

Scenesse® (afamelanotide)

When requesting Scenesse® (afamelanotide), the individual requiring treatment must be diagnosed with an 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)

An individual must meet ALL of the following criteria for approval:

- The diagnosis is confirmed by 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; October 2019.
2. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria. National Organization of Rare Disorders. Updated 2018. Available at: <https://rarediseases.org/rare-diseases/erythropoietic-protoporphyria/>. Accessed on January 2, 2020.
3. Balwani M, Bloomer J, Desnick R, et al.; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic protoporphyria, autosomal recessive. Last updated September 7, 2017. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK100826/>. Accessed on January 2, 2020.
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.
5. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for erythropoietic protoporphyria. *N Engl J Med.* 2015;373(1):48-59.
6. Stözl U, Doss MO, Schuppan D. Clinical guide and update on porphyrias. *Gastroenterology.* 2019;157(2):365-381.e4.