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

Afamelanotide (Scenesse)

Notes:

- 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 four implants in a 12 month period. The recommended number of implants per year is three (depending on length of protection required). Four implants per year is the maximum.

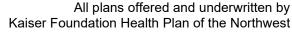
Non-formulary **afamelanotide** (**Scenesse**) requires a clinical review. Appropriateness of therapy will be based on the following criteria:

<u>Initiation (new start) criteria:</u> Non-formulary **afamelanotide (Scenesse)** will be approved for <u>4 months (2 implants)</u> when the following criteria are met:

- Patient has a biochemically confirmed diagnosis of erythropoietic protoporphyria (EPP) confirmed by at least one of the following:
 - o Elevated free protoporphyrin in peripheral erythrocytes OR
 - o 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)
 - o 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.

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Revised: 08/13/20 Effective: 09/17/20





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Afamelanotide (Scenesse)

<u>Criteria for new members entering Kaiser Permanente already taking the</u>
<u>medication who have not been reviewed previously.</u> Non-formulary afamelanotide
(Scenesse) will be covered on the prescription drug benefit for <u>4 months</u> (<u>2 implants</u>)
when the following criteria are met:

- Patient has a biochemically confirmed diagnosis of erythropoietic protoporphyria (EPP) confirmed by at least one of the following:
 - o Elevated free protoporphyrin in peripheral erythrocytes) OR
 - o 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)
 - o 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.
- 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

<u>Continued use criteria (after initial 4 month approval):</u> 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:
 - o Increase in pain free time during sun exposure
 - Reduction in number or severity of phototoxic reactions from pretreatment baseline

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