

POLICY NAME	Scenesse (afamelanotide)	POLICY #	2828P
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Criteria

Coverage Criteria for Phototoxic Reactions from Erythropoietic Protoporphyrria (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

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

Exclusion Criteria – Any of the following prevents coverage

- ☐ **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