# Clinical Policy: Afamelanotide (Scenesse)

Reference Number: PA.CP.PHAR.444
Effective Date: 01/2020
Last Review Date: 01/2024

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 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 both of 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 a 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 one 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*

DLQI: dermatology of life quality index
EPP: erythropoietic protoporphyria
FDA: Food and Drug Administration
MC1-R: melanocortin 1 receptor
QoL: quality of life
XLP/XLEPP: X-linked protoporphyria/X-linked erythropoietic protoporphyria

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): hypersensitivity to the active substance or to any of the excipients
- Boxed warning(s): 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 2022. Available at https://scenesse.com/. Accessed October 16, 2023.
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.
4. Erythropoietic protoporphyria and X-linked protoporphyria. National Organization of Rare Disorders. Updated 2018. Available at: https://rarediseases.org/rare-diseases/erythropoietic-protoporphyria/. Accessed November 10, 2023
5. Balwani M, Bloomer J, Desnick R, et al.; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic protoporphyria, autosomal recessive. Last updated September 7, 2017. Available at: https://www.ncbi.nlm.nih.gov/books/NBK100826/.

## Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-

to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J7352 | Afamelanotide implant, 1 mg |

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created. | 01/2020 |
| 1Q 2021 annual review: no significant changes; references reviewed and updated. | 01/2021 |
| 1Q 2022 annual review: no significant changes; references reviewed and updated | 01/2022 |
| 1Q 2023 annual review: no significant changes; Appendix C updated with contraindications; references reviewed and updated. | 01/2023 |
| 1Q 2024 annual review: no significant changes; references reviewed and updated. | 01/2024 |