

# Scenesse (afamelanotide)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 6 months
Quantity Limit	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 show elevated levels of free protoporphyrin in peripheral erythrocytes (NCT00979745); **AND**
- IV. Individual has 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 is using for a diagnosis of erythropoietic protoporphyria (EPP); **AND**
- II. Documentation is provided that at initial diagnosis, diagnostic tests showed elevated levels of free protoporphyrin in peripheral erythrocytes; **AND**
- III. While on Scenesse, 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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Erythropoietic Protoporphyrin (EPP) and X-Linked Protoporphyrin (XLP). American Porphyrin Foundation (APF) 2010-2022. Available at <https://www.porphyrinfoundation.org/for-patients/types-of-porphyrin/epp-xlp/>. Accessed on January 27, 2023.
4. Langendonk JG, Balwani M, Anderson KE, et. Al. Afamelanotide for Erythropoietic Protoporphyrin. N Engl J Med. 2015 Jul 2;373(1):48-59.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
6. 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 policies may take precedence over the application of this clinical criteria.

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