

Scenesse (afamelanotide)
Effective 06/01/2025

| | | | | |
|------------------------------|--|--|--|--|
| Plan | <input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange | | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit | | | <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Specialty Limitations | N/A | | | |
| Contact Information | Medical Benefit Pharmacy Benefit | | Phone: 833-895-2611 Phone: 800-711-4555 | Fax: 888-656-6671 Fax: 844-403-1029 |
| Exceptions | N/A | | | |

Overview

Scenesse (afamelanotide) 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.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Scenesse, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Diagnosis of erythropoietic protoporphyria
2. Member is ≥18 years of age
3. Prescriber is a dermatologist or consultation notes from dermatologist are provided
4. Documentation that the implant procedure will be performed at a specialized treatment center (e.g., dermatology, surgeon)
5. Appropriate dosing (e.g. one implant every two months)

Continuation of Therapy

Reauthorization by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 2 months
2. Reauthorizations will be granted for up to three implants for 6 months

References

1. Scenesse [package insert]. Menlo Park, CA: Clinuvel Inc.; 2024 Aug.
2. FDA grant marketing approval for SCENESSE [press release on the internet]. Burlingame (CA): CLINUVEL; 2013 Nov 11 [cited 2021 Nov9]. Available from: <https://www.clinuvel.com/wp-content/uploads/2019/10/FDA-GRANTS-MARKETING-APPROVAL-FOR-SCENESSE%C2%AE.pdf>.

3. Clinical significance and benefit from SCENESSE in US Phase III EPP Study [press release on the internet]. Burlingame (CA): CLINUVEL; 2013 Nov 11 [cited 2021 Nov 9]. Available from: <https://www.clinuvel.com/pharmaceutical/scenesse/scenesse/epp>.
4. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyria. *N Engl J Med*. 2015;373(1):48–59.
5. Center for Drug Evaluation and Research. Drug Trials Snapshots: SCENESSE [webpage on the Internet]: U.S. Food and Drug Administration; January 2020 [cited 2021 Nov 9]. Available from: <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-scenesse>

Review History

01/11/23 – Created for P&T. Matched MH UPPL. Created criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Effective 6/1/25

