Banner Medicare Advantage

Internal Pharmacy Prior Authorization Criteria

Applicable Plans:
Banner Medicare Advantage Dual HMO D-SNP (Banner Dual)
Banner Medicare Advantage Prime HMO (Banner Prime)
Banner Medicare Advantage Plus PPO (Banner Plus)

Guidelines for the following ultra-high-cost medications:

- Etranacogene dezaparvovec-drlb (Hemgenix)
- Elivaldogene autotemcel (Skysona)
- Valoctocogene roxaparvovec (Roctavian)

Etranacogene dezaparvovec-drlb (Hemgenix) Guideline

Effective Date: 4/1/2023
Date(s) of Review and Revision: 7/21/2023

APPLICABLE AGENT(S):
- Etranacogene dezaparvovec-drlb (Hemgenix)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Member is 18 years or older with Hemophilia B (congenital Factor IX deficiency) who has FDA approved indication of:
   a. Currently using Factor IX prophylaxis therapy and is stable on it for at least 2 months and has received at least 150 exposure days, or
   b. Has current or historical life-threatening hemorrhage, or
   c. Has repeated, serious spontaneous bleeding episodes
   AND
2. Has not received prior treatment with any gene therapy for hemophilia B
   AND
3. AAV5 Neutralizing Antibody test processing conducted with CSL Behring and documentation provided to demonstrate the patient does not have anti-AAV antibody (eg AAV-5) titers exceeding 1:678)
   AND
4. Must not have history of inhibitors to Factor IX or a positive inhibitor screen as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Hemgenix
   AND
5. Prescribed by hematologist
   AND
6. Member must not have active hepatitis C infection, an active HIV infection or decompensated cirrhosis. Documentation of liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)]
   AND
7. Member will have close monitoring of transaminase levels once per week for 3 months after Hemgenix administration to mitigate the risk of potential hepatotoxicity
   AND
8. Send to medical director for review and MRIoA for review

CRITERIA FOR RENEWAL:
i. N/A. No renewal allowed. One infusion per lifetime.

INSERT QUANTITY LIMITS
1. One infusion per lifetime

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 6 months

Renewal Approval Duration: N/A. No renewal allowed. One infusion per lifetime.

SOURCE OF EVIDENCE OR ADDITIONAL GUIDELINE REFERENCE:

1. Hemgenix [package insert]. King of Prussia, PA. CSL Behring LLC; November 2022.
2. HOPE-B Clinical Trial Protocol, Version 8.0 (Amendment 7.0). February 2022. Phase III trial of AMT-061 in subjects with severe or moderately severe hemophilia B. Available at https://clinicaltrials.gov/ProvidedDocs/91/NCT03569891/Prot_000.pdf.

Elivaldogene autotemcel (Skysona) Guideline

Effective Date: 5/1/23
Date(s) of Review and Revision: 4/12/23

APPLICABLE AGENT(S):
- Elivaldogene autotemcel (Skysona)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Member is a male between 4 years of age and less than 18 years AND
2. Submission of medical records confirming member has a documented diagnosis of early, active cerebral adrenoleukodystrophy (CALD) AND
3. Submission of medical records documenting molecular genetic testing confirms mutation in the ABCD1 gene AND
4. Submission of medical records confirming ALL of the following:
    - Patient has elevated very long chain fatty acid levels
    - Loes score between 0.5 and 9 (inclusive) based on brain MRI assessment
    - Brain MRI utilized Gadolinum enhancement and demonstrated demyelinating lesions
    - Neurologic function score (NFS) less than or equal to 1
5. Member is not eligible for allogenic hematopoietic stem cell transplant with an HLA-matched sibling donor AND
6. Submission of medical records confirming negative test result for:
    - Hepatitis B virus (HBV)
    - Hepatitis C virus (HCV)
    - Human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2)
    - Human immunodeficiency virus (HIV) AND
7. Patient does not have CALD secondary to head trauma AND
8. Prescribed by a stem cell transplant physician or geneticist from a qualified treatment center AND
9. Patient has never received Skysona in their lifetime AND
10. Discontinue prophylactic anti-retroviral medications for at least one month prior to initiating medications for stem cell mobilization and until all cycles of apheresis are completed AND
11. If ALL of the above requirements are met, send to Medical Director for review and approval

CRITERIA FOR RENEWAL:

a. N/A

INSERT QUANTITY LIMITS

1. A Single dose of Skysona containing a minimum of 5.0 x 10^6 CD34+ cells/kg of body weight, in one or more infusion bags

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 6 months
- Renewal Approval Duration: N/A

SOURCE OF EVIDENCE OR ADDITIONAL GUIDELINE REFERENCE:

- Skysona [Package insert]. Somerville, MA. Bluebird Bio, Inc; September 2022.
- Elivaldogene Automecel: First Approval. Mol Diagn Ther. Nov 2021;25(6):803-809. doi: 10.1007/s40291-021-00555-1.

Valoctocogene roxaparvovec (Roctavian) Guideline

Effective Date: November 15, 2023
Date(s) of Review and Revision: September 13, 2023

APPLICABLE AGENT(S):
- Valoctocogene roxaparvovec (Roctavian)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Member is 18 years or older with severe Hemophilia A (Congenital factor VIII deficiency; severe is defined as pre-treatment factor VIII level less than 1 IU/dL) AND
2. The member meets both of the following (a and b).
   a. Member has been adherent to Factor VIII prophylaxis therapy for at least 12 months and has received at least 150 exposure days
   b. Occurrence of one or more serious spontaneous bleeding event while on routine prophylaxis

   AND all of the following:
3. Member has not received prior treatment with any other therapy containing an adeno-associated viral vector
4. Patient has been tested and found negative for active factor VIII inhibitors. Member's inhibitor level assay <1 Bethesda Unit (BU) on two consecutive occasions at least one week apart within the last 12 months. Patient is not receiving a bypassing agent (e.g. Feiba)
5. Member has no pre-existing antibodies to AAV5 capsid as measured by AAV5 total assay FDA-approved test.
6. Member has completed attestation of alcohol abstinence and has received abstinence education from the physician.
7. Prescribed by or in consultation with a hematologist.
8. Provider agrees to monitor the patient according to the FDA approved label. This includes factor VIII level tests, ALT monitoring, and steroid treatment as appropriate.
9. Provider must provide documentation member does not have active infections, either acute or uncontrolled chronic, known significant hepatic fibrosis (stage 3 or 4), or cirrhosis, or known hypersensitivity to mannitol.
10. Send to medical director and MRIoA for review.

CRITERIA FOR RENEWAL:
N/A. No renewal allowed. One infusion per lifetime.

INSERT QUANTITY LIMITS
Dose: 6×10^{13} vector genomes/kg as a single one-time dose per lifetime

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 6 months
- Renewal Approval Duration: N/A. No renewal allowed. One infusion per lifetime.

SOURCE OF EVIDENCE OR ADDITIONAL GUIDELINE REFERENCE:

1. Roctavian [package insert]. Novato, Ca. BioMarin Pharmaceutical Inc.; June 2023.
2. Single-Arm study to Evaluate The Efficacy and Safety of Valoctocogene Roxaparvovec in Hemophilia A Patients (BMN 270-301). December 2022. Available at https://classic.clinicaltrials.gov/ct2/show/NCT03370913