Reference number(s)
3355-A

SPECIALTY GUIDELINE MANAGEMENT

SCENESSE (afamelanotide)

POLICY

I. 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 Indication
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.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests: Increased level of protoporphyrin in peripheral red blood cells.

III. CRITERIA FOR INITIAL APPROVAL

Erythropoietic protoporphyria
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.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Scenesse [package insert]. Burlingame, CA: Clinuvel Inc.; October 2022.