

## 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 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 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 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:**

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*