Mass General Brigham
Health Plan

Scenesse (afamelanotide)
Effective 04/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations			

Contact Information			
	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882

Exceptions	

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.

No PA	Drugs that require PA
N/A	Scenesse (afamelanotide)[MB]

MB This drug is available through the health care professional who administers the drug or in an outpatient Up or inpatient hospital setting.

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 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.; 2019 Oct.
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.