



Health and Community Services

**EVOLOCUMAB (REPATHA 140 MG/ML PREFILLED AUTOINJECTOR, 120mg/ml
AUTOMATED MINI-DOSER WITH PREFILLED CARTRIDGE)**

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (LDL-C less than 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite confirmed adherence to at least 3 months of continuous treatment with:
 - high-dose statin (e.g. atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
 - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial renewal criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent renewal criteria:

- The patient continues to maintain a reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
 - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
 - at least one statin was initiated at the lowest daily starting dose; and
 - other known causes of intolerance have been ruled out.
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease,

- unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- Must be prescribed by a cardiologist or physician with expertise in the diagnosis and treatment of heterozygous familial hypercholesterolemia (HeFH).

Claim Notes:

- Maximum dose approved: 140mg every 2 weeks or 420mg monthly.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

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