PRIOR AUTHORIZATION POLICY

POLICY: Scenesse Prior Authorization Policy
- Scenesse® (afamelanotide subcutaneous implant – Clinuvel)

REVIEW DATE: 01/10/2024

OVERVIEW

Scenesse, a melanocortin 1 receptor agonist, is indicated for the treatment of **erythropoietic protoporphyria (EPP)**, to increase pain-free light exposure in adults with a history of phototoxic reactions.[1] Scenesse is a controlled-release dosage form that is implanted subcutaneously (SC). Scenesse should be administered by a healthcare professional. A single implant which contains 16 mg of afamelanotide is inserted SC above the anterior supra-iliac crest once every 2 months.

Disease Overview

Porphyrias are disorders caused by enzyme defects in heme biosynthesis.[2] There are at least eight different types of porphyrias, which are classified as cutaneous or acute depending on the specific enzyme that is deficient. EPP is a cutaneous porphyria characterized by extreme photosensitivity. It is estimated to occur in 2 to 5 in 1,000,000 individuals.[3]

EPP occurs due to excessive accumulation of protoporphyrin, a heme precursor. Classic EPP is autosomal recessive and occurs due to a defect in the enzyme ferrochelatase, the final enzymatic step in heme biosynthesis.[4] An X-linked subtype of EPP, often referred as X-linked protoporphyria (XLP), accounts for 2% to 10% of all EPP cases. This type develops due to a gain-of-function mutation in an upstream enzyme in heme biosynthesis, leading to excess protoporphyrin production.[3,4] The two subtypes share the same biochemical and clinical features, although females with XLP may be less severely affected. Diagnosis is confirmed by one or both of the following: 1) biochemically via markedly elevated free erythrocyte protoporphyrin, and/or 2) molecular genetic testing.[2,3]

In both EPP subtypes, protoporphyrin accumulation in superficial skin vessels leads to phototoxicity upon light exposure, resulting in the hallmark symptoms of burning, tingling, and itching, which often occur without visible damage.[2-4] Phototoxic pain is not responsive to analgesics, including narcotics; management is focused on prevention of phototoxic episodes.[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Scenesse. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Scenesse as well as the monitoring required for adverse events and long-term efficacy, approval requires Scenesse to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Scenesse is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Erythropoietic Protoporphyria (Including X-Linked Protoporphyria).** Approve for 1 year if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a of at least one porphyric phototoxic reaction; AND
   - **C)** The diagnosis is confirmed by at least one of the following (i or ii):
     - **i.** Free erythrocyte protoporphyrin level above the normal reference range for the reporting laboratory; OR
     - **ii.** Molecular genetic testing consistent with the diagnosis; AND
   - **D)** The agent is prescribed by or in consultation with a dermatologist, gastroenterologist, hepatologist, or physician specializing in the treatment of cutaneous porphyrias.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Scenesse is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Scenesse® subcutaneous implant [prescribing information]. Menlo Park, CA: Clinuvel; October 2022.
2. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria. National Organization of Rare Disorders. Updated 2022. Available at: https://rarediseases.org/rare-diseases/erythropoietic-protoporphyria/. Accessed on December 28, 2023.
3. Balwani M, Bloomer J, Desnick R; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic protoporphyria, autosomal recessive. Updated September 7, 2017. In: GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available at: https://www.ncbi.nlm.nih.gov/books/NBK100826/. Accessed on December 28, 2023.
4. Balwani M, Naik H, Anderson KE, et al. Clinical, biochemical, and genetic characterization of North American patients with erythropoietic protoporphyria and X-linked protoporphyria. *JAMA Dermatol*. 2017;153(8):789-796.