CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Scenesse (Afamelanotide)
BILLING CODE	J7352
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Scenesse, approved by the FDA in 2019, 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). It was the first drug approved for the treatment of EPP. Scenesse is a structural analog of alpha-melanocyte stimulating hormone (alpha-MSH). It increases production of photoprotective eumelanin (a type of melanin pigment) in the skin to help reduce sensitivity to light.
EPP, a subtype of a broader group of disorders known as porphyrias, is a rare inherited metabolic disorder caused by deficiency of the enzyme ferrochelatase (FECH) due to mutations in the *FECH* gene. FECH has a role in the biosynthesis of heme. Low levels of FECH cause excess protoporphyrin to accumulate in certain tissues, which leads to the characteristic symptoms of EPP. The major symptom is skin hypersensitivity to sunlight and some types of artificial light. Complications may include gallbladder dysfunction and liver damage. Less commonly, EPP can be caused by a mutation in the ALAS2 gene. In these cases, it is referred to as X-linked protoporphyria (XLP).

Scenesse (Afamelanotide) will be considered for coverage when the following criteria are met:

Erythropoietic Protoporphyria (EPP)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist, hepatologist, gastroenterologist, or hematologist; AND
3. Member has a documented diagnosis of erythropoietic protoporphyria (EPP), confirmed by at least one of the following methods:
   a) Biochemically (i.e., elevated free protoporphyrin in peripheral erythrocytes)
   b) Genetic testing (i.e., loss of function mutation in the *FECH* gene); AND
4. Member exhibits characteristic symptoms of EPP phototoxicity (e.g., intolerance to light including pain, swelling, burning, itching, and redness of the skin during or after exposure to sunlight) which interferes with their quality of life (i.e., interference with work, activities of daily living, lifestyle choices, etc.); AND
5. Sun avoidance and use of protective measures (i.e., sunscreen, protective clothing, etc.) have been inadequate in controlling EPP phototoxic reactions; AND
6. Member does NOT have any of the following:
   a) EPP with severe hepatic involvement
   b) Untreated malignant or premalignant skin lesions
7. **Dosage allowed/Quantity limit:** One 16 mg subcutaneous implant every 2 months (medical justification is required for requests beyond 3 implants a year for seasonal coverage).
   QL: 1 implant per 60 days; 3 implants per year.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document improvement of signs and symptoms of disease: Increased tolerance to sunlight exposure and/or decreased phototoxic pain; AND
2. Member is receiving skin exams as recommended in the prescribing information.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Scenesse (Afamelanotide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/17/2020	New policy for Scenesse created.
10/24/2022	Updated/added references. Added GI, hepatology, hematology to specialists. Removed pain medications from criteria. Reworded renewal criteria and added skin exam.

References:

1. Scenesse [package insert]. Clinuvel, Inc.; 2020.
2. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyria. *N Engl J Med*. 2015;373(1):48-59. doi:10.1056/NEJMoa1411481
3. American Porphyria Foundation. Erythropoietic protoporphyria (EPP) and X-Linked Protoporphyria (XLP), https://porphyriafoundation.org/for-patients/types-of-porphyria/epp-xlp/
4. Ahmed jan N, Masood S. Erythropoietic Protoporphyria. [Updated 2022 Sep 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK563141/
5. Balwani M, Bloomer J, Desnick R; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic Protoporphyria, Autosomal Recessive. 2012 Sep 27 [Updated 2017 Sep 7]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK100826/
6. Stölzel U, Doss MO, Schuppan D. Clinical Guide and Update on Porphyrias. *Gastroenterology*. 2019;157(2):365-381.e4. doi:10.1053/j.gastro.2019.04.050
7. Balwani M. Erythropoietic Protoporphyria and X-Linked Protoporphyria: pathophysiology, genetics, clinical manifestations, and management. *Mol Genet Metab*. 2019;128(3):298-303. doi:10.1016/j.ymgme.2019.01.020
8. Wensink D, Wagenmakers MAEM, Langendonk JG. Afamelanotide for prevention of phototoxicity in erythropoietic protoporphyria. *Expert Rev Clin Pharmacol*. 2021;14(2):151-160. doi:10.1080/17512433.2021.1879638
9. Gou EW, Balwani M, Bissell DM, et al. Pitfalls in Erythrocyte Protoporphyrin Measurement for Diagnosis and Monitoring of Protoporphyrias. *Clin Chem*. 2015;61(12):1453-1456. doi:10.1373/clinchem.2015.245456

Effective date: 04/01/2023
Revised date: 10/24/2022