Medical Drug Clinical Criteria

Subject:	Scenesse (afamelanotide)		
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Overview

This document addresses the use of Scenesse (afamelanotide), a melanocortin 1 receptor (MC1-R) agent approved for adults with light intolerance from an inherited disorder called erythropoietic protoporphyria.

Porphyria is a group of genetic disorders characterized by defective production of heme, the oxygen-carrying component of red blood cells. Erythropoietic protoporphyria (EPP) is caused by a gene mutation affecting ferrochelatase, the last enzyme in the heme biosynthesis pathway. This defect leads to accumulation of the phototoxic porphyrin, protoporphyrin IX (PPIX) in body tissues. Activation of PPIX by light releases free radicals that damage tissues. Within minutes of sun exposure (or certain types of artificial light), patients with EPP experience prodromal symptoms (e.g., tinging, itching, skin burning). Continued sun exposure causes severe non-blistering pain that does not respond to analgesics and can take days to resolve. In some individuals, EPP can cause obstruction or inflammation of the gallbladder due to disruption in the biliary system, and more rarely, those with EPP may develop liver damage and liver failure requiring transplantation (APF 2010-2022).

Scenesse, a subcutaneous implant, is the first drug to win Food and Drug Administration (FDA) approval to increase pain-free light exposure in adults with EPP. Prior to approval of Scenesse, there was no effective treatment for EPP other than light avoidance. Scenesse is a peptide analogue of human α-melanocyte–stimulating hormone (α-MSH) that increases the production of the pigment, eumelanin, without light exposure. Eumelanin absorbs ultraviolet light, neutralizes free radicals, and acts as a neutral density light filter. In essence, Scenesse works by tanning the skin and protecting it from light exposure, allowing patients to tolerate being in the sun. Scenesse is not, however, expected to reduce the risk of liver damage in EPP because it does not affect porphyrin accumulation.

Scenesse should be administered by a healthcare professional who has completed the training program provided by the manufacturer and proficient in the general subcutaneous implantation procedure. The clinician should be using a device that has been determined by the manufacturer as suitable for implantation of Scenesse. Damage to the implant could result otherwise.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Scenesse (afamelanotide)

Initial requests for Scenesse (afamelanotide) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of erythropoietic protoporphyria (EPP); **AND**
III. Documentation is provided that diagnostic tests ~~confirm~~ show elevated free protoporphyrin in peripheral erythrocytes (NCT00979745); **AND**
IV. Individual has ~~confirmed~~ history of phototoxic reactions from EPP (such as skin burning, itching, and pain).

Continuation requests for Scenesse (afamelanotide) may be approved if the following criteria are met:

I. Individual experienced a clinically significant response to treatment, including a reduction in phototoxic reactions, or an increase in the pain-free period during direct sunlight exposure.

Scenesse (afamelanotide) may not be approved for the following (NCT00979745):

I. Individual has history of melanoma or dysplastic nevus syndrome; **OR**
II. Individual has current diagnosis of Bowen's disease, basal or squamous cell carcinoma, or other malignant or premalignant skin lesions; **OR**
III. Individual has any other photodermatosis, such as polymorphous light eruption (PLE), discoid lupus erythematosus (DLE), or solar urticaria; **OR**
IV. When the above criteria are not met and for all other indications.

Approval Duration:
Initial requests: 6 months
Continuation requests: 1 year

Quantity Limits

Scenesse (afamelanotide) Quantity Limits

Drug	Limit
Scenesse 16 mg subcutaneous implant	1 implant (16 mg) per 2 months

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
J7352	Afamelanotide implant, 1 mg; 1 billable unit = 1 mg
ICD-10 Diagnosis	
E80.0-E80.20	Disorders of porphyrin and bilirubin metabolism
L56.0-L56.8	Other acute skin changes due to ultraviolet radiation

Document History

Revised: 03/11/2024
Document History:

- 03/11/2024 – Annual Review: wording change. Coding Review: No changes.
- 03/13/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 03/14/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 03/15/2021 – Annual Review: Update criteria to add continuation criteria and approval durations. Clarify definition of DLE. Wording and formatting changes. Coding Reviewed: Added HCPCS J7352.
- 02/21/2020 – Annual Review: Add new clinical criteria document for Scenesse (afamelanotide). Add new quantity for Scenesse. Coding Reviewed: Added HCPCS J3490, J3590. Added ICD-10 E80.0-E80.20, L56.0-L56.8. Effective 1/1/2021 Added HCPCS J7352, Removed HCPCS J3490, J3590.

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