
5.90.043

Section:	Prescription Drugs	Effective Date:	October 1, 2023
Subsection:	Topical Products	Original Policy Date:	July 24, 2020
Subject:	Scenesse	Page:	1 of 4

Last Review Date: September 8, 2023

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).

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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:

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

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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

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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.; October 2022.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.