El Paso Health
HEALTH PLANS FOR EL PASOANS. BY EL PASOANS.

MEMORANDUM

TO: Valued STAR and CHIP Providers

FROM: El Paso Health

DATE: 12/12/2023

RE: Coverage of Roctavian Begins Jan. 2024; Prior Authorization Effective Feb. 2024

On Jan. 1, 2024, Roctavian will become a benefit of Medicaid and CHIP. HHSC will require prior authorization for Roctavian (procedure code J1412) for Medicaid and CHIP, effective Feb. 1, 2024.

Roctavian (valoctocogene roxaparvovec-rvox) is an adeno-associated virus vector-based gene therapy indicated to treat adult clients with severe hemophilia A (congenital Factor VIII deficiency with Factor VIII activity less than 1 IU/dL) without pre-existing antibodies to adenoassociated virus serotype 5 (AAV5) detected by an FDA-approved test.

Additional Information:

1.Prior authorization is required for Roctavian (valoctocogene roxaparvovec-rvox).

2.The request for this single-dose therapy must include all the following documentation to support client meets all approval criteria:

a. Client is at least 18 years of age or older.

b. Client has a confirmed diagnosis of severe Hemophilia A (congenital Factor VIII deficiency) as defined by:

i. Factor VIII activity level less than 1 IU/dL (in the absence of exogenous Factor VIII).

c.Evidence of other bleeding disorders not related to Hemophilia A has been ruled out.

d. Client has no history of Factor VIII inhibitors and a negative screening test prior to treatment.

e. Client's baseline test (as determined by an FDA approved test) is negative for preexisting antibodies to adeno-associated virus serotype 5 (AAV5).

f. Client's baseline liver function assessment must be assessed prior to Roctavian infusion.

i. Documentation includes, but not limited to alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin.

ii. Documentation of hepatic ultrasound and elastography or laboratory assessments for liver fibrosis must be provided.

g. Prescriber attests to counseling clients regarding consuming alcohol post-administration of Roctavian.

h. Client does not have any active infections, either acute or chronic.

i. Client does not have stage 3 or 4 liver fibrosis or cirrhosis.

j. Client does not have a known hypersensitivity to mannitol.

k. Client does not have a history of previously receiving treatment with Roctavian infusion.

3. Roctavian, J1412 is limited to once per lifetime.

4. Monitoring parameters after Roctavian infusion:

a. Monitor hepatic function and liver enzymes. ALT should be monitored weekly for at least 26 weeks post-infusion as there are risks of hepatotoxicity. Monitor for and mange adverse reaction from corticosteroid use.

b. Monitor for elevated Factor VIII activity as thromboembolic events may occur with elevated Factor VIII activity above the upper limit of normal (ULN).

c. Monitor for hepatocellular malignancy in patients with risk factors for hepatocellular carcinoma (e.g., hepatitis B or C, non-alcoholic fatty liver disease, chronic alcohol consumption, non-alcoholic steatohepatitis, advanced

age). Perform regular (annually) liver ultrasound and alpha-fetoprotein testing following administration.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements. https://www.tmhp.com/resources/provider-manuals/tmppm

If you have any questions regarding this communication please contact our Provider Relations team at 915-532-3778 or email us at ProviderRelationsDG@elpasohealth.com