Drug Coverage Policy

Effective Date.....3/1/2026
Coverage Policy Number..... IP0159
Policy Title.....Scenesse

Scenesse

- Scenesse® (afamelanotide subcutaneous implant – Clinuvel)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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
Scenesse, a melanocortin 1 receptor agonist, is indicated for the treatment of **erythropoietic protoporphyria (EPP)**, to increase pain-free light exposure in adults with a history of phototoxic

reactions.[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.[2,3,5]

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]

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Scenesse. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Scenesse as well as the monitoring required for adverse events and long-term efficacy, approval requires Scenesse to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Scenesse is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Erythropoietic Protoporphyria (Including X-Linked Protoporphyria).** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
    A. Patient is ≥ 18 years of age; AND
    B. Patient has a history of at least one porphyric phototoxic reaction **[documentation required]**; AND

C. The diagnosis is confirmed by at least ONE of the following (i or ii) **[documentation required]**:
    i. Free erythrocyte protoporphyrin level above the normal reference range for the reporting laboratory; OR
    ii. Molecular genetic testing consistent with the diagnosis; AND
D. The agent is prescribed by or in consultation with a dermatologist, gastroenterologist, hepatologist or physician specializing in the treatment of cutaneous porphyrias.

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

Conditions Not Covered

Scenesse for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

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

References

1. Scenesse® subcutaneous implant [prescribing information]. Menlo Park, CA: Clinuvel; August 2024.
2. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria. National Organization of Rare Disorders. Updated 2022. Available at: https://rarediseases.org/rare-diseases/erythropoietic-protoporphyria/. Accessed on January 02, 2026.
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 02, 2026.
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.
5. Dickey AK, Naik H, Keel SB, et al. Porphyrias Consortium of the Rare Diseases Clinical Research Network. Evidence-based consensus guidelines for the diagnosis and management of erythropoietic protoporphyria and X-linked protoporphyria. *J Am Acad Dermatol.* 2023 Dec;89(6):1227-1237.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	**Conditions Not Covered.** **Removed** 'Other Photosensitivity Disorders or Photodermatoses (for example, polymorphous light eruption, solar urticaria, drug-induced photosensitivity)'	8/1/2024
Annual Revision	No criteria changes.	4/1/2025
Annual Revision	**Erythropoietic Protoporphyria (Including X-Linked Protoporphyria).** **Removed** "of erythropoietic protoporphyria (including X-linked protoporphyria)" **from** diagnosis criteria." **Removed** "medical geneticist" **from** list of prescribers. **Conditions Not Covered** **Updated** statement **from** "Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available)" **to** "Scenesse for any other use is considered not medically necessary. Criteria will be updated as new published data are available."	3/1/2026

The policy effective date is in force until updated or retired.