CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Scenesse (Afamelanotide)
BILLING CODE	J3490
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— One 16 mg subcutaneous implant every 2 months (3 implants per year)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Scenesse (Afamelanotide) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ERYTHROPOIETIC PROTOPORPHYRIA (EPP)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a porphyria specialist or dermatologist; AND
3. Member has a confirmed diagnosis of erythropoietic protoporphyria (EPP), either biochemically (e.g. elevated free protoporphyrin in peripheral erythrocytes) or by genetic testing (e.g. loss of function mutation in the ferrochelatase [FECH] gene); AND
4. Member exhibits characteristic symptoms of EPP phototoxicity (e.g. intolerance to light including pain, swelling, burning, itching, and redness of the skin during or after exposure to sunlight) which interferes with their quality of life (i.e. interference with work, activities of daily living, lifestyle choices, etc.); AND
5. Sun avoidance, use of protective measures (i.e. sunscreen, protective clothing, etc), and pain medications have been inadequate in controlling EPP phototoxicity reactions; AND
6. Member does not have ANY of the following:
   a) EPP with severe hepatic involvement;
   b) Untreated malignant or premalignant skin lesions.
7. **Dosage allowed:** One 16mg subcutaneous implant every 2 months (medical justification is required for requests beyond 3 implants a year for seasonal coverage).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (Increased sunlight exposure tolerance, decreased phototoxic pain, etc.); AND
2. Absence of unacceptable toxicity from the drug.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Scenesse (Afamelanotide) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute Intermittent Porphyria
- Hereditary Coproporphyria
- Variegate Porphyria
- δ-aminolevulinic acid dehydratase
- Porphyria Cutanea Tarda
- Hepatoerythropoietic Porphyria
- Congenital Erythropoietic Porphyria
- Vitiligo
- Polymorphic Light Eruption (PLE)

DATE	ACTION/DESCRIPTION
06/17/2020	New policy for Scenesse (Afamelanotide) created.

References:

1. Scenesse® [package insert]. West Menlo Park, CA: Clinuvel, Inc.; Revised 10/2019
2. Afamelanotide. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 31, 2020.
3. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyria. N Engl J Med. 2015;373(1):48-59. doi:10.1056/NEJMoa1411481
4. American Porphyria Foundation. Erythropoietic protoporphyria (EPP) and X-Linked Protoporphyria (XLP), https://porphyriafoundation.org/for-patients/types-of-porphyria/epp-xlp/
5. Genetic and Rare Diseases Information Center, National Center for Advancing Translational Sciences. Gaithersburg, MD. Accessed 5/2020.

Effective date: 07/20/2020
Revised date: 06/17/2020