119
**Truxima™** (rituximab-abbs) Q5115

| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Rituxan Hycela<br>i. FDA approved indications<br>ii. Trial and failure, contraindication, or intolerance to intravenous rituximab<br>b. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list |

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| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Treatment continued until disease progression or unacceptable toxicity |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
| LCD/NCD | https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35026&ver=75& |
| **Rivfloza™** (nedosiran)<br>**HCPCS:** J3490 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation<br>b. FDA approved age<br>c. Patient has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2<br>d. Patient does not have a history of kidney or liver transplant<br>e. Trial and failure to at least 3 months, contraindication, OR intolerance to a course of high-dose vitamin B-6 therapy<br>f. The member will self-administer Rivfloza unless clinically unable to do so<br>g. Will not be used in combination with Oxlumo<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | One year at a time |

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| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Roctavian™** (valoctocogene roxaparvovec)<br>**HCPCS:** J1412 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of severe hemophilia A with factor VIII level < 1% IU/dL<br>c. Must not have detectable pre-existing immunity to the adeno-associated virus serotype 5 (AAV5) capsid<br>d. Must not have a history of inhibitors to factor VIII or a positive factor VIII inhibitor screen defined as greater than or equal to 0.6 Bethesda units prior to administration of Roctavian<br>e. Must have been treated with or exposed to factor VIII concentrates or cryoprecipitate for a minimum of 150 exposure days<br>f. Must be treatment experienced with Hemlibra® for at least 6 months and experienced treatment failure defined as any of the following:<br>i. Spontaneous soft tissue bleeding event<br>ii. Micro-bleeding into a joint<br>iii. Ongoing joint pain of a known target joint<br>g. Must not have received prior treatment with any gene therapy for hemophilia A or are being considered for treatment with any other gene therapy for hemophilia A<br>h. Must be being treated at a federally recognized hemophilia treatment center site |

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| | i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan.<br>j. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 3 months |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Ryoncil®** (remestemcel-L)<br>**HCPCS:** J3590 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Member has demonstrated progression of disease by day 5 or nonresponse by day 7 while on corticosteroids.<br>d. Trial and failure, contraindication, or intolerance to Jakafi® (ruxolitinib) when age appropriate per FDA labeling.<br>e. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan.<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |

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| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Rystiggo®** (rozanolixizumab-noli)<br>**HCPCS:** J9333 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Documented anti-acetylcholine receptor (AChR) antibody positive myasthenia gravis (MG) identified by:<br>i. Lab record or chart notes identifying the patient is positive for anti-AChR antibodies<br>AND<br>ii. One of the following confirmatory tests:<br>1. Positive edrophonium test<br>2. History of clinical response to oral cholinesterase inhibitors (for example: pyridostigmine)<br>3. Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>OR |

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| | d. Documented anti-muscle-specific tyrosine kinase (MuSK) antibody positive MG identified by:<br>i. Lab record or chart notes identifying the patient is positive for anti-MuSK antibodies<br>AND<br>ii. Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>e. Patients must NOT have a history of:<br>i. Thymectomy within 6 months<br>ii. Current thymoma<br>iii. Other neoplasms of the thymus<br>f. Previous treatment courses of at least 12 weeks with one of the following standards of care have been ineffective: methotrexate, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, or tacrolimus unless all are contraindicated or not tolerated<br>g. Patient is currently receiving, and will continue to receive, a stable standard of care regimen<br>h. Must not be used with other biologic therapies for myasthenia gravis or immunoglobulin therapy<br>i. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Rytelo™** (imetelstat)<br>**HCPCS:** J0870 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Must have anemia requiring at least 4 units of red blood cells over an 8-week period<br>d. World Health Organization (WHO)/French American British (FAB) classification that meets IPSS classification of low or intermediate-1 risk disease<br>e. Must be refractory, intolerant, or ineligible to receive an erythropoietin stimulating agent (ESA) unless serum erythropoietin is greater than 500 mU/mL defined as at least one of the following:<br>i. Documentation of non-response or response that is no longer maintained to prior ESA-containing regimen of either recombinant human erythropoietin > 40,000 IU/week for at least 8 doses or equivalent OR darbepoetin alpha > 500 µg every 3 weeks for at least 4 doses or equivalent<br>ii. Documentation of discontinuation of prior ESA-containing regimen at any time after introduction due to intolerance or an adverse event<br>f. Must not have myelodysplastic syndrome (MDS) associated with del 5q cytogenetic abnormality<br>g. Must not have secondary MDS known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases<br>h. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Saphnelo™** (anifrolumab-fnia)<br>**HCPCS:** J0491 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Patients have tested positive for serum antibodies at 2 independent time points<br>d. Patients must have active disease<br>e. Patient does not have active lupus nephritis or central nervous system lupus<br>f. Previous treatment courses of at least 12 weeks each with 2 or more of the following have been ineffective: chloroquine, hydroxychloroquine, methotrexate, azathioprine, cyclophosphamide OR mycophenolate mofetil, unless all are contraindicated or not tolerated<br>g. Patient is currently receiving, and will continue to receive, a stable standard of care regimen. Standard of care treatment regimen comprised of any of the following drug classes, alone or in combination:<br>i. Antimalarials<br>ii. Corticosteroids<br>iii. Non-biologic immunosuppressants<br>h. Not to be used in combination with other biologics (ex Benlysta®)<br>i. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's medical utilization management drug list |
| Authorization Period | One year at a time |

