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Medical benefit drug policies are a source for WyoBlue Advantage medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/03/2024

Cosentyx® IV (secukinumab)

HCPCS: C9166

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indications
   b. FDA approved age
   c. Diagnosis of psoriatic arthritis (PsA)
   d. Diagnosis of ankylosing spondylitis (AS)
   e. Diagnosis of non-radiographic axial spondyloarthritis (NRAS)
   f. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication
   g. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in WyoBlue Advantage's prior authorization and step therapy documents and/or WyoBlue Advantage's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Cosentyx IV is an interleukin-17 (IL-17) receptor A antagonist indicated for the following:
  - Active psoriatic arthritis in patients 2 years of age and older
  - Adults with active ankylosing spondylitis

- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation

- Cosentyx is available in a self-administered subcutaneous (SC) formulation and an intravenous (IV) infusion for adults with psoriatic arthritis, active ankylosing spondylitis, and active NRAS. The IV formulation requires a healthcare provider for administration.

- Clinical reasons a patient may be unable to self-administer Cosentyx include:

  - Patient or caregivers are unable to perform subcutaneous injections with proper technique.

  - Member requires monthly medical support from the physician.

- Psoriatic Arthritis

  - PsA is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.

  - Per the 2018 American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF) guideline for the treatment of psoriatic arthritis:

    - All recommendations for treatment-naive patients with active PsA are conditional based on low- to very-low quality evidence.

    - In treatment-naïve patients, oral systemic medications (OSMs), such as methotrexate, sulfasalazine, cyclosporine, and leflunomide, may be used in patients without severe psoriatic arthritis and without severe psoriasis. OSMs have robust longitudinal safety and efficacy data in patients with PsA. Maximal response to OSMs are most commonly achieved within 3 months of therapy.

    - If PsA remains active despite OSM therapy, switching to a tumor necrosis factor inhibitor (TNFi), an IL (interleukin)-17 inhibitor (IL-17i), or an IL-12/23i biologic is recommended over switching to a different OSM; switching to a TNFi biologic over an IL-17i or IL-12/23i biologic is conditionally recommended in this scenario based on moderate quality evidence. Additional treatment options include Orencia® (abatacept) and Xeljanz® (tofacitinib). The detailed recommendations for subsequent therapies can be found in the 2018 ACR/NPF guideline for the treatment of psoriatic arthritis.

- Ankylosing Spondylitis

  - Axial spondyloarthritis, comprising AS and NRAS, is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

  - The 2019 American College of Rheumatology recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with NSAIDS, treatment with TNFi biologics are

recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx® (secukinumab) or Taltz® (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.

- Non-Radiographic Axial Spondyloarthritis

    - Axial spondyloarthritis, comprising AS and NRAS, is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

    - The 2019 ACR recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with NSAIDS, treatment with TNFi are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx (secukinumab) or Taltz (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.

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Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*