afamelanotide (Scenesse®)	Place of Service Office Administration Outpatient Facility Administration HCPCS: J7352 per 1 mg

Condition listed in policy (*see criteria for details*)

- Erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP)

AHFS therapeutic class: Hyperpigmentation agents, systemic

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

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for afamelanotide (Scenesse®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP)

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

Covered Dose:
Single SC implant (16mg) every 2 months

Coverage Period
Indefinite

ICD-10:
E80.0

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for afamelanotide (Scenesse®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 16 mg implant

(6) References

- AHFS®. Available by subscription at http://www.lexi.com

- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Scenesse® (afamelanotide) [Prescribing information]. Burlingame, CA: Clinuvel, Inc.; 10/2022.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee