Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 274.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Spevigo (spesolimab-sbzo)

I. Policy:
Spevigo (spesolimab-sbzo)

II. Purpose/Objective:
To provide a policy of coverage regarding Spevigo (spesolimab-sbzo)

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:
Spevigo (spesolimab-sbzo) is a humanized monoclonal antibody that binds to interleukin-36 (IL36) receptor and prevents binding of endogenous IL36 which prevents activation of proinflammatory and profibrotic pathways by endogenous IL36. The precise role of reduced IL36 receptor activity in generalized pustular psoriasis (GPP) is unknown.

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

Spevigo (spesolimab-sbzo) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation that Spevigo is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of generalized pustular psoriasis (GPP) **AND**
- Medical record documentation of a generalized pustular psoriasis (GPP) flare of moderate to severe intensity and all of the following:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
    - Presence of fresh pustules (new appearance or worsening of pustules) **AND**
    - ≥5% of body surface area covered with erythema and presence of pustules

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

QUANTITY LIMIT: 15 milliliters (2 vials) per claim (Darwin authorization by GPI-14)

AUTHORIZATION DURATION: Initial approval will be for **one dose** of 900 mg (2 vials) for one week. A subsequent approval of Spevigo will be given for **one dose** of 900 mg (2 vials) if the following criteria are met:

- Medical record documentation that member is experiencing persistent symptoms of an acute generalized pustular psoriasis (GPP) flare of moderate to severe intensity AND all of the following criteria:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 2 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
    - Spevigo will be administered no sooner than 1 week after the initial dosage was administered.

AND

- Medical record documentation that member has not already received two doses of Spevigo for treatment of the current generalized pustular psoriasis (GPP) flare

REAUTHORIZATION OF NEW GPP FLARES:
Treatment of new generalized pustular psoriasis (GPP) flares will require reevaluation of coverage for a new initial approval for **one dose** of 900 mg (2 vials) for a duration of one week and the following criteria will be required:

- Medical record documentation the member is being treated for a new generalized pustular psoriasis (GPP) flare of moderate to severe intensity AND all of the following
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
    - Presence of fresh pustules (new appearance or worsening of pustules) **AND**
    - ≥5% of body surface area covered with erythema and presence of pustules **AND**
    - At least 12 weeks have elapsed since the last dose of Spevigo

One subsequent approval of Spevigo for the treatment of persistent symptoms of a repeat generalized pustular psoriasis (GPP) flare will be given for **one dose** of 900 mg (2 vials) for a duration one week if the following reauthorization criteria are met:

- Medical record documentation that member is experiencing persistent symptoms of an acute generalized pustular psoriasis (GPP) flare of moderate to severe intensity AND all of the following criteria:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 2 (moderate to severe) **AND**

- Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
- Spevigo will be administered no sooner than 1 week after the initial dosage was administered.

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: 2/24/23

Revised:

Reviewed: