Repatha® private insurance (PI) coverage: Tips for completing PI Special Authorization (SA) forms

To assist your clinic in completing PI Special Authorization forms for your patients who have been prescribed Repatha®, the following suggestions and tips have been compiled. You may find these tips useful for filling in reimbursement criteria and history as requested, according to your individual patient's diagnosis and treatment history.

Repatha® is covered by the majority of private drug plans in Canada for HeFH and ASCVD and by most Canadian provincial formularies for HeFH.[1-9]*

Please ensure that the primary indication for treatment is specified:[10]

- Adult patients with ASCVD: prevention of cardiovascular events: adjunct to diet and standard of care therapy to reduce risk of MI, stroke and coronary revascularization; or
- Primary hyperlipidemia including HeFH: reduction of elevated LDL-C. See below for Repatha® indications.

If the patient is diagnosed with both HeFH and ASCVD, HeFH is documented more often as the underlying reason for their ASCVD. **Most insurers accept probable diagnosis of HeFH** through Simon Broome assessment or the Dutch Lipid Clinic Network criteria.

LDL-C ≥2 mmol/L documented with recent (within the last 3 months) lab test.

- Include lab values documentation with all submissions as most insurers require **recent (within the last 3 months) lab result** that shows the patient has an **LDL-C ≥2 mmol/L** on current treatment.

* 90% of the top private insurance companies currently list Repatha®; coverage varies depending on the patient's plan.

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol

RepathaREADY® PATIENT SUPPORT PROGRAM
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Pr Repatha® (evolocumab)

Repatha® private insurance (PI) coverage: Tips for completing PI Special Authorization (SA) forms

- Please provide complete **history of lipid-lowering treatments**.

  Please provide your patient's history with lipid-lowering medication(s).

  - Remember to document intolerance, different trials, as well as re-challenges or contraindications to prior lipid-lowering medication(s) such as statins and ezetimibe.

- Many insurers require LDL-C level verification prior to renewal.

Ensure the patient has their **LDL-C level checked** 1 to 3 months prior to the insurance expiry date, which varies depending on the patient's insurance plan (most are 6 months or 1 year).

Repatha® is covered for HeFH by these provincial formularies

- British Columbia Pharmacare (Special Authority)
- Ontario Drug Benefit program (LU CODE 527)
- Alberta Drug Benefit List (Special Authorization)
- RAMQ† (Exceptional Medication)
- Saskatchewan Drug Benefit List for HeFH (Exception Drug Status)
- New Brunswick Drug Plan Formulary (Exception Drug Status)
- Manitoba Drug Benefits and Interchangeability Formulary (Exception Drug Status)
- Nova Scotia Pharmacare Formulary (Exception Drug Status)

Questions? Call toll-free 1-888-Repatha (1-888-737-2842)

† RAMQ is the official mark of the Régie de l'assurance maladie du Québec. Please consult the *List of Medications* at https://www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/2020/liste_med_2020_03_04_en.pdf.

HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol

RepathaREADY® PATIENT SUPPORT PROGRAM
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Pr Repatha® (evolocumab)

Repatha® (evolocumab) is indicated:

- as an adjunct to diet and standard of care therapy (including moderate- to high-intensity statin therapy alone or in combination with other lipid-lowering therapy) to reduce the risk of myocardial infarction, stroke and coronary revascularization in adult patients with atherosclerotic cardiovascular disease;
- for the reduction of elevated low density lipoprotein cholesterol (LDL-C) in adult patients with primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) as an adjunct to diet and statin therapy, with or without other lipid-lowering therapies, in patients who require additional lowering of LDL-C; or as an adjunct to diet, alone or in combination with non-statin lipid-lowering therapies, in patients for whom a statin is contraindicated.

Please consult the Product Monograph at www.amgen.ca/Repatha_PM.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen Medical Information at 1-866-502-6436.

References: 1. British Columbia PharmaCare. www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-evolocumab. Accessed July 12, 2020. **2.** Alberta Drug Benefit List. Alberta Drug Benefit List. idbl.ab.bluecross.ca/idbl/load.do. Accessed April 21, 2020. **3.** Saskatchewan Drug Plan. formulary.drugplan.ehealthsask.ca/SearchFormulary/BG/596951. Accessed April 21, 2020. **4.** Manitoba Drug Benefits and Interchangeability Formulary, Bulletin #106, March 2, 2020. www.gov.mb.ca/health/mdbif/docs/bulletins/bulletin106.pdf. Accessed April 21, 2020. **5.** Ontario Drug Benefit Program. www.ontario.ca/page/medication-coverage-results/?q=evolocumab. Accessed April 21, 2020. **6.** Régie de l'assurance maladie du Québec. List of Medications, September 30, 2020. www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-09-30-en.pdf. Accessed November 3, 2020. **7.** New Brunswick Drug Plan Formulary, November 2020. www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf. Accessed November 6, 2020. **8.** Nova Scotia Pharmacare Formulary, October 2020. novascotia.ca/dhw/pharmacare/documents/formulary.pdf. Accessed November 3, 2020. **9.** Amgen Canada, Letter on File. **10.** Repatha® (evolocumab) Product Monograph. Amgen Canada Inc., June 11, 2019.