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| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Simponi Aria®** (golimumab)<br>**HCPCS:** J1602 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of rheumatoid arthritis (RA):<br>i. Trial and failure of at least a 3-month trial of one disease-modifying anti-rheumatic drug (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine<br>ii. Used in combination with methotrexate (unless contraindicated)<br>c. Diagnosis of psoriatic arthritis (PsA)<br>d. Diagnosis of ankylosing spondylitis (AS)<br>e. Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)<br>i. Trial and failure of at least a 3-month trial of one DMARD unless contraindicated or not tolerated. Examples include methotrexate and leflunomide<br>f. The member must self-administer Simponi unless clinically unable to do so<br>g. Not to be used in combination with other biologics or targeted DMARDs for the same indication<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |

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| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Skyrizi™** (risankizumab-rzaa)<br>**HCPCS:** Skyrizi SC: J3590; Skyrizi IV: J2327 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation*.<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age.<br>b. Diagnosis of psoriasis<br>i. Trial and failure, contraindication, or intolerance to one topical corticosteroid<br>c. Diagnosis of psoriatic arthritis<br>d. Diagnosis of Crohn's disease (CD)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated.<br>e. Diagnosis of ulcerative colitis (UC)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated.<br>f. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication |

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| | g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing. |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Spevigo**® (spesolimab-sbvo)<br>**HCPCS: J1747** | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Patient has a history of generalized pustular psoriasis (GPP) as defined by the European Rare and Severe Psoriasis Expert Network<br>d. For the treatment of GPP flares:<br>i. Patient is experiencing a GPP flare of moderate-to-severe intensity defined by all of the following:<br>1. A Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score $\geq$ 3<br>2. New or worsening pustules<br>3. GPPGA pustulation sub-score $\geq$ 2 |

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| | 4. ≥ 5% of body surface area (BSA) with erythema and the presence of pustules<br>ii. Trial and failure, contraindication, or intolerance to one of the following systemic therapies: acitretin, cyclosporine, methotrexate, infliximab<br>e. For the prevention of GPP flares:<br>i. A GPPGA total score of 0 or 1<br>ii. A history of at least 2 past moderate-to-severe GPP flares with new or worsening pustulation<br>iii. Member must have tried at least one of the following systemic therapies for the prevention of GPP flares and continued to experience GPP flares either during treatment, following dose reduction, or following/within one year of treatment discontinuation, unless contraindicated or not tolerated: acitretin, methotrexate, cyclosporine, infliximab.<br>f. Not to be used in combination with other biologics or targeted DMARDs<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents. |
| Authorization Period | i. Spevigo IV: 12 weeks<br>ii. Spevigo SC: One year at a time |
| Renewal Criteria | i. Spevigo IV: Not applicable as no further authorization will be provided.<br>ii. Spevigo SC: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Spinraza®** (nusinersen)<br>**HCPCS:** J2326 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.* |

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| | A. Coverage of the requested drug is provided when all the following are met:<br>a. Types 1, 2, or 3 Spinal Muscular Atrophy (SMA) confirmed by genetic testing<br>b. FDA approved age<br>c. Prescribed by or in consultation with a neurologist specializing in pediatric neuromuscular disorders<br>d. Patient is not fully ventilator dependent<br>e. Patient is not concurrently taking SMN2-targeting antisense oligonucleotide or SMN2 splicing modifier or gene therapy AND patient has not received prior treatment with any gene therapy for SMA (such as Zolgensma)<br>f. Submission of a baseline, age appropriate exam to establish baseline motor function and ability. Examples of baseline motor ability assessments include:<br>i. Hammersmith Infant Neurological Exam (HINE)<br>ii. Hammersmith Functional Motor Scale Expanded (HFMSE)<br>iii. Upper Limb Module (ULM) Test (nonambulatory patients)<br>iv. Six-Minute Walk Test (6MWT) (ambulatory patients only)<br>v. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)<br>g. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>h. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents |
| Authorization Period | 6 months at a time |
| Renewal Criteria | Continuation of coverage requires submission of repeat motor ability assessment and documentation of response to therapy defined as a clinically significant improvement in SMA-associated motor milestones and motor function (for example, progression, stabilization, or decreased functional motor decline) compared to predicted natural history and progression |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Syfovre™** (pegcetacoplan)<br>**HCPCS:** J2781 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Must not have geographic atrophy (GA) secondary to a condition other than dry age-related macular degeneration (AMD)<br>d. Must have a visual acuity in the affected eye(s) of 20/320 or better<br>e. Must not be used in combination with Izervay™ or any other medication for GA<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tecartus™** (brexucabtagene autoleucel) | |

| **HCPCS:** Q2053 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Prescribed by on in consultation with an oncologist<br>c. Treatment of adult patients with relapsed or refractory mantle cell lymphoma:<br>i. Subjects must have received adequate prior therapy including at a minimum:<br>1. An anthracycline or bendamustine-containing chemotherapy<br>2. An anti-CD20 monoclonal antibody therapy<br>3. A Bruton's tyrosine kinase (BTK) inhibitor:<br>ii. Must have 1 measurable lesion<br>iii. Patient must meet all of the following:<br>1. ECOG performance status 0 - 2<br>2. Platelet count greater than 75,000/µL<br>3. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal<br>4. Creatinine clearance greater than 30 mL/min<br>5. Cardiac ejection fraction greater than 40%<br>6. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>8. No prior allogeneic HSCT<br>9. No known active central nervous system malignancy<br>10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>11. No thromboembolic events within 6 months<br>12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug- |

induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening

13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis

d. Diagnosis of relapsed[a]/refractory[b] B-cell precursor acute lymphoblastic leukemia (ALL)

i. Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to or have failed 2 lines of tyrosine kinase inhibitor therapy (TKI), or if TKI therapy is contraindicated

ii. Patient must meet all of the following:

