Clinical Policy: Afamelanotide (Scenesse)

Reference Number: ERX.SPA.362
Effective Date: 03.01.20
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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;
8. EPP/XLP cutaneous reactions are associated with both of the following (a and 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. Significant EPP/XLP-associated liver disease;
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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Erythropoietic Protoporphyria and X-Linked Protoporphyria (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EPP: erythropoietic protoporphyria
FDA: Food and Drug Administration
QOL: quality of life
XLP/XLEPP: X-linked protoporphyria/X-lined erythropoietic protoporphyria

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/drugsatfda_docs/label/2019/210797s000lbl.pdf. Accessed November 24, 2021.
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.	11.19.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.22.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.16.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.