Clinical Policy: Afamelanotide (Scenesse)

Reference Number: PA.CP.PHAR.444
Effective Date: 01/2020
Last Review Date: 01/2025

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) 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);
2. Prescribed by or in consultation with a dermatologist or hematologist;
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. 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;
6. 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]);
7. 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;
8. 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.PHARM.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.PHARM.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. August 2024. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/210797s007lbl.pdf. Accessed October 21, 2024.
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 15, 2024.
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/.
6. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria: Pathophysiology, genetics, clinical manifestations, and management. Mol Genet Metab. 2019 November;123(3):298-303.
7. Dickey AK, Naik H, Keel SB et al. Evidence-based consensus guidelines for the diagnosis and management of erythropoietic protoporphyria and x-linked protoporphyria. J Am Acad Demeratol 2023;89(6):1227-37.

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
1Q 2025 annual review: removed requirement for gene sequencing per consensus guidelines as not required for primary diagnosis and recommended as follow-up tests; references reviewed and updated.	01/2025