1. ECOG performance status 0 - 2
2. No diagnosis of Burkitt's lymphoma
3. No grade 2 to 4 graft-versus-host disease
4. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal
5. Creatinine clearance greater than 30 mL/min
6. Cardiac ejection fraction greater than 40%
7. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
8. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
9. Has not received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to Tecartus infusion
10. No known active central nervous system malignancy
11. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
12. No thromboembolic events within 6 months
13. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
14. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis

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| | e. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>f. Only to be administered at certified bone marrow/stem cell transplant centers<br>g. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list<br>h. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>i. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee<br><br>[a] Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, ie, failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).<br>[b] Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic stem cell transplant |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tecelra®** (afamitresgene autoleucel)<br>**HCPCS:** J3590 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Patients must have been treated with at least one of the following:<br>i. An anthracycline-containing chemotherapy regimen<br>ii. An ifosfamide-containing chemotherapy regimen<br>d. Must be HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive<br>e. Tumor must show MAGE-A4 expression of greater than or equal to 2+ staining in greater than or equal to 30% of the cells by immunohistochemistry<br>f. Must have measurable disease<br>g. Must not have any of the following:<br>i. ECOG performance status greater than 1<br>ii. Absolute neutrophil count (ANC) less than or equal to 1 x $10^9$/L<br>iii. Platelets less than 75,000/$mm^3$<br>iv. Alanine transaminase (ALT) and aspartate transaminase (AST) greater than 2.5 times the upper limit of normal (ULN)<br>v. Creatinine clearance less than 40 mL/min<br>vi. Left ventricular ejection fraction (LVEF) less than 40%<br>vii. Symptomatic central nervous system metastases<br>viii. History of another primary malignancy that is not considered to be in complete remission<br>ix. Infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>x. HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable; or human T-cell leukemia virus<br>xi. Any primary immunodeficiency<br>h. Have not received prior treatment with any autologous SPEAR T-cell therapy despite indication or any other autologous SPEAR T-cell therapy or are being considered for treatment with any other autologous SPEAR T-cell therapy |

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| | i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list<br>k. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tecvayli™** (teclistamab-cqyv)<br>**HCPCS:** J9380 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with an oncologist<br>d. Treatment of patients with relapsed or refractory multiple myeloma after at least 4 prior lines of therapy<br>e. Patients must have been treated with all of the following:<br>i. An immunomodulatory agent<br>ii. A proteasome inhibitor |

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| | iii. An anti-CD38 antibody<br>f. Patients must meet all of the following<br>i. ECOG performance status of 0 - 2<br>ii. No known central nervous system involvement with myeloma<br>iii. No allogenic stem cell transplant within the past 6 months<br>iv. No autologous stem cell transplant within the past 12 weeks<br>g. Have not received prior treatment with any bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager therapy<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | Treatment may be continued until disease progression or until unacceptable toxicity occurs |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tepezza™** (teprotumumab-trbw)<br>**HCPCS:** J3241 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with an endocrinologist or ophthalmologist<br>d. Must have treated thyroid disease defined as: |

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| | i. Euthyroid function with free triiodothyronine (T3) and thyroxine (T4) within the normal limits for the range of the laboratory<br>OR<br>ii. Thyroid function is normalizing with both T3 and T4 levels being less than 50% above or 50% below the normal limits for the range of the laboratory<br>e. Treatment with an adequate course of oral or intravenous (IV) corticosteroids (for example 30 mg/day prednisone for 4 weeks) has been ineffective, not tolerated, or is contraindicated<br>f. Physician attestation a discussion has been had with the member to stop smoking if they are a current smoker<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's medical utilization management drug list |
| Authorization Period | 6 months |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tezspire™** (tezepelumab-ekko)<br>**HCPCS:** J2356 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Criteria:<br>h. FDA approved indication<br>i. FDA approved age<br>j. For severe asthma, including eosinophilic, allergic, and OCS dependent phenotypes: |

