Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Scenesse® (afamelanotide)

Effective: January 1, 2026

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

Public Plans Products

☒ 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

☒ 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

Erythropoietic protoporphyria (EPP) is an inherited cutaneous porphyria characterized by painful, non-blistering photosensitivity usually first noted in early childhood and occurring acutely after sunlight exposure but leaving little residual skin damage. EPP results from reduction of FECH activity to less than approximately 30 percent of normal, due to loss-of-function variants affecting both FECH alleles (located on chromosome 18).

An increase in erythrocyte protoporphyrin that is primarily free (not complexed with zinc) is diagnostic of EPP. Because laboratory methods and terminology are inconsistent, measurement of total erythrocyte protoporphyrin is preferred for initial screening, followed, if elevated, by fractionation of free and zinc protoporphyrin.

Approval of Scenesse was based on the CUV029 and CUV039 trials in which patients received treatment or placebo every 60 days for a six-month and a nine-month period, respectively, mostly during the summer months. The results of both trials demonstrate an increased number of hours in direct sunlight without pain in patients treated with Scenesse compared to placebo.

Food and Drug Administration - 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 Scenesse when **ALL** the following criteria is met:

1. Documented diagnosis of erythropoietic protoporphyria confirmed by at least **one (1)** 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 18 years of age or older

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 or older

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. Scenesse (afamelanotide) [package insert]. West Menlo Park, CA: Clinuvel, Inc.; August 2024.
2. Stolzel U, et al. Clinical Guide and Update on Porphyrias. Gastroenterology. 2019;157:365-81.
3. Stein P, et al. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. Ann Clin Biochem. 2013;50:217-23.
4. Anderson KE, et al. Recommendations for the diagnosis and treatment of the acute porphyrias. Annals of Internal Medicine. 2005 March; 142 (6): 439-450.
5. Langendonk JG, et al. Afamelanotide for erythropoietic protoporphyria. N Engl J Med 2015; 373:48-59.
6. Mittal S, et al. Erythropoietic protoporphyria and X-linked protoporphyria. UpToDate. Sep 20, 2023.

Approval And Revision History

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

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- December 12, 2023: Removed Limitation Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Added confirmation of diagnoses by requiring at least one of the following: Elevated free erythrocyte protoporphyrin levels in peripheral erythrocytes or Presence of loss of function mutation in the ferrochelatase (FECH) gene (eff 2/1/24).
- November 12, 2024: Added prescriber specialty, and re-authorization requirements (eff 4/1/25)
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically

appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.