SmartPA Criteria Proposal

Drug/Drug Class:	Scenesse Clinical Edit
First Implementation Date:	August 4, 2022
Revised Date:	August 4, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Scenesse (afamelanotide).

Why Issue Selected: In October 2019, Scenesse® (afamelanotide) was FDA approved for treatment of adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP). Scenesse was granted priority review and orphan drug status as the first implant therapy to treat EPP by increasing pain free light exposure. EPP is a rare autosomal recessive disorder that is caused by a pathogenic or likely pathogenic variant in the *FECH* gene that leads to impaired ferrochelatase (FECH) activity. This variant affects heme production and causes an accumulation of protoporphyrin IX (PPIX) in the body, which can cause intense pain and skin changes (redness and thickening) when the skin is exposed to light. Rarely EPP patients will develop hepatic complications, including cholelithiasis or chronic liver disease progressing to rapid acute liver failure. Prevalence of EPP is not well characterized in the United States but comprises approximately 90% of phenotypic presentations. In the Netherlands and Wales, prevalence is estimated to be 1 in 75,000 and 1 in 200,000, and in 17 European countries it is estimated to be 1 in 140,000. According to the American Gastroenterological Association, first line treatment for EPP includes symptom and preventative management, involving sun and ultraviolet light exposure avoidance or protection, vitamin D supplementation, pain control and anti-inflammatory agent use, and routine monitoring and interventions.

Scenesse is a synthetic tridecapeptide and a structural analog of the α-melanocyte stimulating hormone (α-MSH). It acts as an agonist of the melanocortin receptor and binds primarily to the melanocortin 1 receptor (MC1-R). Scenesse works to increase the production of eumelanin in the skin without exposure to sunlight or artificial ultraviolet light.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Scenesse.

Program-Specific Information:

Drug	Cost per implant (AWP)	Cost per year* (AWP)
SCENESSE 16 MG IMPLANT	$56,339.00	$169,017.00

*based on limit of 3 implants per year

Type of Criteria:	☐ **Increased risk of ADE**	☐ **Preferred Drug List**
	☒ **Appropriate Indications**	☒ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Scenesse (afamelanotide)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

Initial Therapy

- Prescribed by or in consultation with an appropriate specialist for the treated disease state **AND**
- Documented diagnosis of EPP confirmed by:
  - Metal-free protoporphyrin in hemolyzed anticoagulated whole blood (PEE/Porphyrins Evaluation, Whole Blood) **AND**
  - Genetic testing demonstrating pathogenic or likely pathogenic variant in *FECH* gene **AND**
- Dermatologic evidence of EPP (i.e. edema, sun-induced erythema, acute painful photodermatitis, urticaria) **AND**
- Participant is aged ≥ 18 years **AND**
- Documented recent baseline whole body skin exam (within last 3 months)
- Initial approval for one treatment

Continuation of Therapy:

- Subsequent treatments may be approved with documentation of the following:
  - Full body skin examination twice yearly to monitor pre-existing and new skin pigmentary lesions.
  - Annual documentation of improvement or stability in disease state based on assessment of decrease in phototoxic reactions and increase in sun exposure time without phototoxic reaction based on lack of new lesion development with skin exams.

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant
- Claim exceeds 1 implant per 2-month period, or 3 implants per 12-month period
- Documented history of Bowen's disease, basal cell carcinoma, squamous cell carcinoma, other malignant or premalignant skin lesions, melanoma or dysplastic nevus syndrome, and any other photodermatosis such as polymorphic light eruption, discoid lupus erythematosus or solar urticaria

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☒

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 month

References

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2. U.S. Food & Drug Administration. “FDA approves first treatment to increase pain-free light exposure in patients with a rare disorder”. https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-increase-pain-free-light-exposure-patients-rare-disorder. Accessed January 5, 2022.
3. Scenesse [package insert]. West Menlo Park, CA: Clinuvel Pharmaceuticals; March, 2020.
4. IPDanalytics. Scenesse New Drug Approval. Accessed January 5, 2022.
5. Gastroenterology. Clinical Guide and Update on Porphyrias. https://www.gastrojournal.org/article/S0016-5085(19)40883-4/pdf. Accessed November 7, 2019.
6. Mayo Clinic Laboratories. Testing Catalog. https://www.mayocliniclabs.com/test-catalog/Clinical+and+Interpretive/35421. Accessed January 5, 2022.
7. Clinuvel. Summary of Product Characteristics. https://www.clinuvel.com/wp-content/uploads/2019/05/SCENESSE-afamelanotide16mgSmPC.pdf. Accessed January 5, 2022.