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| | h) Must be used as add-on maintenance treatment with severe uncontrolled asthma and patient will continue to receive standard of care regimen<br>i) Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with:<br>1. Long acting inhaled β2 agonist (LABA) for at least 3 months fails to maintain adequate control<br>OR<br>2. Leukotriene modifier for at least 3 months fails to maintain adequate control<br>OR<br>3. LAMA (long-acting muscarinic antagonists) for at least 3 months fails to maintain adequate control<br>d. Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)<br>i. Patient is currently receiving, and will continue to receive standard of care regimen<br>ii. Recurring severe CRSwNP despite previous treatment with intranasal corticosteroids<br>e. For eosinophilic asthma:<br>i. History of treatment failure, intolerance or contraindication to at least a 4-month trial of an anti-interleukin 5 therapy (e.g., Fasenra®, Nucala®), AND<br>ii. History of treatment failure, intolerance or contraindication to at least a 4-month trial of Dupixent®<br>f. For allergic asthma:<br>i. History of treatment failure, intolerance or contraindication to at least a 4-month trial of Xolair®<br>g. For OCS dependent asthma:<br>i. History of treatment failure, intolerance or contraindication to at least a 4-month trial of Dupixent<br>h. Not to be used in combination with other biologics or targeted DMARDs for the same indication.<br>i. The member will self-administer Tezspire unless clinically unable to do so<br>j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tocilizumab Products**<br>**Actemra**® (tocilizumab) J3262<br>**Avtozma**® **(**tocilizumab-anoh) J3590<br>**Tocilizumab-aazg** Q5135<br>**Tofidence™** (tocilizumab-bavi) Q5133<br>**Tyenne™** (tocilizumab-aazg) Q5135 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indications<br>b. FDA approved age<br>c. Diagnosis of rheumatoid arthritis (RA):<br>i. Trial and failure of at least 3 months of one disease-modifying anti-rheumatic agent (DMARD) unless contraindicated or not tolerated. Examples include methotrexate, hydroxychloroquine, leflunomide, sulfasalazine<br>d. Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)<br>i. Trial and failure of at least 3 months of one DMARD unless contraindicated or not tolerated. Examples include methotrexate and leflunomide<br>e. Diagnosis of Still's disease, including systemic juvenile idiopathic arthritis (sJIA) and adult-onset Still's disease (AOSD)<br>i. Trial and treatment failure with one of the following: glucocorticoids or NSAIDs<br>f. Diagnosis of cytokine release syndrome (CRS)<br>i. Prescribed by or in consultation with an oncologist<br>ii. Severe or life-threatening CRS associated with chimeric antigen receptor (CAR)-T cell therapy<br>g. Diagnosis of giant cell arteritis (GCA) |

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| | h. Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)<br>i. Inadequate response to (as evidenced by disease progression - e.g. worsening of pulmonary function) or not a candidate for either mycophenolate mofetil OR cyclophosphamide<br>i. The member will self-administer tocilizumab unless clinically unable to do so.<br>j. Not to be used in combination with other biologics or other targeted DMARDs for the same indication<br>k. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>l. Trial and failure of the preferred products as specified in the plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | i. RA, pJIA, sJIA, GCA, AOSD, SSc-ILD: One year at a time<br>ii. CRS: 60 days |
| Renewal Criteria | i. RA, pJIA, sJIA, GCA, AOSD, SSc-ILD: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit<br>ii. CRS: Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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**Trastuzumab Class Policy**

**Herceptin**® (trastuzumab) J9355
**Hercessi**™ (trastuzumab-strf) Q5146
**Herzuma**® (trastuzumab-pkrb) Q5113
**Kanjinti**™ (trastuzumab-anns) Q5117
**Ogivri**™ (traztuzumab-dkts) Q5114
**Ontruzant**® (trastuzumab-dttb) Q5112
**Trastuzumab-dttb** J3590
**Trastuzumab-pkrb** J3590
**Trazimera**™ (trastuzumab-qyyp) Q5116

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Must have human epidermal growth factor receptor 2 (HER2) positive breast cancer, metastatic gastric cancer, gastroesophageal junction adenocarcinoma, or colorectal cancer defined as in situ hybridization (ISH) positive by any of the following:<br>i. Single probe average HER2 copy number greater than or equal to 6.0 signals/cell<br>OR<br>ii. Dual-probe HER2/CEP17 ratio greater than or equal to 2.0<br>OR<br>iii. Dual-probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell<br>b. Must be used with concomitant treatment according to FDA indication or NCCN category 1 or 2A recommendation<br>c. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |
| Renewal Criteria | i. When used as adjuvant breast cancer treatment: Treatment continued until unacceptable toxicity or disease progression for up to a total of 52 weeks of therapy<br>ii. For metastatic breast cancer, colorectal cancer, or gastric or gastroesophageal junction cancer: Treatment continued until unacceptable toxicity or disease progression |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Tremfya® IV** (guselkumab)<br>**HCPCS:** J1628 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. FDA approved weight<br>c. Diagnosis of ulcerative colitis (UC)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>d. Diagnosis of Crohn's disease (CD)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>e. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication<br>f. The member will self-administer Tremfya unless clinically unable to do so.<br>g. Trial and failure of the preferred products as listed in the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Trogarzo**® (ibalizumab-ulyk)<br>**HCPCS:** J1746 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age.<br>b. Will be used in combination with other anti-retroviral therapy for the treatment of human immunodeficiency virus type 1 (HIV-1)<br>c. Patient is heavily treatment-experienced with multidrug resistant HIV-1 infection based on the following:<br>i. Documented resistance to at least one antiretroviral medication from three different classes of drugs.<br>d. Failing their current antiretroviral regimen<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Tzield**™ (teplizumab-mzwv)<br>**HCPCS:** J9381 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Patient has Stage 2 type 1 diabetes confirmed by the following:<br>i. Documentation of the presence of at least two of the following pancreatic islet autoantibodies:<br>a) Glutamic acid decarboxylase 65 (GAD65) autoantibody<br>b) Insulin autoantibody (IAA)<br>c) Insulinoma-associated antigen 2 autoantibody (IA-2A)<br>d) Zinc transporter 8 autoantibody (ZnT8A)<br>e) Islet cell autoantibody (ICA)<br>ii. Documentation of dysglycemia without overt hyperglycemia as demonstrated by at least ONE of the following results on an oral glucose tolerance test (OGTT). If an OGTT is not available, an alternative method for diagnosis of dysglycemia without overt hyperglycemia may be appropriate:<br>a) Fasting blood glucose level of 100 to <126 mg/dL<br>b) 2-hour post-prandial glucose of 140 to <200 mg/dL<br>c) Postprandial glucose level at 30, 60, or 90 minutes $\geq$ 200 mg/dL<br>b. Clinical history of patient does not suggest presence of type 2 diabetes<br>c. FDA approved age<br>d. Prescribed by or in consultation with an endocrinologist<br>e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 60 days |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |

