Scenesse® (afamelanotide)

When requesting Scenesse® (afamelanotide), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Scenesse is indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).

Coverage Guidelines

Erythropoietic protoporphyria (including X-linked protoporphyria)

Patient must meet **all** of the following criteria:

- Diagnosis is confirmed by one of the following:
  - Free erythrocyte protoporphyrin level above the normal reference range for the reporting laboratory; OR
  - Molecular genetic testing consistent with the diagnosis
- Has a history of at least one porphyric phototoxic reaction;
- Is 18 years of age or older;
- Scenesse is prescribed by or in consultation with one of the following specialists: dermatologist, gastroenterologist, hepatologist, or a physician specializing in the treatment of cutaneous porphyrias.

Approval duration: 12 months

Dosing Recommendation

The recommended dose of Scenesse is a single Scenesse implant inserted subcutaneously above the anterior supra-iliac crest every 2 months.

References

1. Scenesse® subcutaneous implant [prescribing information]. Menlo Park, CA: Clinuvel; August 2024.
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 January 02, 2025.
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 January 02, 2025.
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.