# 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.

Scenesse 3355-A SGM P2023.docx

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