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| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Ultomiris®** (ravulizumab)<br>**HCPCS:** J1303 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH):<br>i. Flow cytometric confirmation of PNH type III red cells<br>ii. Had at least 1 transfusion in 24 months preceding ravulizumab<br>OR<br>iii. Documented history of major adverse thrombotic vascular events from thromboembolism<br>OR<br>iv. Patient has high disease activity defined as a lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms<br>1. Weakness<br>2. Fatigue<br>3. Hemoglobinuria<br>4. Abdominal pain<br>5. Dyspnea<br>6. Hemoglobin < 10 g/dL<br>7. A major vascular event<br>8. Dysphagia<br>9. Erectile dysfunction<br>v. Must not be used in combination with Soliris®, Empaveli™, or other medications to treat PNH |

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| | vi. Trial and failure, contraindication, or intolerance to Empaveli<br>c. Documentation diagnosis of atypical hemolytic uremic syndrome (aHUS)<br>i. Common causes of typical hemolytic uremic syndrome have been ruled out, including infectious causes of HUS and thrombotic thrombocytopenic purpura (TTP)<br>ii. Must present with the following symptoms:<br>1. Hemoglobin < 10 g/dL<br>2. Platelets < 150,000/$mm^3$<br>3. Documented evidence of hemolysis, such as, elevated lactate dehydrogenase levels, decreased haptoglobin level, or schistocytosis<br>4. Increased serum creatinine OR currently undergoing dialysis<br>iii. Must not be used in combination with Soliris or other medications to treat aHUS<br>d. Diagnosis of refractory generalized myasthenia gravis (MG) (IV formulation only)<br>i. Documented diagnosis of refractory, anti-acetylcholine receptor (AChR) antibody positive MG identified by:<br>1. Lab record or chart notes identifying the patient is positive for anti-AChR antibodies<br>AND<br>2. One of the following confirmatory tests:<br>a. Positive edrophonium test<br>b. History of clinical response to oral cholinesterase inhibitors (for example: pyridostigmine)<br>c. Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>ii. Patients must NOT have a history of:<br>1. Thymectomy within 12 months<br>2. Current thymoma<br>3. Other neoplasms of the thymus<br>iii. Must have class II – IV disease<br>iv. Previous treatment courses of at aleast 12 weeks with one of the following standards of care have been ineffective: methotrexate, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, or tacrolimus unless all are contraindicated or not tolerated<br>v. Patient is currently receiving, and will continue to receive, a stable standard of care regimen |

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| | vi. Must not be using with other biologic therapies for myasthenia gravis or immunoglobulin therapy<br>e. Diagnosis of aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) (IV formulation only):<br>i. FDA approved age<br>ii. Must not be used in combination with Uplizna™, Enspryng™, or other medications to treat neuromyelitis optica spectrum disorder (NMOSD)<br>iii. Adequate trial and failure of an adequate trial of, contraindication, or intolerance to Uplizna, and Enspryng<br>f. For the subcutaneous self-administered formulation, patients must have received the first intravenous loading dose under the guidance of a health care provider<br>g. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Uplizna™** (inebilizumab)<br>**HCPCS:** J1823 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age |

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| | c. Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)<br>i. Prescribed by or in consultation with a neurologist<br>ii. Must not be used in combination with Soliris®, Enspryng™, or other medications to treat NMOSD<br>iii. Adequate trial and failure of, contraindication, or intolerance to Enspryng<br>d. Diagnosis of IgG4 related disease (IgG4-RD)<br>i. Confirmation of diagnosis with a score greater than or equal to 20 on the 2019 ACR/EULAR Classification Criteria for IgG4-RD<br>ii. Trial and failure, contraindication, or intolerance to prednisone at a dose of a least 30 mg/day<br>iii. Trial and failure, contraindication, or intolerance to a steroid sparing agent or rituximab or a rituximab biosimiliar<br>e. Diagnosis of myasthenia gravis<br>i. Documented anti-acetylcholine receptor (AChR) antibody positive myasthenia gravis (MG) identified by:<br>1. Lab record or chart notes identifying the patient is positive for anti-AChR antibodies AND<br>2. One of the following confirmatory tests:<br>a) Positive edrophonium test<br>b) History of clinical response to oral cholinesterase inhibitors (for example: pyridostigmine)<br>c) Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>OR<br>ii. Documented anti-muscle-specific tyrosine kinase (MuSK) antibody positive MG identified by:<br>1. Lab record or chart notes identifying the patient is positive for anti-MuSK antibodies AND<br>2. Electrophysiological evidence of abnormal neuromuscular transmission by repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG)<br>iii. Patients must NOT have a history of:<br>1. Thymectomy within 6 months<br>2. Current thymoma<br>3. Other neoplasms of the thymus<br>iv. Previous treatment courses of at least 12 weeks with one of the following standards of care have been ineffective: methotrexate, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, or tacrolimus unless all are contraindicated or not tolerated<br>v. Patient is currently receiving, and will continue to receive, a stable standard of care regimen<br>vi. Must not be used with other biologic therapies for myasthenia gravis or immunoglobulin therapy |

