Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 220.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Scenesse (afamelanotide)

I. Policy:
Scenesse (afamelanotide)

II. Purpose/Objective:
To provide a policy of coverage regarding Scenesse (afamelanotide)

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:
Scenesse (afamelanotide) is a synthetic Alpha-Melanocyte Stimulating Hormone Analog. Afamelanotide is a melanocortin receptor agonist that binds predominantly to MC1-R; increases production of eumelanin in the skin independently of exposure to sunlight or artificial UV light sources

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

Scenesse (afamelanotide) will be considered medically necessary when ALL of the following criteria are met:

- Prescription prescribed by, or in consultation with, a hematologist, dermatologist, gastroenterologist, or other specialist with expertise in the diagnosis and management of EPP **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of erythropoietic protoporphyria (EPP) as confirmed by elevated total erythrocyte protoporphyrin* **AND**
- Medical record documentation of one of the following:
    - o Erythrocyte fractionation showing a greater percentage of metal-free protoporphyrin compared to zinc protoporphyrin** **OR**
    - o Gene sequencing showing an FECH or ALAS2 mutation

AND

- Medical record documentation of a history of phototoxic reaction (e.g. pain, stinging, redness, swelling) AND
- Medical record documentation that sun and light protection measures will be maintained during treatment with Scenesse.

*Note to reviewer: Increased total erythrocyte protoporphyrin with EPP is usually 300-8000 mcg/dL; (normal <80 mcg/dL).

**Note to reviewer: In patients with EPP due to FECH defects, the excess protoporphyrin is almost always > 85% metal-free protoporphyrin and < 15% zinc protoporphyrin. Patients with X-linked form of EPP have 50-85% of porphyrins as metal-free protoporphyrin. Laboratories that measure free protoporphyrin and zinc protoporphyrin include: Porphyria Laboratory and Center, University of Texas Medical Branch at Galveston and Mayo Medical Laboratories.

QUANTITY LIMIT: Darwin: 1 implant every 60 days; max qty supply: 1; min and max day supply: 60.

AUTHORIZATION DURATION: Initial approval will be for 6 months and subsequent approvals will be for 6 months.

REAUTHORIZATION:

- Medical record documentation of reduction in pain associated with light exposure or an increase in light exposure tolerance **AND**
- Medical record documentation that the member received a full skin examination by a dermatologist within the last six months **AND**
- Medical record documentation that sun and light protection measures will be maintained during treatment with Scenesse.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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: 8/27/20

Revised: 8/26/22 (Medicaid PARP language), 9/27/22 (prescriber per DHS)

Reviewed: 8/26/21