

Clinical Policy: Afamelanotide (Scenesse)

Reference Number: LA.PHAR.444

Effective Date: 09.29.23

Last Review Date: ~~02.24.25~~03.21.24

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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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 Louisiana Healthcare Connections[®] 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);
 - ~~2.1. Prescribed by or in consultation with a dermatologist;~~
 - ~~2.1. Age \geq 18 years;~~
 - ~~4.1. Evidence of EPP/XLP-associated acute non-blistering 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 \geq 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);**
2. Prescribed by or in consultation with a dermatologist;
3. Age $>$ 18 years;
4. Evidence of EPP/XLP-associated acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;

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~~7-5.~~ Sun avoidance and use of sunscreen, protective clothing, and pain medication have proven inadequate in controlling EPP-associated painful skin reactions;

~~8-6.~~ EPP/XLP cutaneous reactions are associated with both of the following (a and b):

- Moderate to severe pain as measured on a pain-intensity Likert scale;
- 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]);

~~9-7.~~ Member does not have any of the following conditions:

- Current Bowen's disease, basal cell carcinoma, or squamous cell carcinoma;
- Personal history of melanoma or dysplastic nevus syndrome;
- Significant EPP/XLP-associated liver disease;

~~10-8.~~ 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)

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

- If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
- If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business: LA.PMN.53 for Medicaid.~~

II. Continued Therapy

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

- Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
- Member is responding positively to therapy as evidenced by any of the following (a or b):
 - Improvement in acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;
 - Improvement on a pain-intensity Likert scale or QOL questionnaire;
- Member has received a full skin examination by a dermatologist within the last six months;
- 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)

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

- If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

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2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business~~-LA.PMN.53 ~~for Medicaid~~.

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 – LA.PMN.53 ~~for Medicaid~~.

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

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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

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VI. Product Availability

Implant*: 16 mg

**Not supplied with implantation device; consult manufacturer for list of recommended devices.*

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VII. References

1. Scenesse Prescribing Information. West Menlo Park, CA; Clinuvel, Inc. ~~October 2022~~August 2024. Available at https://scenesse.com/-/www.accessdata.fda.gov/drugsatfda_docs/label/2024/210797s0071bl.pdf. Accessed October ~~16, 2023~~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 ~~10, 2023~~15, 2024
5. Balwani M, Bloomer J, Desnick R, et al.; Porphyrrias 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 Dermatol 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	LDH Approval Date
Policy created.	05.09.23	08.28.23
Annual review: no significant changes; references reviewed and updated	03.21.24	05.23.24
<u>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.</u>	02.24.25	

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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