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| | f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 1 year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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**Ustekinumab Products**

**Imuldosa™ (ustekinumab-srlf)** Q5098
**Otulfi™ (ustekinumab-aauz)** Q9999
**Pyzchiva® (ustekinumab-ttwe)** Q9997
**Selarsdi™ (ustekinumab-aekn)** Q9998
**Starjemza (ustekinumab-hmny)** J3590
**Stelara® (ustekinumab)** J3358
**Steqeyma® (ustekinumab-stba)** Q5099
**Ustekinumab** J3590
**Ustekinumab-aauz** J3590
**Ustekinumab-aekn** J3590
**Ustekinumab-auub** Q5138
**Ustekinumab-srif** Q5098
**Ustekinumab-stba** Q5099
**Ustekinumab-ttwe** J3590
**Wezlana™** (ustekinumab-auub) Q5138
**Yesintek™** (ustekinumab-kfce) Q5100

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indications<br>b. FDA approved age<br>c. Diagnosis of Crohn's disease (CD)<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>d. Diagnosis of ulcerative colitis<br>i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated<br>e. Not be used in combination with other biologic agents or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication<br>f. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met<br>g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in The plan's utilization management medical drug list and/or the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Vabysmo™** (faricimab-svoa)<br>**HCPCS:** J2777 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Treatment with bevacizumab or a bevacizumab biosimilar has been ineffective, not tolerated or contraindicated<br>i. Trial and failure of bevacizumab is NOT required for those with a diagnosis of diabetic macular edema when visual acuity in the affected eye(s) is less than or equal to 20/50<br>d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | For at least 60 days and up to one year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Veopoz™** (pozelimab-bbfg)<br>**HCPCS:** J9376 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |

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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Confirmed biallelic CD55 loss-of-function mutation<br>d. Trial and failure, intolerance, or a contraindication to Soliris® or a Soliris biosimilar<br>e. Must not be used in combination with Soliris or any other C5 complement inhibitor<br>f. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the plan's medical utilization management drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Vyjuvek™** (beremagene geperpavec-svdt)<br>**HCPCS:** J3401 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of dystrophic epidermolysis bullosa (DEB) confirmed by genetic test results documenting mutations in the *COL7A1* gene<br>c. Presence of open wounds requiring treatment |

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| | d. Prescriber attestation that member is receiving and adherent to standard wound care interventions<br>e. Patient must not have current evidence or a history of squamous-cell carcinoma or active infection in the area undergoing treatment<br>f. Not to be used in combination on the same wound with other gene therapies for the treatment of DEB<br>g. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | Six months |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Wainua™** (eplontersen)<br>**HCPCS:** J3490 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (formerly known as familial amyloid polyneuropathy, or FAP) |

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| | i. Signs and symptoms of ocular or cerebral area involvement (such as in ocular amyloidosis or primary/leptomeningeal amyloidosis), if present, must not predominate over polyneuropathy symptomology associated with hATTR<br>c. Documentation of TTR gene mutation<br>d. Documentation of clinical signs and symptoms of peripheral neuropathy (such as: tingling or increased pain in the hands, feet and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)<br>AND/OR<br>Documentation of clinical signs and symptoms of autonomic neuropathy symptoms (such as: orthostasis, abnormal sweating, dysautonomia [constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety])<br>e. Must have a baseline FAP or Coutinho Stage 1 or 2<br>f. Wainua will not be used in combination with other therapies approved for transthyretin-mediated amyloidosis<br>g. Must not have New York Heart Association (NYHA) heart failure classification > 2<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's prior authorization and step therapy documents |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Waskyra** (etuvetidigene autotemcel)<br>**HCPCS:** J3590 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Diagnosis of Wiskott-Aldrich syndrome (WAS) confirmed via genetic testing showing a mutation of the WAS gene with one of the following:<br>i. Absence of WAS protein expression<br>ii. WAS clinical score greater than or equal to 3<br>d. Must not have had a prior hematopoietic stem cell transplant (HSCT) or currently be eligible for a HSCT with an HLA matched family donor. For children younger than 5 years of age, no suitable 10/10 matched unrelated donor or 6/6 unrelated cord blood donor<br>e. Must not have presence of HIV-1, HIV-2, hepatitis B, or hepatitis C infection<br>f. Have not received prior treatment with any gene therapy or are being considered for treatment with any other gene therapy for WAS<br>g. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Yartemlea**® (narsoplimab-wuug)<br>**HCPCS:** J3590 | |

| PA/ST CRITERIA | CRITERIA DETAILS |
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| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Must have persistent hematopoietic stem-cell transplantation–associated thrombotic microangiopathy (HSCT-TMA) defined as meeting all of the following for a period greater than or equal to 2 weeks after modification or discontinuation of calcineurin inhibitor (CNI) therapy or greater than or equal to 30 days after transplantation:<br>i. Platelet count less than 150 x $10^9$/L<br>ii. Evidence of microangiopathic hemolysis defined by the presence of schistocytes, serum lactate dehydrogenase (LDH) above the upper limit of normal (ULN), or haptoglobin below the lower limit of normal<br>iii. Kidney dysfunction defined as a doubling of serum creatinine from pretransplant<br>d. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | One year at a time |
| Renewal Criteria | Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Yervoy**® (ipilimumab)<br>**HCPCS:** J9228 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.* |

