| Reference number(s) |
| --- |
| 6487-A |

# Standard Medicare Part B Management
# Beqvez

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Beqvez | fidanacogene elaparvovec-dzkt |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications[1]

Beqvez is an adeno-associated virus vector-based gene therapy indicated for treatment of adults with moderate to severe Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes, and,
- Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.


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# Documentation

The following documentation must be available, upon request, for all submissions:

Chart notes, lab tests documenting all of the following (where applicable):

- Severe or moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX).
- Absence of Factor IX inhibitors (lab test results required).
- Current use of Factor IX prophylaxis therapy.
- History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes.
- Negative adeno-associated virus serotype Rh74var (AAVRh74var) antibody test result.

# Prescriber Specialties

This medication must be prescribed by or in consultation with a hematologist.

# Coverage Criteria

## Hemophilia B[1]

Authorization of 3 months for one dose total may be granted for the treatment of hemophilia B when all of the following criteria are met:

- Member is 18 years of age or older.
- Member meets both of the following:
    - Member does not have a history of Factor IX inhibitors (e.g., ≥ 0.6 Bethesda units [BU]).
    - Member has a negative Factor IX inhibitor test result within the past 30 days (e.g., < 0.6 Bethesda units [BU]).
- Member has severe or moderately severe Factor IX deficiency (≤ 2% of normal circulating Factor IX) and meets any of the following:
    - Member is currently using Factor IX prophylactic therapy.
    - Member has a current or history of a life-threatening hemorrhage.
    - Member has a history of repeated, serious spontaneous bleeding episodes.
- Member has a negative adeno-associated virus serotype Rh74var (AAVRh74var) antibody test result.
- Member has not received Beqvez or any other gene therapy previously.

# Summary of Evidence

The contents of this policy were created after examining the following resources:


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- The prescribing information for Beqvez.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Beqvez are covered.

# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

# References

1. Beqvez [package insert]. New York, NY: Pfizer Inc.; April 2024.


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