

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Scenesse (afamelanotide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

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

APPROVAL CRITERIA

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. Diagnostic tests confirm elevated free protoporphyrin in peripheral erythrocytes (NCT00979745); **AND**
- IV. Individual has confirmed history of phototoxic reactions from EPP (such as skin burning, itching, and pain).

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 light eruption (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.: 2019. 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: December 12, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Erythropoietic Protoporphyrin (EPP) and X-Linked Protoporphyrin (XLP). American Porphyria Foundation (APF) 2010-2019. Available at <https://www.porphyrifoundation.org/for-patients/types-of-porphyrin/epp-xlp/>. Accessed on December 12, 2019.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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5. Langendonk JG, Balwani M, Anderson KE, et. Al. Afamelanotide for Erythropoietic Protoporphyrria. N Engl J Med. 2015 Jul 2;373(1):48-59.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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>. Accessed on December 12, 2019.

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