SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Scenesse® (afamelanotide) Implant (J7352) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]: 73372-0116-01

- Scenesse 16 mg implant: 1 implant every 2 months

B. Max Units (per dose and over time) [HCPCS Unit]:

- 16 billable units every two months

C. Billable units:

- 1 mg = 1 billable unit

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is ≥18 years of age
- ❑ Medication is prescribed by or in consultation with a dermatologist
- ❑ Member has confirmed diagnosis of EPP or X-linked protoporphyria (known as XLP or XLEPP; ICD10 E80.0) **(must submit documentation)**
- ❑ Member has evidence of EPP/XLP-associated acute non-blistering cutaneous reactions (e.g., moderate to severe pain, stinging, redness, swelling, blanching) following exposure to sun **(must submit documentation)**
- ❑ EPP/XLP is confirmed by **BOTH** of the following **(must submit testing)**:
  - ❑ Elevated total erythrocyte protoporphyrin (e.g., 300 to 5,000 mcg/dL vs. normal at < 80 mcg/dL)
  - ❑ Erythrocyte fractionation shows ≥ 50% metal-free vs. zinc protoporphyrin
- ❑ Gene sequencing shows a FECH, CLPX, or ALAS2 mutation **(must submit genetic testing)**
- ❑ Member does **NOT** have any of the following conditions:
  - Current Bowen's disease, basal cell carcinoma, or squamous cell carcinoma
  - Personal history of melanoma or dysplastic nevus syndrome
  - Significant EPP/XLP-associated liver disease
- ❑ Requested dose does **NOT** exceed one 16 mg implant every 2 months

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must continue to meet all initial authorization criteria
- ❑ Member is responding positively to therapy as evidenced by at least **ONE** of the following **(must submit documentation)**:
  - ❑ Improvement in acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun
  - ❑ Improvement on a pain-intensity Likert scale or QOL questionnaire
- ❑ Member has received a full skin examination by a dermatologist within the last six months

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Medication being provided by (check box below that applies):

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapuetics Committee**: 5/21/2020
REVISED/UPDATED/REFORMATTED: ~~9/09/2020;~~ **12/28/2023**