

afamelanotide acetate (Scenesse)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: DERMATOLOGICAL AGENTS

Mechanism of Action: Melanocortin 1 receptor (MC1-R) agonist

HCPCS:

J7352:Afamelanotide implant, 1 mg

How Supplied:

16 mg implant

Condition(s) listed in policy (see coverage criteria for details)

- Erythropoietic Protoporphyrina (EPP) or X-Linked Protoporphyrina (XLP)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Erythropoietic Protoporphyrina (EPP) or X-Linked Protoporphyrina (XLP)

Meets medical necessity if all the following are met:

1. Patient is 18 years of age or older
2. Prescribed by or in consultation with a dermatologist

Covered Doses:

Single subcutaneous implant (16 mg) every 2 months

Coverage Period:

Indefinite

ICD-10:

E80.0

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Effective: 08/01/2025

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References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Scenesse (afamelanotide) Prescribing Information. Clinuvel, Inc., Burlingame, CA: 8/2024.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee