Pharmacy Drug Policy & Procedure

Policy Name:	Scenesse (afamelanotide)	Policy#:	2828P

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 and Health Alliance Northwest 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 Protoporphyria (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
HCPCS Codes	
J7352	Afamelanotide implant, 1mg

References

1. Scenesse (afamelanotide) [prescribing information]. Burlingame, CA: Clinuvel Inc; October 2022.
2. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyria. 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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DISCLAIMER
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