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| **Section:** | Prescription Drugs | **Effective Date:** | October 1, 2024 |
| **Subsection:** | Topical Products | **Original Policy Date:** | July 24, 2020 |
| **Subject:** | Scenesse | **Page:** | 1 of 4 |

***Last Review Date:*** September 6, 2024

# Scenesse

## Description

## Scenesse (afamelanotide)

**Background**
Scenesse (afamelanotide) is a synthetic tridecapeptide and a structural analog of α-melanocyte stimulating hormone (α-MSH). Scenesse is a melanocortin receptor agonist and binds predominantly to MC1-R (1).

**Regulatory Status**
FDA-approved indication: Scenesse is a melanocortin 1 receptor (MC1-R) agonist indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP) (1).

Scenesse should be administered by a health care professional. All healthcare professionals should be proficient in the subcutaneous implantation procedure and have completed the training program provided by the manufacturer prior to administration of the Scenesse implant (1).

A single Scenesse implant is inserted subcutaneously above the anterior supra-iliac crest every 2 months (1).

Sun and light protection measures should be maintained during treatment with Scenesse to prevent phototoxic reactions related to EPP (1).

Scenesse may lead to generalized increased skin pigmentation and darkening of pre-existing nevi and ephelides because of its pharmacologic effect. A full body skin examination (twice yearly) is recommended to monitor pre-existing and new skin pigmentary lesions (1).

The safety and effectiveness of Scenesse in pediatric patients less than 18 years of age have not been established (1).

**Related policies**

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Scenesse may be considered **medically necessary** if the conditions indicated below are met.

Scenesse may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

History of phototoxic reactions from erythropoietic protoporphyria (EPP)

**AND ALL** of the following:

a. Scenesse is being used to increase pain free light exposure
b. Will be administered by a health care professional who completed the training program and is proficient in the subcutaneous implantation procedure
c. Patient will use with sun and light protection measures to prevent phototoxic reactions related to EPP
d. Prescriber agrees to monitor pre-existing and new skin pigmentary lesions

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

History of phototoxic reactions from erythropoietic protoporphyria (EPP)

**AND ALL** of the following:

a. Patient has experienced a decrease in phototoxic pain
b. Will be administered by a health care professional who completed the training program and is proficient in the subcutaneous implantation procedure
c. Patient will use with sun and light protection measures to prevent phototoxic reactions related to EPP
d. Prescriber agrees to monitor pre-existing and new skin pigmentary lesions

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Quantity** 3 implants

**Duration** 6 months

## Prior – Approval *Renewal* Limits

**Quantity** 6 implants

**Duration** 12 months

## Rationale

**Summary**
Scenesse (afamelanotide) is a synthetic tridecapeptide and a structural analog of α-melanocyte stimulating hormone (α-MSH). Scenesse is a melanocortin receptor agonist and binds predominantly to MC1-R. The safety and effectiveness of Scenesse in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Scenesse while maintaining optimal therapeutic outcomes.

**References**

1. Scenesse [package insert]. West Menlo Park, CA: Clinuvel, Inc.; December 2023.

## Policy History

| Date | Action |
|---|---|
| July 2020 | Addition to PA |
| September 2020 | Annual review |
| September 2021 | Annual review and reference update |
| September 2022 | Annual review |
| September 2023 | Annual review and reference update |
| September 2024 | Annual review and reference update |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.**