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| | A. Coverage of the requested drug is provided when all the following are met:<br>a. Diagnosis of:<br>i. Unresectable or metastatic melanoma in adults and pediatric patients 12 years and older as a single agent or in combination with nivolumab<br>ii. Adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy<br>iii. Advanced (stage IV) renal cell carcinoma (RCC) when used in combination with Opdivo<br>1. Previously untreated<br>2. Must be predominant clear cell histology<br>3. Must have at least ONE of the following risk factors:<br>a. Less than one year from the time of diagnosis to the start of systemic therapy<br>b. Karnofsky performance status of < 80%<br>c. Hemoglobin < 12 g/dL<br>d. Calcium > 10.2 mg/dL<br>e. Neutrophils > 7.0 x $10^9$/L<br>f. Platelets > 400,000/mcL<br>iv. A diagnosis of metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC):<br>1. In combination with Opdivo<br>2. Patient age ≥ 12 years old,<br>v. Unresectable or metastatic hepatocellular carcinoma (HCC) in patients previously treated with sorafenib<br>1. In combination with Opdivo<br>2. Patient age ≥ 18 years old<br>3. Must be Child-Pugh class A<br>vi. First-line unresectable of metastatic hepatocellular carcinoma (HCC)<br>1. In combination with Opdivo<br>2. Previously untreated<br>3. Patient age ≥ 18 years old<br>4. Must be Child-Pugh class A |

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| | vii. Metastatic non-small cell lung cancer (NSCLC)<br>1. In combination with Opdivo<br>2. Previously untreated<br>3. Patient age ≥ 18 years old<br>4. Must not have and EGFR or ALK genomic tumor aberrations<br>viii. Advanced or metastatic non-small cell lung cancer (NSCLC)<br>1. In combination with Opdivo and 2 cycles of platinum-doublet chemotherapy<br>2. Previously untreated<br>3. Patient age ≥ 18 years old<br>4. Must not have and EGFR or ALK genomic tumor aberrations<br>ix. Malignant pleural mesothelioma<br>1. In combination with Opdivo<br>2. Previously untreated<br>3. Patient age ≥ 18 years old<br>4. Must not be eligible for curative surgery<br>x. Unresectable advanced or metastatic esophageal squamous cell carcinoma<br>1. In combination with Opdivo<br>2. Previously untreated<br>3. Patient age ≥ 18 years old<br>4. Must express PD-L1 ≥ 1% as determined by a FDA-approved test<br>b. Prescribed by or in consultation with an oncologist<br>c. ECOG performance score of 0 – 2<br>d. Should not be used if treatment failure has occurred with Yervoy or another PD-L1 inhibitor used in combination with Yervoy<br>e. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant<br>f. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in the plan's utilization management medical drug list |
| Authorization Period | Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time |

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| Renewal Criteria | i. Unresectable or metastatic melanoma (adults and pediatrics): Will be reviewed on a case-by-case basis<br>ii. Adjuvant melanoma: Continuation of therapy until disease progression or unacceptable toxicity<br>iii. Advanced renal cell carcinoma: Will be reviewed on a case-by-case basis<br>iv. Metastatic colorectal cancer: Will be reviewed on a case-by-case basis<br>v. Hepatocellular carcinoma: Will be reviewed on a case-by-case basis<br>vi. Metastatic non-small cell lung cancer: Continuation of therapy until disease progression or unacceptable toxicity<br>vii. Malignant pleural mesothelioma: Continuation of therapy until disease progression or unacceptable toxicity<br>viii. Unresectable advanced or metastatic esophageal squamous cell carcinoma: Continuation of therapy until disease progression or unacceptable toxicity |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Yescarta™** (axicabtagene ciloleucel)<br>**HCPCS:** Q2041 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Prescribed by or in consultation with an oncologist<br>c. Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (TFL)<br>i. Subjects must have received adequate prior therapy including at a minimum:<br>1. Anti-CD20 monoclonal antibody unless investigator determines that tumor is CD20-negative and |

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| | 2. An anthracycline containing chemotherapy regimen<br>3. For subjects with transformed FL must have received prior chemotherapy for follicular lymphoma and subsequently have chemorefractory disease after transformation to DLBCL<br>ii. Patient must meet all of the following:<br>1. No prior allogeneic HSCT<br>2. No known active central nervous system malignancy<br>3. ECOG performance status 0 - 2<br>4. Absolute lymphocyte count greater than 100/µL<br>5. Creatinine clearance greater than 30 mL/min<br>6. Hepatic transaminases less than 5 times the upper limit of normal<br>7. Cardiac ejection fraction greater than 40%<br>8. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>9. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>11. No thromboembolic events within 6 months<br>12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>d. Treatment of adult patients with relapsed or refractory follicular lymphoma (FL)<br>i. Subjects must have received at least 2 prior lines of therapy one of which is an anti-CD20 monoclonal antibody combined with an alkylating agent<br>ii. Must have measurable disease<br>iii. Patient must meet all of the following:<br>1. No prior allogeneic HSCT<br>2. No known active central nervous system malignancy |

