

Specialty Guideline Management

Scenesse

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Scenesse	afamelanotide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Scenesse 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).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Initial requests: Increased level of protoporphyrin in peripheral red blood cells.

Reference number(s)
3355-A

Coverage Criteria

Erythropoietic Protoporphyria (EPP)¹

Authorization of 12 months may be granted for the treatment of biochemically confirmed erythropoietic protoporphyria in adult members who have a protoporphyrin level above the lab reference range in peripheral red blood cells.

Continuation of Therapy

Authorization of 12 months may be granted for adult members with an indication in the coverage criteria section who are experiencing benefit from therapy while receiving Scenesse.

References

1. Scenesse [package insert]. Burlingame, CA: Clinuvel Inc.; August 2024.