Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Scenesse® (afamelanotide)

Effective: April 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) - Approved Indications

Scenesse (afamelanotide) is a melanocortin 1 receptor agonist indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Scenesse for Members when the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of erythropoietic protoporphyria confirmed by at least one of the following:
   a. Elevated free erythrocyte protoporphyrin levels in peripheral erythrocytes
   b. Presence of loss of function mutation in the ferrochelatase (FECH) gene

AND

2. Member is at least 18 years of age

AND

3. Medication is prescribed by, or in consultation with, a dermatologist, gastroenterologist, hepatologist, medical geneticist, or physician specializing in the treatment of cutaneous porphyrias

Reauthorization Criteria

1. Documented diagnosis of erythropoietic protoporphyria confirmed by at least one of the following:
   a. Elevated free erythrocyte protoporphyrin levels in peripheral erythrocytes
   b. Presence of loss of function mutation in the ferrochelatase (FECH) gene

AND

2. Member is at least 18 years of age

AND

3. Medication is prescribed by, or in consultation with, a dermatologist, gastroenterologist, hepatologist, medical geneticist, or physician specializing in the treatment of cutaneous porphyrias

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least one (1) of the following:
   a. Increase in pain free time during light/sun exposure
   b. Reduction in number of phototoxic reactions from pretreatment baseline
   c. Decrease in severity of phototoxic reactions from pretreatment baseline

Limitations

- Initial authorization will be for 6 months. Reauthorization will be for 12 months.
- Members new to the plan stable on Scenesse should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J7352	Afamelanotide implant, 1 mg

References

1. Kim ES, Garnock-Jones KP. Afamelanotide: a review in erythropoietic protoporphyria. Am J Clin Dermatol. 2016; 17:179-85.
2. Langendonk JG, Balwani M, Anderson KE et al. Afamelanotide for erythropoietic protoporphyria. N Engl J Med. 2015; 373:48-59.
3. Lengweiler S, Kreim S, Barman-Aksozen J et al. Evaluation of the immunogenicity of the synthetic α-melanocyte-stimulating hormone (α-MSH) analogue afamelanotide ([Nle4-D-Phe7]-α-MSH, Scenesse®) in erythropoietic protoporphyria patients by ELISA detecting both anti -afamelanotide and anti-α-MSH antibodies. Skin Pharmacol Physiol. 2015; 28(2):103-13.
4. National Institute of Health and Care Excellence (NICE). Afamelanotide for treating erythropoietic protoporphyria [ID927]. 2019 March. URL: https://www.nice.org.uk/guidance/indevelopment/gid - hst10009. Available from Internet. Accessed 2020 April 24.
5. Scenesse (afamelanotide) [package insert]. West Menlo Park, CA: Clinuvel, Inc.; August 2024.
6. Stolzel U, Doss MO, Schuppan D. Clinical guide and update on porphyrias. Gastroenterology. 2019; 157(2):365-81.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).
- October 10, 2023: Removed the Limitation The plan will not authorize the use of Scenesse (afamelanotide) for the treatment of any condition not listed above (effective 11/1/2023).
- November 12, 2024: Added requirement to be prescribed by a specialist to both initial and re-authorization criteria (effective 4.1.2025)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.