Medica (formerly WellFirst Health)

Scenesse® (afamelanotide)
(Subcutaneous Implant)

Document Number: IC-0512

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I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed annually thereafter.

II. Dosing Limits

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

- 16 billable units every two months

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

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

- Patient 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**
- Patient 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 patients with a history of phototoxic reactions; **AND**
- Patient 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]

Coverage can be renewed based upon the following criteria:

- Patient 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**
- Patient 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 2025.
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; 1993-2022. 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 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