OPTIMA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION 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 the information provided is not complete, correct, or legible, the authorization process 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 (J3490) (Medical)**
NDC: 73372-0116-01 (CPT 11981)

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Members Current Weight: _____

- **Quantity Limit:** Scenesse 16 mg implant: every 2 months
- **Max Units:** Coverage will be provided for 6 months or to the member's renewal date, whichever is loner (medical justification is required for request beyond 3 implants a year for seasonal coverage)

❑ 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.

(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 Approval: 6 months

❑ Member is ≥18 years of age

AND

❑ Member has confirmed diagnosis of EPP or X-linked protoporphyria (known as XLP or XLEPP; ICD10 E80.0)

AND

❑ Medication is prescribed by or in consultation with a dermatologist

AND

(Continued on next page)

- ❑ Member has evidence of EPP/XLP-associated acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;

AND

- ❑ EPP/XLP is confirmed by the following tests (a and b):
  - **a.** Elevated total erythrocyte protoporphyrin (e.g., 300 to 5,000 mcg/dL vs. normal at < 80 mcg/dL);
  - **b.** Erythrocyte fractionation shows ≥ 50% metal-free vs. zinc protoporphyrin

AND

- ❑ Gene sequencing shows an FECH, CLPX, or ALAS2 mutation (genetic testing)

AND

- ❑ Sun avoidance and use of sunscreen, protective clothing, and pain medication have proven inadequate in controlling EPP-associated painful skin reactions;

AND

- ❑ EPP/XLP cutaneous reactions are associated with moderate to severe pain

AND

- ❑ 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;

AND

- ❑ Dose does not exceed one 16-mg implant every 2 months

Reauthorization Approval: 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.

- **Continued Therapy for Erythropoietic Protoporphyria and X-Linked Protoporphyria** (all criteria must be met):
  - ❑ Member is currently receiving medication via Optima Health or member has previously met initial approval criteria;

AND

  - ❑ Member is responding positively to therapy as evidenced by any of the following (a or b):
    - **a.** Improvement in acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun
    - **b.** Improvement on a pain-intensity Likert scale or QOL questionnaire;

AND

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- ❑ Member has received a full skin examination by a dermatologist within the last six months

AND

- ❑ If request is for a dose increase, new dose does not exceed one 16 mg implant every 2 months

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

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 5/21/2020
REVISED/UPDATED: 9/9/2020;