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| | 3. ECOG performance status 0 - 2<br>4. No transformed FL<br>5. No histological grade 3b FL<br>6. Creatinine clearance greater than 30 mL/min<br>7. Hepatic transaminases less than 5 times the upper limit of normal<br>8. Cardiac ejection fraction greater than 40%<br>9. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>10. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>11. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>12. No thromboembolic events within 6 months<br>13. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>14. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>e. Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy<br>i. Subjects must have received adequate prior therapy with an anti-CD20 monoclonal antibody unless investigator determines that tumor is CD20-negative and an anthracycline containing chemotherapy regimen<br>ii. Patient must meet all of the following:<br>1. No prior allogeneic HSCT<br>2. No known or suspected central nervous system involvement<br>3. ECOG performance status of 0 - 2<br>4. Absolute lymphocyte count greater than 100/µL<br>5. Creatinine clearance greater than 30 mL/min<br>6. Hepatic transaminases less than 5 times the upper limit of normal<br>7. Cardiac ejection fraction greater than 40% |

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| | 8. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable<br>9. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy<br>10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months<br>11. No thromboembolic events within 6 months<br>12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening<br>13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis<br>f. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy<br>g. Only to be administered at certified bone marrow/stem cell transplant centers<br>h. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the plan's utilization management medical drug list<br>i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>j. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the plan's Pharmacy and Therapeutics Committee |
| Authorization Period | 3 months with the allowance of only one dose per lifetime |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |

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| **Zevaskyn™** (prademagene zamikeracel)<br>**HCPCS:** J3389 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. Diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) confirmed by genetic test results documenting mutations in the *COL7A1* gene<br>b. Age ≥ 6 years old<br>c. Wound sites requiring treatment must be open and meet ALL the following:<br>i. Total wound area must be ≥ 200 $cm^2$<br>ii. Present for at least 6 months<br>iii. Classified as a stage 2 wound, defined as partial thickness loss of dermis presenting as a shallow open ulcer with a pink or red wound bed, without slough or bruising<br>d. Prescriber attestation that the member is receiving and adherent to standard wound care interventions<br>e. Must not have current evidence or a history of squamous cell carcinoma or active infection in the area undergoing treatment<br>f. Not to be used in combination on the same wound with other gene therapies for the treatment of RDEB<br>g. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by the plan<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | Six months |
| Renewal Criteria | Not applicable as no further authorization will be provided |

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| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Zilretta**® (triamcinolone acetonide extended-release)<br>**HCPCS:** J3304 | |
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| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved age<br>b. Osteoarthritis of the knee with a Kellgren-Lawrence grade of 2 or greater<br>i. Coverage will not be provided for injections into any joint besides the knee<br>c. Inadequate response to TWO or more of the following:<br>i. Resistance exercise (such as structured weightlifting or resistance band program) or cardiovascular exercise (such as walking, biking, stationary bike, or aquatic exercises)<br>ii. Weight reduction (in those that are overweight defined as a BMI of 25 or greater) by 5% from baseline<br>iii. Utilizing durable medical equipment (such as: wearing medially-directed patellar taping, wearing wedged insoles, or using walking aids)<br>iv. Physical therapy or occupational therapy<br>d. Trial and failure of ALL of the following unless contraindicated or clinically significant adverse events are experienced:<br>i. Oral non-steroidal anti-inflammatory drug (NSAID) at maximal therapeutic dosage<br>1. Oral NSAID not required if the member is at least 65 years of age or under 65 years of age and unable to take an oral NSAID<br>ii. Topical NSAID<br>iii. Immediate-release intra-articular triamcinolone acetonide injection |

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| | 1. Treatment failure is defined as any of the following:<br>- Inadequate pain relief<br>- Frequent need for continued rescue doses of NSAIDs<br>- Inability to increase activity levels or need to decrease activity levels<br>- Adequate pain relief but experienced steroid-induced hyperglycemia<br>2. Please provide a credible explanation why Zilretta is expected to work if triamcinolone acetonide has not<br>e. Must not have had a previous intra-articular corticosteroid injection within the past 3 months.<br>f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 3 months to allow for scheduling |
| Renewal Criteria | Not applicable as no further authorization will be provided |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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| **Zinplava™** (bezlotoxumab)<br>**HCPCS:** J0565 | |
| **PA/ST CRITERIA** | **CRITERIA DETAILS** |
| Criteria | *Requests must be supported by submission of chart notes and patient specific documentation.*<br>A. Coverage of the requested drug is provided when all the following are met:<br>a. FDA approved indication<br>b. FDA approved age<br>c. Prescribed by or in consultation with a gastroenterologist or infectious disease specialist |

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| | d. Patient with a confirmed diagnosis of *Clostridioides difficile* infection (CDI) and stool test with toxin A/B positive results<br>e. Patient at high risk for CDI recurrence e.g.<br>i. Patients aged 65 years and older,<br>ii. History of CDI in the past 6 months,<br>iii. Immunocompromised state,<br>iv. Severe CDI at presentation<br>v. Clostridium difficile ribotype 027<br>f. Used in conjunction with standard of care antibacterial agents (i.e. metronidazole, fidaxomicin, or vancomycin)<br>g. Not to be used in combination with fecal microbiota products, such as Rebyota® or Vowst™<br>h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the plan's utilization management medical drug list. |
| Authorization Period | 60 days |
| Renewal Criteria | Not applicable as no further authorization will be provided. Safety and efficacy of repeat administration of Zinplava in patients with CDI has not been studied |
| Quantity Limitations | Align with FDA recommended dosing |
| References & Summary of Evidence | Medicare Part B References & Summary of Evidence document |
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