

# 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 Indications<sup>1</sup>

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 Protoporphyrin (EPP)<sup>1</sup>

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.