Geisinger Health Plan

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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 (immunomodulator) indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

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 when all of the following criteria are met:

1. **Plaque Psoriasis:**
   - Prescription must be written by a dermatologist **AND**
   - Member must be 18 years of age or older **AND**
   - Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by $\geq$ 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals. **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - A therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy.

2. **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

3. **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 medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, 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.

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)

Reviewed: 5/16/17, 1/30/19, 1/10/20, 1/9/21