Pr Repatha® (evolocumab)

RepathaREADY® PATIENT SUPPORT PROGRAM
YOUR PARTNER IN CARE, EVERY STEP OF THE WAY

REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

AMGEN®
Cardiovascular

Repatha® is covered by British Columbia PharmaCare (Special Authority) for HeFH

and by the majority of private drug plans for HeFH and ASCVD

SPECIAL AUTHORITY CRITERIA: INITIAL APPROVAL (12 WEEKS)

For the treatment of HeFH* as an adjunct to maximally tolerated HMG-CoA Reductase Inhibitors (statins) therapy in adult patients who are unable to reach target LDL-C levels† when:

- The patient has confirmed adherence to treatment with atorvastatin 80 mg or rosuvastatin 40 mg for a minimum of 6 months.
  OR
  - The patient is unable to tolerate at least two HMG-CoA Reductase Inhibitors (statins).‡
  OR
  - The patient has confirmed rhabdomyolysis.
  OR
  - Treatment with HMG-CoA Reductase Inhibitors (statins) is contraindicated.
  AND
  - The patient has confirmed adherence to treatment with ezetimibe for a minimum of 3 months.

Special Notes

* Definite or probable diagnosis of HeFH is determined using the Simon Broome or Dutch Lipid Network criteria or genetic testing.

† Target LDL-C levels are:
- For primary prevention, a ≥50% reduction in LDL-C from untreated baseline.
- For secondary prevention, an LDL-C <2.0 mmol/L.

‡ Inability to tolerate at least two HMG-CoA Reductase Inhibitors (statins): Dose reduction and re-challenge of each HMG-CoA Reductase Inhibitor (statin) must be attempted to resolve intolerable symptoms or biomarker abnormality (CK >5 times the ULN) before discontinuing a treatment.

See following screen for more criteria

ASCVD=atherosclerotic cardiovascular disease; CK=creatine kinase; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; ULN=upper limit of normal

Reference: British Columbia PharmaCare. www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-evolocumab. Accessed July 12, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by British Columbia PharmaCare (Special Authority) for HeFH

and by the majority of private drug plans for HeFH and ASCVD

Special authority renewal criteria (1 year)[1]*†

Approval will be granted if the following criteria are met:

- The patient is adherent to therapy.

AND

- The patient has achieved a reduction in LDL-C of at least 40% from baseline within 4-8 weeks after initiation of evolocumab.

AND

- The patient maintains a significant reduction in LDL-C (with continuation of evolocumab) of at least 40% from baseline since initiation of evolocumab.

Special Notes

* Patients prescribed evolocumab 140 mg every 2 weeks are limited to 26 of 140 mg prefilled autoinjectors per year.

† Patients prescribed evolocumab 420 mg monthly are limited to 12 prefilled cartridges per year.

ASCVD=atherosclerotic cardiovascular disease; LDL-C=low-density lipoprotein cholesterol

Reference: British Columbia PharmaCare. www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-evolocumab. Accessed July 12, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the Alberta Drug Benefit List for HeFH (Special Authorization) and by the majority of private drug plans for HeFH and ASCVD

CLINICAL CRITERIA FOR SPECIAL AUTHORIZATION

For the treatment of HeFH in patients who meet the following criteria: Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing

AND

LDL-C target and treatment: Unable to reach 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 for primary prevention) despite confirmed adherence to high-dose statin (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least a total of 3 months

OR

Confirmed adherence to ezetimibe for at least a total of 3 months and inability to tolerate high-dose statin defined as:

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 (CK >5xULN) 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 the following:

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

OR

Patient developed confirmed and documented rhabdomyolysis

OR

Confirmed adherence to ezetimibe for at least 3 months
AND
Patient is statin-contraindicated, i.e., active liver disease, unexplained persistent elevations of serum transaminases exceeding 3xULN

See following screen for more criteria

ASCVD=atherosclerotic cardiovascular disease; CK=creatine kinase; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; PCSK9=proprotein convertase subtilisin/kexin type 9; ULN=upper limit of normal

Reference: Alberta Drug Benefit List. idbl.ab.bluecross.ca/idbl/load.do. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the Alberta Drug Benefit List for HeFH (Special Authorization) and by the majority of private drug plans for HeFH and ASCVD

Initial coverage may be approved for either 140 mg every 2 weeks or 420 mg every month for a period of 3 months. Patients prescribed evolocumab 420 mg every month must use the 420 mg/dose formulation. Patients will be limited to receiving a one-month supply of evolocumab per prescription at their pharmacy.

