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, 12/07/2023, 01/04/2024		

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.

Summary of Evidence:
Scenesse is a subcutaneously administered synthetic analog of the endogenous alpha-melanocyte-stimulating hormone (α-MSH) that activates melanocortin 1 receptor (MC1-R), resulting in increased production of eumelanin pigment in the skin. Clinical trials demonstrated significant reductions in the number of phototoxic reactions and the severity of pain experienced by patients with EPP following sunlight exposure. Scenesse was associated with improvements in patient-reported outcomes, including quality of life measures and functional impairment related to phototoxicity. Commonly reported adverse reactions include implant-site reaction, nasopharyngitis, and hyperpigmentation of the skin.

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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD)

Policy Rationale:
Scenesse was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Scenesse according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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., October 2023. Accessed November 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/.