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| **Department:** | Pharmacy Management | **Original Approval:** | 09/04/2020 |
| **Policy No:** | PM157 | **Last Approval:** | 06/12/2026 |
| **Policy Title:** | Afamelanotide implant Scenesse Clinical Coverage Criteria | | |
| **Approved By:** | UM Criteria Subcommittee | | |
| **Applicable Line(s) of Business:** | ☐ **Washington Apple Health (Medicaid)**<br>☐ **Behavioral Health Services Only**<br>☐ **Apple Health Expansion**<br>☒ **Medicare Advantage/Special Needs Plan**<br>☒ **Medicare Advantage Only**<br>☒ **Cascade Select** | | |

## Required Clinical Documentation for Review

Documentation required to determine medical necessity for Afamelanotide implant (Scenesse):

1. History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
2. Diagnosis
3. Labs/Diagnostics
4. Dosing and duration requested
5. Initial/Extended approval
6. Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
7. Prescribed by or in consultation with a specialist, when indicated

## Background

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] The agent 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]

Two subtypes of EPP exist which differ in their genetic inheritance patterns. Classic EPP is inherited in an autosomal recessive fashion (sometimes referred to as EPP-AR). In this form of EPP, mutations in the *FECH* gene lead to decreased activity of ferrochelatase, the final enzymatic step in heme biosynthesis.[4] This results in accumulation of an intermediate metabolite called protoporphyrin. An X-linked subtype of EPP, often referred to in the literature 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 the erythroid form of 5-aminolevulinate synthase 2 (ALAS2). This enzyme is responsible for an earlier step in heme biosynthesis; hyperactivity of the ALAS2 enzyme leads 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 accumulates in the bone marrow and is taken up by the liver and vascular endothelium.[3,4] 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] Some patients may also be sensitive to artificial light, as the photosensitivity is primarily due to visible blue light.[5,6] Phototoxic pain is not responsive to analgesics, including narcotics; management is focused on prevention of phototoxic episodes.[3]

## Definitions

None.

## Indications/Criteria

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| **Medicaid Members** | ***Excluded benefit. Authorization and billing required directly through WA Apple Health Fee for Service only. Call 800-562-3022.*** |
| **Individual & Family (Cascade Select) members** | ***Continue to criteria for approval below.*** |

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| **Medicare Members** | ***Follow the criteria below. Medicare does not have a National Coverage Determination (NCD) or Local Coverage Determinations (LCDs) for Afamelanotide (Scenesse).*** |

Coverage of Scenesse is recommended in those who meet the following criteria:

**FDA-Approved Indications**

1. **Erythropoietic Protoporphyria (Including X-Linked Protoporphyria).** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient has a history of at least one porphyric phototoxic reaction; AND
   - **C)** The diagnosis is confirmed by at least one of the following (i or ii):
     - **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 Recommended for Approval**

Scenesse has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Special Considerations

None.

## Limitations/Exclusions

Please see link to member coverage documents below:

| Line of Business | Link to Member Coverage Documents |
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| Medicare Advantage Plans (Including D-SNP) | https://medicare.chpw.org/<br>Select the appropriate plan from the "Plans" drop down on the top navigation bar. |
| Apple Health | https://www.chpw.org/for-members/benefits-and-coverage-imc/ |
| Individual & Family (Cascade Select) | https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/ |

## List of Appendices

None.

**Citations & References**

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| **CFR** | 42 CFR § 438.210 | |
| **WAC** | WAC 284-43-2050 | |
| **RCW** | | |
| **LOB & Contract Citation** | ☐ **WAHIMC** | |
| | ☐ **BHSO** | |
| | ☐ **Wraparound** | |
| | ☐ **SMAC** | |
| | ☐ **HH** | |
| | ☐ **AHE** | |
| | ☒ **MA/DSNP** | P&P supports all LOB requirements |
| | ☒ **CS** | P&P supports all LOB requirements |
| **Other Requirements** | | |
| **NCQA Elements** | | |
| **References** | 1. Scenesse® subcutaneous implant [prescribing information]. Menlo Park, CA: Clinuvel; May 2026.<br>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 2, 2020.<br>3. Balwani M, Bloomer J, Desnick R, et al.; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic protoporphyria, autosomal recessive. Last updated September 7, 2017. Available at: | |

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| | https://www.ncbi.nlm.nih.gov/books/NBK100826/. Accessed on January 2, 2020.<br>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.<br>5. Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for erythropoietic protoporphyria. *N Engl J Med*. 2015;373(1):48-59.<br>6. Stözlel U, Doss MO, Schuppan D. Clinical guide and update on porphyrias. *Gastroenterology*. 2019;157(2):365-381.e4. |

## Revision History

| Revision Date | Revision Description | Revision Made By |
|---|---|---|
| 08/07/2020 | New Policy | Jennifer Farley, PharmD |
| 08/20/2020 | Approval | UM Pharmacy Subcommittee |
| 09/04/2020 | Approval | UM Committee |
| 09/01/2021 | Annual Review. Formatting changes. No criteria change. | Christa Laosantos, PharmD Candidate<br>Alan Gabot, PharmD |
| 09/02/2021 | Approval | UM Pharmacy Subcommittee |
| 06/14/2022 | Annual Review. Updated coverage to note that afamelanotide (Scenesse) will be carved out and covered by the HCA. | Alan Gabot, PharmD |
| 06/15/2022 | Approval | UM Pharmacy Subcommittee |
| 03/01/2023 | Annual Review. No criteria change. | Alan Gabot, PharmD |
| 03/02/2023 | Approval | UM Pharmacy Subcommittee |
| 12/26/2023 | Annual Review. No criteria change. | Alan Gabot, PharmD |
| 01/10/2024 | Approval | UM Criteria Subcommittee |

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| 11/12/2024 | Annual Review. No criteria change. | Alan Gabot, PharmD |
| 11/13/2024 | Approval | UM Criteria Subcommittee |
| 08/21/2025 | Annual Review. No criteria change. | Michael Tom, PharmD |
| 09/10/2025 | Approval | UM Criteria Subcommittee |
| 06/11/2026 | Annual Review. No criteria changes. | Alan Gabot, PharmD |
| 06/12/2026 | Approval | UM Criteria Subcommittee |