Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PHAR.444	**Effective Date: 01/2020** **Revision Date: 01/2021**
Policy Name: Afamelanotide (Scenesse)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:**

Clinical Policy: Afamelanotide (Scenesse)

Reference Number: PA.CP.PHAR.444
Effective Date: 01/2020
Last Review Date: 01/2021

Revision Log

Description
Afamelanotide (Scenesse®) is a melanocortin 1 receptor (MC1-R) agonist.

FDA Approved Indication(s)
Scenesse is indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Scenesse is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Erythropoietic Protoporphyria and X-Linked Protoporphyria (must meet all)**:**

1. Diagnosis of EPP or X-linked protoporphyria (known as XLP or XLEPP);
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Evidence of EPP/XLP-associated acute nonblistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;
5. EPP/XLP is confirmed by the following tests (a and b):
   a. Elevated total erythrocyte protoporphyrin (e.g., 300 to 5,000 mcg/dL vs. normal at < 80 mcg/dL);
   b. Erythrocyte fractionation shows ≥ 50% metal-free vs. zinc protoporphyrin (certified laboratories include University of Texas Medical Branch at Galveston - Porphyria Center, and Mayo Medical Laboratories);
6. Gene sequencing shows an FECH, CLPX, or ALAS2 mutation (genetic testing is available through the Porphyria Center at Mount Sinai Medical Center and Mayo Medical Laboratories);
7. Sun avoidance and use of sunscreen, protective clothing, and pain medication have proven inadequate in controlling EPP-associated painful skin reactions, or are not tolerated;
8. EPP/XLP cutaneous reactions are associated with both of the following (a or b):
   a. Moderate to severe pain as measured on a pain-intensity Likert scale;
   b. Negative impact on quality of life (QOL) as measured by a QOL questionnaire (e.g., Dermatology of Life Quality Index [DLQI], EPP-Quality of Life [QoL]);
9. Member does not have any of the following conditions:
   a. Current Bowen's disease, basal cell carcinoma, or squamous cell carcinoma;
   b. Personal history of melanoma or dysplastic nevus syndrome;

c. Clinically significant EPP/XLP-associated liver disease, as determined by the prescriber;

10. Dose does not exceed one 16-mg implant every 2 months.

Approval duration: 6 months (medical justification is required for requests beyond 3 implants for seasonal coverage)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Erythropoietic Protoporphyria and X-Linked Protoporphyria (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by any of the following (a or b):
   a. Improvement in acute nonblistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;
   b. Improvement on a pain-intensity Likert scale or QOL questionnaire;
3. Member has received a full skin examination by a dermatologist within the last six months;
4. If request is for a dose increase, new dose does not exceed one 16 mg implant every 2 months.

Approval duration: 6 months (medical justification is required for requests beyond 3 implants a year for seasonal coverage)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
EPP: erythropoietic protoporphyria
FDA: Food and Drug Administration
XLP/XLEPP: X-linked protoporphyria/X-linked erythropoietic protoprophyria

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: Manufacturer's Dosing/Administration Information (Prescribing Information)
Scenesse should be administered by a health care professional. All healthcare professionals should be proficient in the subcutaneous implantation procedure and have completed the training program provided by Clinuvel prior to administration of the Scenesse implant.

- A single Scenesse implant is inserted subcutaneously above the anterior supra-iliac crest every 2 months.
- Use the SFM Implantation Cannula to implant Scenesse. Contact Clinuvel, Inc., for other implantation devices that have been determined by the manufacturer to be suitable for implantation of Scenesse.
- Maintain sun and light protection measures during treatment with Scenesse to prevent phototoxic reactions related to EPP.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
EPP	One 16 mg implant SC every 2 months	One implant/2 months

VI. Product Availability

Implant*: 16 mg
**Not supplied with implantation device; consult manufacturer for list of recommended devices.*

VII. References

1. Scenesse Prescribing Information. West Menlo Park, CA; Clinuvel, Inc. October 2019. Available at https://www.accessdata.fda.gov. Accessed October 20, 2020.
2. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for erythropoietic protoporphyria. N Engl J Med. 2015;373(1):48.
3. Gou EW, Balwini M, Bissell DM, et al. Pitfalls in erythrocyte protoporphyrin measurement for diagnosis and monitoring of protoporphyrias. Clin Chem. 2015 December; 61(12): 1453–1456. doi:10.1373/clinchem.2015.245456.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01/2020	
1Q 2021 annual review: no significant changes; references reviewed and updated.	01/2021	