THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: SCENESSE (afamelanotide) **Revision Date:** 5/25

DESCRIPTION

SCENESSE (afamelanotide) implant is a controlled-release dosage form for subcutaneous administration. Afamelanotide is a melanocortin-1 receptor (MC1-R) agonist. Each SCENESSE implant contains 16 mg of afamelanotide (equivalent to 18 mg of afamelanotide acetate), and 15.3-19.5 mg of poly (DL-lactide-co-glycolide). Afamelanotide increases production of eumelanin in the skin independently of exposure to sunlight or artificial UV light sources. The FDA approved SCENESSE in 2019 to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).

APPLICABILITY

This policy applies to all OSU Health Plan (OSUHP) benefit plans.

DEFINITIONS

Erythropoietic Protoporphyria (EPP): A rare inherited metabolic disorder characterized by a deficiency of the enzyme ferrochelatase (FECH). It is characterized by abnormally elevated levels of protoporphyrin IX in red blood cells and plasma, and by sensitivity to visible light. EPP can result either from mutations of the ferrochelatase gene (FECH), or less commonly from the delta-aminolevulinic acid synthase-2 gene (ALAS2).

X-linked Protoporphyria (XLP): EPP caused by an ALAS2 mutation.

POLICY

OSU Health Plan considers an initial 6-month approval of SCENESSE (afamelanotide) medically necessary when all of the following criteria are met:

- Covered person is 18 years of age or older; and
- Medication is prescribed by or in consultation with a dermatologist; and
- Medication will be administered by a center trained and accredited, as approved by the US FDA, to prescribe and administer SCENESSE (Refer to *MMPP 41.0 Site of Care* for hospital administration criteria); and
- Covered person has a diagnosis of EPP/XLP as confirmed by the following:
    - FECH or ALAS2 mutation; or
    - Evidence of EPP/XLP-associated acute non-blistering photosensitivity (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun, and all of the following:
        - Elevated total erythrocyte porphyrins (usually 300 – 8,000 mcg/dl, normal <80 mcg/dl); and
        - Fractionation to distinguish between metal-free and zinc protoporphyrin shows the following:
            - Primarily metal-free protoporphyrin (>85% in EPP and 50 – 85% in XLP); and
            - 0% - 50% zinc protoporphyrin (approximately 0-15% in EPP and 15-50% in XLP);
- Sun avoidance and use of sunscreen, protective clothing, and pain medication is ineffective at controlling EPP-associated symptoms; and
- Symptoms impact activities of daily living (ADL) and quality of life (QOL) as evidenced by one or more of the following:
    - Negative impact on QOL as measured by a QOL questionnaire (e.g., Dermatology of Life Quality Index [DLQI], EPP-Quality of Life [QoL]); or
    - Negative impact on ADLS as measured by the Katz Index of Independence in Activities of Daily Living, the Lawton Instrumental Activities of Daily Living (IADL) Scale or other standardized assessment tool; or
- Covered person is not pregnant; and
- Covered person does not have hepatic or renal impairment.

OSU Health Plan considers continued SCENESSE treatment medically necessary when all of the

following criteria are met:

- Covered person previously met initial criteria; and
- Medication is prescribed by or in consultation with a dermatologist; and
- Medication will be administered by a center trained and accredited, as approved by the US FDA, to prescribe and administer SCENESSE (Refer to *MMPP 41.0 Site of Care* for hospital administration criteria); and
- Covered person's symptoms have improved with SCENESSE as evidenced by one or more of the following:
    - Improvement documented in standardized pain assessment; or
    - Improvement documented in QOL questionnaire; or
    - Improvement documented in ADL assessment; or
    - Medical records document improvement in acute non-blistering photosensitivity (e.g., pain, stinging, redness, swelling, blanching) after sun exposure
- Covered person has received a full body skin examination within the last 6 months.

PROCEDURE

Initial Request: If the initial criteria are met, SCENESSE 16 mg will be approved every 2 months for a total of 6 months of treatment (3 implants).

Continuation: If the criteria for continued treatment are met, SCENESSE 16 mg will be approved every 2 months for a total of 12 months of treatment (6 implants).

PRIOR AUTHORIZATION

Prior authorization is required for SCENESSE (afamelanotide).

EXCLUSIONS

OSU Health Plan considers SCENESSE (afamelanotide) experimental and investigational for all other

indications. Only one SCENESSE 16 mg implant is covered every 2 months. Higher dosing or more frequent administration has not been studied and is considered experimental.

CODES

HCPCS codes covered when criteria are met:

Code	Description
J7352	Afamelanotide implant, 1 mg

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