Pr Evkeeza®
evinacumab for injection

MANITOBA

PrEVKEEZA® (evinacumab for injection) is eligible for public reimbursement in Manitoba for patients with HoFH based on the reimbursement criteria detailed below under the Manitoba Drug Benefits Formulary.

What Is EVKEEZA and How Does It Work?

EVKEEZA is the first and only ANGPTL3 inhibitor indicated as an adjunct to diet and other LDL-C lowering therapies for the treatment of adult and pediatric patients aged 6 months and older with homozygous familial hypercholesterolemia (HoFH).

The effects of EVKEEZA on cardiovascular morbidity and mortality have not been determined.

Please consult the Product Monograph at https://www.ultragenyx.ca/evkeezaproductmonograph for important information relating to warnings and precautions, adverse reactions, breastfeeding, drug interactions, and dosing information.

The Product Monograph is also available by calling us at 1-833-388-5872.

The EVKEEZA Reimbursement Criteria for the Manitoba Drug Benefits Formulary Are as Follows:

For the treatment of adult and pediatric patients aged 5 years and older with homozygous familial hypercholesterolemia (HoFH) who meet all of the following conditions:

Initiation Criteria:

1. Clinically or genetically confirmed diagnosis of HoFH, defined as:
   (a) Clinical Criteria:
      i. Untreated total cholesterol (TC) > 12.93 mmol/L and triglycerides (TGs) < 3.39 mmol/L; AND
      ii. Both parents have documented TC > 6.47 mmol/L, indicative of heterozygous familial hypercholesterolemia (HeFH); OR
      History of cutaneous or tendinous xanthoma before 10 years of age.

   OR

   (b) Genetic Criteria:
      i. Documented functional mutation(s) in both low-density lipoprotein receptor (LDLR) alleles; OR
      ii. Documented homozygous or compound heterozygous mutations in apolipoprotein B (Apo B) or proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1), or at least 2 such variants at different loci;

2. Elevated low-density lipoprotein cholesterol (LDL-C) despite an adequate trial of other accessible lipid-lowering therapies for at least 3 months, defined as LDL-C > 1.8 mmol/L for adults and > 3.4 mmol/L for children.

3. The physician must provide the pre-treatment baseline LDL-C when the initial request for reimbursement occurs after all other treatment options of lipid-lowering therapies have been exhausted.

   Pre-treatment baseline refers to the LDL-C level taken prior to initiation of evinacumab, rather than the untreated LDL-C level.

4. Evinacumab is used as an adjunct to diet and other LDL-C lowering therapies.

Initial approval duration: 6 months

Renewal Criteria:
For renewal after initial authorization and for subsequent renewals, the physician must provide proof of beneficial clinical effect, defined as a reduction in LDL-C from baseline that is considered clinically beneficial by the treating physician.

Renewal duration: 12 months

Prescribing Condition:
Evinacumab must be prescribed by, or in consultation with, specialists with qualifications and experience in the diagnosis and management of HoFH (e.g., [pediatric] endocrinologists, cardiologists, lipidologists).

For more information on applying for EVKEEZA® coverage, we can arrange an appointment at your convenience, or you can go to the UltraCare website. You can also find the UltraCare Enrolment Form on the UltraCare website.