Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 131.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Cosentyx (secukinumab) vials

I. Policy:
Cosentyx (secukinumab) vials

II. Purpose/Objective:
To provide a policy of coverage regarding Cosentyx (secukinumab) vials

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Cosentyx (secukinumab) is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Cosentyx (secukinumab) vials will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. **Psoriatic Arthritis:**
   - Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
     - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
   - Prescription must be written by a rheumatologist or dermatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - **For peripheral disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary NSAIDs **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
   - **For axial disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDs **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
   - Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion

2. **Ankylosing Spondylitis:**
   - Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
   - Prescription must be written by a rheumatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - A therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy **AND**
   - Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion.

3. **Non-radiographic Axial Spondylarthritis:**
   - Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
   - Prescription must be written by a rheumatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of at least one of the following:
     - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
     - Sacroiliitis on magnetic resonance imaging (MRI)

     AND

- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion

Note: The recommended dosing for PsA, AS, and nr-axSpA is listed below.

- With loading dose:
  - 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max. maintenance dose 300 mg per infusion).
- Without loading dose:
  - 1.75 mg/kg every 4 weeks (max. maintenance dose 300 mg per infusion).

AUTHORIZATION DURATION: Approval will be given for an initial duration of one (1) year. Subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of the treated indication while on Cosentyx therapy.

Cosentyx (secukinumab) vials will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. **Psoriatic Arthritis:**
   - Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
     - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
   - Prescription must be written by a rheumatologist or dermatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion

2. **Ankylosing Spondylitis:**
   - Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
   - Prescription must be written by a rheumatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion.

3. **Non-radiographic Axial Spondylarthritis:**
   - Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
   - Prescription must be written by a rheumatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of at least one of the following:
     - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
     - Sacroiliitis on magnetic resonance imaging (MRI)

     AND
   - Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion

Note: The recommended dosing for PsA, AS, and nr-axSpA is listed below.

- With loading dose:
  - 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max. maintenance dose 300 mg per infusion).
- Without loading dose:
  - 1.75 mg/kg every 4 weeks (max. maintenance dose 300 mg per infusion).

AUTHORIZATION DURATION: Approval will be given for an initial duration of one (1) year. Subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of the treated indication while on Cosentyx therapy.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Cosentyx [Prescribing Information]. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. November 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/21/15

Revised: 7/19/16 (updated indication, psoriatic arthritis, ankylosing spondylitis), 3/20/18 (duplicate therapy, formulary alternatives), 4/24/18 (per DHS, grandfather), 2/23/24 (policy and prior auth reinstated, logo, Medicaid Business Segment, description, LOB carve out, revised indications per P&T/new label, references)

Reviewed: 5/16/17, 1/30/19, 1/10/20, 1/9/21, 12/23/21 (Policy retired, Cosentyx vial not on market. Manufacturer with no plans to market product.)

MA UM Committee approval: Pending