Scenesse® (afamelanotide)
(Subcutaneous Implant)

Document Number: IC-0512

Last Review Date: 05/05/2026
Date of Origin: 01/03/2020
Dates Reviewed: 01/2020, 01/2021, 01/2022, 01/2023, 01/2024, 05/2025, 05/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be provided every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 16 billable units every two months

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Erythropoietic Protoporphyria (EPP) † Φ [1-3]

- Member does not have any malignant or premalignant skin lesions (e.g., melanoma, dysplastic nevus syndrome, Bowen's disease, basal cell or squamous cell carcinomas, etc.) as evidenced by a baseline full body skin examination for pre-existing skin lesions; **AND**
- Member has a definitive diagnosis of erythropoietic protoporphyria as confirmed by one of the following:
    - Elevated free protoporphyrin in peripheral erythrocytes; **OR**
    - Identification of biallelic pathogenic variants in ferrochelatase (*FECH)* on molecular genetic testing; **AND**
- Used to increase the pain free light exposure in members with a history of phototoxic reactions; **AND**
- Member will continue to maintain sun and light protection measures during treatment to prevent phototoxic reactions

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious hypersensitivity reactions including anaphylaxis, severe skin darkening, etc.; **AND**
- Disease response as evidenced by an increase in pain free time during light exposure and/or a decrease in the number of phototoxic reactions; **AND**
- Member is monitored with full body skin examinations (twice yearly) for pre-existing or new skin pigmentary lesions

V. Dosage/Administration [1]

Indication	Dose
Erythropoietic Protoporphyria (EPP)	**For subcutaneous implant only.** • Insert a single Scenesse implant (containing 16 mg of afamelanotide) subcutaneously above the anterior supra-iliac crest every 2 months
• *Scenesse should be administered by a health care professional.* • *All healthcare professionals should be proficient in the subcutaneous implantation procedure and have completed the training program provided by Clinuvel prior to administration of the Scenesse implant.* • *Use the SFM Implantation Cannula to implant Scenesse.* • *Maintain sun and light protection measures during treatment with Scenesse to prevent phototoxic reactions related to EPP.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J7352 – Afamelanotide implant, 1 mg; 1 billable unit = 1 mg

NDC:

- Scenesse implant, 16 mg, for subcutaneous administration: 73372-0116-xx

VII. References

1. Scenesse [package insert]. Burlingame, CA; Clinuvel, Inc., August 2024. Accessed April 2026.
2. Balwani M, Bloomer J, Desnick R; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic Protoporphyria, Autosomal Recessive. 2012 Sep 27 [Updated 2017 Sep 7]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. Available from: https://www.ncbi.nlm.nih.gov/books/NBK100826/.

3. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyria. N Engl J Med. 2015 Jul 2;373(1):48-59. doi: 10.1056/NEJMoa1411481. PMID: 26132941; PMCID: PMC4780255.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E80.0	Hereditary erythropoietic porphyria

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC