afamelanotide acetate (Scenesse)

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 Protoporphyria (EPP) or X-Linked Protoporphyria (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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

Erythropoietic Protoporphyria (EPP) or X-Linked Protoporphyria (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:

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E80.0

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