Policy Title:	Scenesse (afamelanotide) Implant		
		Department:	PHAPHA
Effective Date:	08/01/2020		
Review Date:	7/13/2020, 6/24/2021, 4/14/2022, 3/16/2023		
Revision Date:	7/13/2020		

Purpose: To support safe, effective and appropriate use of Scenesse (afamelanotide).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Scenesse (afamelanotide) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Scenesse (afamelanotide) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

Erythropoietic Protoporphyria (EPP)

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

- Patient must be 18 years or older; **AND**
- 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

Continuation of Therapy Criteria:

- Patient meets initial criteria; **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

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 1mg)
EPP	1 implant every 2 months	16 units every two months

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J7352	Afamelanotide implant, 1mg

References:

1. Scenesse [package insert]. West Menlo Park, CA; Clinuvel, Inc., January 2023. Accessed March 2023.
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/.