Mass General Brigham
Health Plan

Scenesse (afamelanotide)
Effective 06/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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 SCENESSEin 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