

<b>Policy Name:</b>	<b>Scenesse (afamelanotide)</b>	<b>Policy#:</b>	<b>2828P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Scenesse (afamelanotide) indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria.

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Scenesse (afamelanotide) under the specialty medical benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria for Phototoxic Reactions from Erythropoietic Protoporphyrin (EPP)

- 1.1 Documented diagnosis of EPP defined by the following:
  - Gene sequencing confirms an FECH mutation
  - Substantially elevated erythrocyte total protoporphyrin (between 300 – 5,000 mcg/dL)
- 1.2 Documentation that the patient has non-blistering photosensitivity (e.g., pain, erythema, swelling) following sunlight exposure
- 1.3 Provider documentation indicating that the member is expected to have regular sun exposure in the next 3 months with a risk of skin reactions
- 1.4 Age 18 years or older
- 1.5 Prescribed by or in consultation with a dermatologist (skin doctor) or porphyria specialist
- 1.6 Documented failure, intolerance, or contraindication to high potency oral beta-carotene and pain medication (e.g., NSAIDs)
- 1.7 Documented concurrent use of sunscreen, sun avoidance, and/or protective clothing

### 2. Exclusion Criteria

- 2.1 Patient has a current diagnosis of Bowen’s disease, basal cell carcinoma, squamous cell carcinoma, or other malignant or premalignant skin conditions
- 2.2 History of melanoma or dysplastic nevus syndrome
- 2.3 Significant EPP-associated liver disease

### 3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Subsequent Approvals: 12 months with positive response to therapy and full skin examination by dermatologist (skin doctor)

## CPT Codes

11981-11983	Insertion/removal, non-biodegradable drug delivery implant
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## HCPCS Codes

J7352	Afamelanotide implant, 1mg
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## References

1. Scenese (afamelanotide) [prescribing information]. Burlingame, CA: Clinuvel Inc; October 2022.
2. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyrria. *N Engl J Med* 2015; 373:48.
3. Dickey AK, Naik H, Keel SB, et al. Evidence-based consensus guidelines for the diagnosis and management of erythropoietic protoporphyria and X-linked protoporphyria. *J Am Acad Dermatol.* 2022 Aug 27;S0190-9622(22)02611-1.

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