

Repatha[®] is covered by Manitoba Drug Benefits and Interchangeability Formulary (Exception Drug Status) for HeFH and by the majority of private drug plans for HeFH and ASCVD



MANITOBA FORMULARY REIMBURSEMENT CRITERIA

Diagnosis: Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing.

Treatment: Patient must be on a high-dose statin (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least a total of 3 months.

LDL-C target: Patient is unable to reach low-density lipoprotein cholesterol (LDL-C) target (i.e., LDL-C <2.0 mmol/L for secondary prevention) or at least a 50% reduction in LDL-C from untreated baseline despite confirmed adherence to treatment

OR

For patients unable to tolerate high-dose statin:

Inability to tolerate at least two statins with at least one started at the lowest starting daily dose

AND

For each statin (two statins in total), dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase [CK] >5 times the upper limit of normal [ULN]) resolution rather than discontinuation of statin altogether

AND

For each statin (two statins in total), intolerable symptoms (myopathy) or abnormal biomarkers (CK >5xULN) changes are reversible upon statin discontinuation but reproducible by rechallenge of statins where clinically appropriate

AND one of either:

Other known determinants of intolerable symptoms or abnormal biomarkers have been ruled out

OR

Patient developed confirmed and documented rhabdomyolysis

OR

Patient is statin-contraindicated, i.e., active liver disease, unexplained persistent elevations of serum transaminases exceeding 3xULN

AND

Confirmed adherence to ezetimibe for at least a total of 3 months

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia

Reference: Manitoba Drug Benefits and Interchangeability Formulary, Bulletin #106, March 2, 2020. www.gov.mb.ca/health/mbdif/docs/bulletins/bulletin106.pdf Accessed February 19, 2020.

