I. Medication Description

Cosentyx® (secukinumab) is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, which inhibits its interaction with the IL-17A receptor. IL-17A is involved in normal inflammatory and immune responses. Elevated concentrations of IL-17A are found in psoriatic plaques.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

Cosentyx vial for injection is considered a medical benefit (healthcare professional administration only).

Cosentyx Sensoready® pens or prefilled syringes are considered a pharmacy benefit.

III. Policy

Coverage for Cosentyx is provided for adult members for the following conditions when the listed criteria are met:

- Ankylosing spondylitis (active disease):
  - Prescribed by a rheumatologist AND
  - The member has had inadequate results with at least two NSAIDs (unless NSAIDs are contraindicated)

- Plaque psoriasis (moderate to severe disease):
  - Prescribed by a rheumatologist or dermatologist AND
  - At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement AND
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated AND
  - Member has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

- Psoriatic arthritis (active disease):
  - Prescribed by a rheumatologist or dermatologist AND
  - One of the following:
    - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDS are contraindicated) OR
    - If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated)
IV. Quantity Limitations

Quantity will be limited according to indication as follows:

- Ankylosing spondylitis:
  - With a loading dose: 150 mg (1 syringe) at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
  - Without a loading dose: 150 mg (1 syringe) every 4 weeks
- Plaque psoriasis:
  - 300 mg (2 syringes) by subcutaneous injection at weeks 0, 1, 2, 3, and every 4 weeks thereafter
- Psoriatic arthritis:
  - With a loading dose: 150 mg (1 syringe) at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
  - Without a loading dose: 150 mg (1 syringe) every 4 weeks
  - Dosage of 300 mg can be considered if continued active psoriatic arthritis

V. Coverage Duration

Coverage will be authorized for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Clinical response or remission of disease is maintained with continued use AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Cosentyx is available as follows:

- Medical benefit: 150 mg single-use vial for injection (1 vial per carton)
- Pharmacy benefit: 150 mg/mL Sensoready® pens or prefilled syringes (1 or 2 vials per carton)

VIII. Summary of Policy Changes

- 6/15/15: new policy
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 1/19/16: criteria for coverage of the treatment of ankylosing spondylitis and psoriatic arthritis added in response to new FDA-approved indications
- 9/15/16: no policy changes
- 1/1/17: step therapy rules updated; trials with Enbrel and Humira no longer required
- 9/8/17: obsolete lyophilized powder vial removed from policy
- 10/11/17: no policy changes
- 11/1/18: added new vial formulation and clarified medical/pharmacy benefit
IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.