Pharmacy Medical Necessity Guidelines: Scenesse® (afamelanotide)

Effective: May 18, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT/ MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

All Commercial Products:
PRECERT:
617.972.9409

Tufts Health Public Plans Products:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

COVERAGE GUIDELINES

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

Initial Therapy

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

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. Documentation the Member has experienced a therapeutic response as defined by at least one 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 (afamelanotide) should be reviewed against Reauthorization Criteria.
- The plan will not authorize the use of Scenesse (afamelanotide) for the treatment of any condition not listed above in the Coverage Guidelines.

CODES

The following HCPCS/CPT code(s) are:

Code	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.; October 2019.
6. Stolzel U, Doss MO, Schuppan D. Clinical guide and update on porphyrias. *Gastroenterology.* 2019; 157(2):365-81.

APPROVAL HISTORY

May 12, 2020: Reviewed by Pharmacy & Therapeutics Committee.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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