Medical Policy
Scenesse (afamelanotide) for Treatment of Erythropoietic Protoporphyria (EPP)

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Policy Number: 077
BCBSA Reference Number: N/A
NCD/LCD: N/A

Related Policies
None

Policy¹
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Scenesse (afamelanotide) for the treatment of erythropoietic protoporphyria (EPP) is considered INVESTIGATIONAL.

Prior Authorization Information
Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Product</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO Blue℠</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO Blue℠</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

There is no specific CPT code for this procedure.

**Description**

Erythropoietic protoporphyria (EPP) is a rare condition that results in the build up of protoporphyrin in the blood marrow, red blood cells, blood plasma, skin and liver. EPP is caused by a genetic mutation on the FECH gene, which is responsible for the normal production of heme. The build-up of protoporphyrin can cause extreme skin reactions to sunlight, including severe pain, burns and blisters, and edema. Protoporphyrin is excreted through the liver putting patients with EPP at risk of chronic liver disease and recurrent gallstones. In extreme cases, patients may experience rapid acute liver failure. EPP affects 75,000-200,000 people worldwide and is often diagnosed in infancy and early childhood after noticeable symptoms due to sun exposure. Genetic testing can provide confirmatory diagnosis.

Patients with EPP are recommended to reduce exposure to sunlight and avoid sun exposure whenever possible. In some patients, the use of tanning creams demonstrated increase tolerance to sun exposure by increasing the amount of pigmentation in the skin. Protoporphyrin levels should be monitored annually to assess for damage to the liver. Patients with severe cases of EPP may require liver and bone marrow transplants if there is significant liver damage. There are currently no oral or topical medications available for the treatment of EPP.

In October of 2019, the FDA approved a subcutaneous injectable medication that increases the pigmentation of the skin and allows patients to have longer periods of sun exposure without reaction. Scenessse is indicated for patients with confirmatory genetic testing and into the torso and is administered every 2 months. For individuals with EPP without significant liver involvement, the evidence includes three randomized controlled trials evaluating the effect of Scenessse in reducing phototoxic reactions and pain. In all of the available studies, patients were administered with either Scenessse or a “vehicle.” In the Scenessse groups, patients reported no pain after spending a median of 6 hours per day outside in direct sunlight. In the control groups, patients reported “no pain” over the median time of .75 hours per day.

**Summary**

Erythropoietic Protoporphyria is a rare, genetic mutation that causes an abnormal production of protoporphyrina in the bone marrow, red blood cells, plasma, skin and liver. As a result, patients experience phototoxic reactions when exposed to the sun. While symptoms vary, patients can experience pain, reddening of skin, blisters and burns to exposed skin and edema. In severe cases, patients might experience disease of the liver. There are currently no oral or topical medications that are approved to treat EPP. The FDA has approved a subcutaneous implant, Scenessse (afamelanotide), that is injected every 2 months in adult patients without significant liver involvement.

The evidence includes two randomized controlled trials. Of the 167 patients included, 86 patients with EPP without significant liver involvement received Scenessse and were evaluated on the primary endpoint of number of hours spent outside. Patients documented degree of pain during sun exposure each day. Over the course of 270 days, patients in the treatment group reported improvement over the controlled group for number of hours spent outside without symptom reaction and with reduced pain. Controlled studies are needed to evaluate the risks and benefits affecting health outcomes in the long term. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Policy History**

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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:
References

1 Based on expert opinion