DRUG DETERMINATION POLICY

Title: DDP-48 Scenesse

Effective Date: 01/14/2022

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Scenesse is a specialty drug indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria. These criteria were developed and implemented to ensure appropriate use for the intended diagnosis, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Erythropoietic Protoporphyria (EPP) [must meet all listed below]:

   A. Age: at least 18 years.

   B. Prescriber: dermatologist, gastroenterologist, hepatologist.

   C. Diagnosis [must meet one listed below]:

      1. Elevated metal-free erythropoietic protoporphyrin levels in peripheral erythrocytes (must be above 85 percent of total porphyrins).

      2. Presence of loss of function mutation in the ferrochelatase (FECH) gene.

   D. Dosage regimen and administration [must meet all listed below]:

      1. Dosage regimen: Scenesse (afamelanotide) - 16mg implant once every two months.

2. Must be administered by a healthcare professional proficient in the subcutaneous implantation procedure.

3. Administering healthcare professional has completed requisite procedural training provided by product manufacturer.

E. Approval.

1. Initial: six months.

2. Re-approval: six months [must meet one listed below]:

a. Increase in pain free time during sun exposure.

b. Reduction in the number of phototoxic reactions from baseline.

c. Decrease in severity of phototoxic reactions from baseline.

II. X-Linked Protoporphyria (XLP) [must meet all listed below]:

A. Age: at least 18 years.

B. Prescriber: dermatologist, gastroenterologist, hepatologist.

C. Diagnosis [must meet one listed below]:

1. Elevated metal-free erythropoietic protoporphyrin levels in peripheral erythrocytes (must be above 85 percent of total porphyrins).

2. Presence of loss of function mutation in the delta-aminolevulinic acid synthase (ALAS2) gene.

D. Dosage regimen and administration [must meet all listed below]:

1. Dosage regimen: Scenesse (afamelanotide) 6mg implant once every two months.

2. Must be administered by a healthcare professional proficient in the subcutaneous implantation procedure.

3. Administering healthcare professional has completed requisite procedural training provided by product manufacturer.

E. Approval.

1. Initial: six months.

2. Re-approval: six months [must meet one listed below]:

a. Increase in pain free time during sun exposure.

b. Reduction in the number of phototoxic reactions from baseline.

c. Decrease in severity of phototoxic reactions from baseline.

4.0 Coding:

CODES AFFECTED				
Code	**Brand**	**Generic**	**Billing (1u)**	**Prior Approval Required**
J7352	Scenesse	afamelanotide	16mg	Y

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Scenesse accessed December 2020.
2. Langendonk JG, Balwani M, Anderson KE et al. Afamelanotide for erythropoietic protoporphyria. N Engl J Med. 2015; 373:48-59.
3. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria: pathophysiology, genetics, clinical manifestations, and management. Mol Gen Metab. 2019; 128(3):298-303.
4. Scenesse [prescribing information]. West Menlo Park, CA: Clinuvel; April 2020.

6.0 Appendices:

See pages 4-5.

7.0 Revision History:

Original Effective Date: 01/14/2022

Next Review Date: 01/14/2023

Revision Date	Reason for Revision
9/21	Changed code for Scenesse
12/21	Annual review, formatting changes

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Scenesse (afamelanotide)	• Gastrointestinal: nausea (19%) • Local: application site reaction (21%) • Central nervous system: fatigue (6%), dizziness (4%), drowsiness (2%) • Dermatologic: melanocytic nevus (4%), skin hyperpigmentation (4%), skin irritation (2%) • Endocrine & metabolic: porphyria (2%) • Local: local skin discoloration (10%) • Respiratory: oropharyngeal pain (7%), cough (6%), respiratory tract infection (4%)	• Full body skin examination twice yearly	None

Appendix II: EPP and XLP Diagnosis Algorithm