Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Afamelanotide (Scenesse)

Notes:

- Quantity Limits: Yes
- Afamelanotide (Scenesse) can only be inserted by a trained health care professional at a designated erythropoietic protoporphyria (EPP) center. EPP centers are listed here: https://scenesse.com/public/epp-centers/
- Patients should receive no more than 6 implants in a 12-month period (1 implant per 60 days).

Non-formulary **afamelanotide (Scenesse)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **afamelanotide (Scenesse)** will be approved for 6 months (3 implants) when the following criteria are met:

- Patient has a biochemically confirmed diagnosis of erythropoietic protoporphyria (EPP) confirmed by at least one of the following:
  - Elevated free protoporphyrin in peripheral erythrocytes OR
  - Presence of loss of function mutation in the ferrochelatase [FECH] gene
- Medication will be administered by a porphyria specialist at a designated EPP center
- Patient is at least 18 years of age
- Patient has documented symptoms of EPP phototoxicity affecting quality of life including intolerance to light due to itching, burning, pain, erythema, or scarring of the skin on contact with sunlight
- Patient does NOT have any of the following conditions:
  - Significant hepatic dysfunction (cirrhosis)
  - Personal history of melanoma or dysplastic nevus syndrome
  - Current Bowen's disease, basal cell carcinoma, squamous cell carcinoma, or other malignant or premalignant skin lesions
  - Other photodermatosis including polymorphic light eruption, actinic prurigo, discoid lupus erythematosus, chronic actinic dermatitis or solar urticaria.

Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **afamelanotide (Scenesse)** will be approved for 6 months (3 implants) when the following criteria are met:

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    - Other photodermatosis including polymorphic light eruption, actinic prurigo, discoid lupus erythematosus, chronic actinic dermatitis or solar urticaria.
- Documentation that the patient has experienced a therapeutic response as defined by at least one of the following:
    - Increase in pain free time during sun exposure
    - Reduction in number or severity of phototoxic reactions from pretreatment baseline

Continued use criteria (after initial 6 month approval): Non-formulary **afamelanotide (Scenesse)** will be approved for continued use when the following criteria are met:

- Documentation that the patient has experienced a therapeutic response as defined by at least one of the following:
    - Increase in pain free time during sun exposure
    - Reduction in number or severity of phototoxic reactions from pretreatment baseline