Scenesse® (afamelanotide)
(Subcutaneous Implant)

Document Number: IC-0512

Last Review Date: 01/05/2021
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Dates Reviewed: 01/2020, 01/2021

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Scenesse 16 mg implant: 1 implant every 2 months

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

- 16 billable units every two months

III. Initial Approval Criteria[1,2]

Coverage is provided in the following conditions:

- Patient must be 18 years or older; AND

Erythropoietic Protoporphyria (EPP) † Φ

- 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 elevated free protoporphyrin in peripheral erythrocytes and/or by the identification of 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); 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 the following: 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 for pre-existing or new lesions

V. Dosage/Administration

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. Contact Clinuvel Inc. for other implantation devices that have been determined by the manufacturer to be suitable for implantation of 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:

- J3490 – Unclassified drugs
- J7352 – Afamelanotide implant, 1 mg; 1 billable unit = 1 mg *(Effective 1/1/2021)*

NDC:

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

VII. References

1. Scenesse [package insert]. West Menlo Park, CA; Clinuvel, Inc., March 2020. Accessed December 2020.
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, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2019. Available from: https://www.ncbi.nlm.nih.gov/books/NBK100826/.

Appendix 1 – Covered Diagnosis Codes

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

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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