PrEvkeeza®
evinacumab for injection

NEWFOUNDLAND AND LABRADOR

PrEVKEEZA® (evinacumab for injection) is eligible for public reimbursement in Newfoundland and Labrador for patients with HoFH based on the reimbursement criteria detailed below under the Newfoundland and Labrador Prescription Drug Program (NLPDP).

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 Newfoundland and Labrador Prescription Drug Program Are as Follows:

Special Authorization:

EVINACUMAB (EVKEEZA 150 MG/ML IV SOLUTION single dose vial)

For the treatment of homozygous familial hypercholesterolemia (HoFH) in adult and pediatric patients aged 5 years and older with a clinically or genetically confirmed diagnosis if the following criteria are met:

Clinical criteria:

- Untreated total cholesterol (TC) >12.93 mmol/L and triglycerides (TGs) <3.39 mmol/L, AND
- Both parents with documented TC >6.47 mmol/L, indicative of HeFH (heterozygous familial hypercholesterolemia), or patient with cutaneous or tendinous xanthoma before the age of 10 years

Genetic criteria:

- Documented functional mutation or mutations in both low-density lipoprotein receptor (LDLR) alleles, OR
- 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

AND

- Patients must have elevated LDL-C despite an adequate trial of other accessible lipid-lowering therapies; “elevated LDL-C” is defined as LDL-C greater than 1.8 mmol/L at baseline for adult patients and greater than 3.4 mmol/L for children.

Initial and Subsequent Renewals:

- The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as reduction in LDL-C from baseline that is considered clinically beneficial by the treating physician.

Clinical Notes:

- Must be prescribed by specialists with qualifications and experience in the diagnosis and management of HoFH (e.g., [pediatric] endocrinologists, cardiologists, lipidologists).
- The physician must provide the baseline LDL-C when the initial request for reimbursement occurs after all other treatment options of lipid-lowering therapies have been exhausted.
- Initial Approval: 24 weeks.
- Renewal Approval: 1 year.
- Approvals will be for a maximum of 15 mg/kg every 4 weeks.

- **Billing Instructions:** For claims that exceed the maximum allowable claim amount of **$99999.99 per claim**, please contact (709) 729-1780 for billing guidance.

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.