Effective Date **8/1/2023**
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Coverage Policy Number **IP0159**

Afamelanotide

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for afamelanotide subcutaneous implant (**Scenesse®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Afamelanotide (Scenesse) is considered medically necessary when the following are met:

Erythropoietic Protoporphyria (Including X-Linked Protoporphyria). Individual meets **ALL** of the following criteria:

A. Age 18 years or older
B. Documented history of at least one porphyric phototoxic reaction
C. Diagnosis of erythropoietic protoporphyria (including X-linked protoporphyria) confirmed by documentation of **ONE** of the following:

i. Free erythrocyte protoporphyrin level above the normal reference range for the reporting laboratory
ii. Molecular genetic testing consistent with the diagnosis (for example, pathogenic or likely pathogenic variant in *FECH*, *CLPX* or *ALAS2*)

D. Medication is prescribed by, or in consultation with, a dermatologist, gastroenterologist, hepatologist, medical geneticist, or physician specializing in the treatment of cutaneous porphyrias

Dosing. A single Scenesse implant (containing 16 mg of afamelanotide) inserted subcutaneously no more frequently than once every 2 months

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of afamelanotide (Scenesse) is considered medically necessary for erythropoietic protoporphyria when the above medical necessity criteria are met **AND** there is documentation of beneficial response (for example, improvement in acute nonblistering cutaneous reactions following sun exposure, improvement on a pain-intensity Likert Scale or Quality of Life questionnaire, reduction in number of phototoxic reactions, increase duration of pain-free sun exposure).

Authorization Duration

Initial approval duration is up to 6 months.
Reauthorization approval duration is up to 6 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

Other Photosensitivity Disorders or Photodermatoses (for example, polymorphous light eruption, solar urticaria, drug-induced photosensitivity)

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7352	Afamelanotide implant, 1 mg

Background

OVERVIEW
Scenesse, a melanocortin 1 receptor agonist, is indicated to increase pain-free light exposure in adults with a history of phototoxic reactions from **erythropoietic protoporphyria (EPP)**.[1] Scenesse is a controlled-release dosage form that is implanted subcutaneously (SC). Scenesse should be administered by a healthcare professional. A single implant which contains 16 mg of afamelanotide is inserted SC above the anterior supra-iliac crest once every 2 months.

Disease Overview
Porphyrias are disorders caused by enzyme defects in heme biosynthesis.[2] There are at least eight different types of porphyrias, which are classified as cutaneous or acute depending on the specific enzyme that is deficient. EPP is a cutaneous porphyria characterized by extreme photosensitivity. It is estimated to occur in 2 to 5 in 1,000,000 individuals.[3]

EPP occurs due to excessive accumulation of protoporphyrin, a heme precursor. Classic EPP is autosomal recessive and occurs due to a defect in the enzyme ferrochelatase, the final enzymatic step in heme biosynthesis.[4] An X-linked subtype of EPP, often referred as X-linked protoporphyria (XLP), accounts for 2% to 10% of all EPP cases. This type develops due to a gain-of-function mutation in an upstream enzyme in heme biosynthesis, leading to excess protoporphyrin production.[3,4] The two subtypes share the same biochemical and clinical features, although females with XLP may be less severely affected. Diagnosis is confirmed by one or both of the following: 1) biochemically via markedly elevated free erythrocyte protoporphyrin, and/or 2) molecular genetic testing.[2,3]

In both EPP subtypes, protoporphyrin accumulation in superficial skin vessels leads to phototoxicity upon light exposure, resulting in the hallmark symptoms of burning, tingling, and itching, which often occur without visible damage.[2-4] Phototoxic pain is not responsive to analgesics, including narcotics; management is focused on prevention of phototoxic episodes.[3]

References

1. Scenesse® subcutaneous implant [prescribing information]. Menlo Park, CA: Clinuvel; October 2022.
2. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria. National Organization of Rare Disorders. Updated 2018. Available at: https://rarediseases.org/rare-diseases/erythropoietic-protoporphyria/. Accessed on January 6, 2023.
3. Balwani M, Bloomer J, Desnick R; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic protoporphyria, autosomal recessive. Updated September 7, 2017. In: GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available at: https://www.ncbi.nlm.nih.gov/books/NBK100826/. Accessed on January 6, 2023.
4. Balwani M, Naik H, Anderson KE, et al. Clinical, biochemical, and genetic characterization of North American patients with erythropoietic protoporphyria and X-linked protoporphyria. *JAMA Dermatol.* 2017;153(8):789-796.