Scenesse (afamelanotide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Continuation requests: 1 year

Medications	Quantity Limit
Scenesse 16 mg subcutaneous implant	1 implant (16 mg) per 2 months

APPROVAL CRITERIA

Initial requests for Scenesse (afamelanotide) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of erythropoietic protoporphyria (EPP); **AND**
III. Documentation is provided that diagnostic tests confirm elevated levels of free protoporphyrin in peripheral erythrocytes (NCT00979745); **AND**
IV. Individual has confirmed history of phototoxic reactions from EPP (such as skin burning, itching, and pain).

Continuation requests for Scenesse (afamelanotide) may be approved if the following criteria are met:

I. Individual experienced a clinically significant response to treatment, including a reduction in phototoxic reactions, or an increase in the pain-free period during direct sunlight exposure.

Scenesse (afamelanotide) may not be approved for the following (NCT00979745):

I. Individual has history of melanoma or dysplastic nevus syndrome; **OR**
II. Individual has current diagnosis of Bowen's disease, basal or squamous cell carcinoma, or other malignant or premalignant skin lesions; **OR**
III. Individual has any other photodermatosis, such as polymorphous light eruption (PLE), discoid lupus erythematosus (DLE), or solar urticaria; **OR**
IV. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: February 23, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Erythropoietic Protoporphyria (EPP) and X-Linked Protoporphyria (XLP). American Porphyria Foundation (APF) 2010-2021. Available at https://www.porphyriafoundation.org/for-patients/types-of-porphyria/epp-xlp/. Accessed on February 23, 2021.
5. Langendonk JG, Balwani M, Anderson KE, et. Al. Afamelanotide for Erythropoietic Protoporphyria. N Engl J Med. 2015 Jul 2;373(1):48-59.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
7. NCT00979745. ClinicalTrials.gov. U.S. National Library of Medicine. Available at https://clinicaltrials.gov/ct2/show/NCT00979745?cond=nct00979745&draw=2&rank=1.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.