Clinical Policy: Afamelanotide (Scenesse)

Reference Number: LA.PHAR.444
Effective Date:
Last Review Date: 05.09.23
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

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);
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;
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 (must meet 1 or 2)**:**

1. 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
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.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit 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 non-blistering 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. 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
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

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 November 16, 2022.

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/
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	LDH Approval Date
Policy created.	05.09.23	

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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