Louisiana Medicaid Fidanacogene elaparvovec-dzkt (BeqvezTM)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for fidanacogene elaparvovec-dzkt (BeqvezTM).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available <u>HERE</u>.

Approval Criteria

- The recipient is a male; **AND**
- The recipient is 18 years of age or older on the date of the request; AND
- The recipient has a diagnosis of moderate to severe hemophilia B (congenital factor IX deficiency) **AND ONE** of the following is true and is **stated on the request**:
 - Currently use factor IX prophylaxis therapy, **OR**
 - Have current or historical life-threatening hemorrhage, **OR**
 - Have repeated, serious spontaneous bleeding episodes, AND
- The recipient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; **AND**
- The medication is prescribed by a physician experienced in the treatment of hemophilia; **AND**
- ALL of the following are true and are stated on the request:
 - **ONE** of the following:
 - The recipient does not have HIV infection; **OR**
 - The recipient does not have either CD4+ cell count ≤ 200 mm³ or viral load > 20 copies/mL in case of serological evidence of HIV-1 or HIV-2 infection; AND
 - The recipient does not have active factor IX inhibitors (has not had a positive test [≥ 0.6 Bethesda Units (BU)]) or a prior history for factor IX inhibitor); AND
 - The recipient does not have any of the following current liver-related coagulopathy, hypoalbuminemia, persistent jaundice, cirrhosis, portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis, or active viral hepatitis; **AND**
 - The recipient does not have active Hepatitis B or C infection.
- The recipient **has never received a dose** of any gene therapy.

Duration of approval: 6 months - allow 1 dose per lifetime

Reference

Beqvez (fidanacogene elaparvovec-dzkt) [package insert]. New York, NY: Pfizer Inc.; April 2024. <u>https://labeling.pfizer.com/ShowLabeling.aspx?id=20452</u>

Revision / Date	Implementation Date
Policy Created / May 2024	October 2024