For continued coverage beyond 3 months, the patient must meet the following criteria:

- Patient is adherent to therapy
- Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of evolocumab)

Continued coverage may be approved for 140 mg every 2 weeks or 420 mg every month for a period of 12 months. Patients prescribed evolocumab 140 mg every 2 weeks are limited to 26 doses per year. Patients prescribed evolocumab 420 mg every month are limited to 12 doses per year.

Ongoing coverage may be considered only if the following criteria are met at the end of each 12-month period:

- Patient is adherent to therapy
- Patient continues to have a significant reduction in LDL-C (with continuation of evolocumab) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (i.e., every 6 months)

All requests (including renewal requests) for evolocumab for HeFH must be completed using the Evolocumab for Heterozygous Familial Hypercholesterolemia Special Authorization Request Form (ABC 60060).

ASCVD=atherosclerotic cardiovascular disease; CK=creatine kinase; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; PCSK9=proprotein convertase subtilisin/kexin type 9; ULN=upper limit of normal

Reference: Alberta Drug Benefit List. idbl.ab.bluecross.ca/idbl/load.do. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the Saskatchewan Drug Benefit List for HeFH (Exception Drug Status) and by the majority of private drug plans for HeFH and ASCVD

CLINICAL CRITERIA FOR EXCEPTION DRUG STATUS

For the treatment of HeFH in patients who meet the following criteria: Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing

AND

Who are unable to reach 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 high-dose statin (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least a total of 3 months

OR

Unable to tolerate high-dose statin defined as all of the following:

Confirmed adherence to ezetimibe for at least a total of 3 months **AND** 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 (CK >5xULN) 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 the following:

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

See following screen for more criteria

ASCVD=atherosclerotic cardiovascular disease; CK=creatine kinase; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; ULN=upper limit of normal

Reference: Saskatchewan Drug Plan. formulary.drugplan.ehealthsask.ca/SearchFormulary/BG/596951. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the Saskatchewan Drug Benefit List for HeFH (Exception Drug Status) and by the majority of private drug plans for HeFH and ASCVD

Quantity limits

- Patients prescribed Repatha® 140 mg every 2 weeks are limited to 26 prefilled syringes per year
- Patients prescribed Repatha® 420 mg every month must use the automated mini doser (AMD) and are limited to 12 AMDs per year

Discontinuation criteria

Treatment with Repatha® should be discontinued if the patient does not meet all of the following:

- Adherent to therapy
- Achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of Repatha®)
- Continues to have a significant reduction in LDL-C (with continuation of Repatha®) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (i.e., every 6 months)

ASCVD=atherosclerotic cardiovascular disease; CK=creatine kinase; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; ULN=upper limit of normal

Reference: Saskatchewan Drug Plan. formulary.drugplan.ehealthsask.ca/SearchFormulary/BG/596951. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

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/mdbif/docs/bulletins/bulletin106.pdf. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by Ontario Drug Benefit program for HeFH (LU CODE 527) and by the majority of private drug plans for HeFH and ASCVD

LU CODE 527 CLINICAL CRITERIA

For the treatment of HeFH in patients 18 years of age or older who meet the following criteria: Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing;

AND

LDL-C target and treatment: Unable to reach LDL-C target (i.e., LDL-C less than 2.0 mmol/L for secondary prevention) or at least a 50% reduction in LDL-C from untreated baseline despite confirmed adherence to high-dose statin (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least a total of 3 months

OR

Confirmed adherence to ezetimibe for at least a total of 3 months and inability to tolerate high-dose statin defined as:

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 biomarker (CK >5xULN) changes are reversible upon statin discontinuation but reproducible by rechallenge of statins where clinically appropriate

AND one of the following:

Other known determinants of intolerable symptoms or abnormal biomarker 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

See following screen for more criteria

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; LU=limited use; PCSK9=proprotein convertase subtilisin/kexin type 9

Reference: Ontario Drug Benefit Program. www.ontario.ca/page/medication-coverage-results/?q=evolocumab. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by Ontario Drug Benefit program for HeFH (LU CODE 527) and by the majority of private drug plans for HeFH and ASCVD

Treatment with Repatha® should be discontinued if the patient does not meet all of the following:

1. Patient is adherent to therapy
2. Patient has achieved a reduction in LDL-C of at least 40% from baseline (4-8 weeks after initiation of Repatha®).
3. Patient continues to have a significant reduction in LDL-C (with continuation of Repatha®) of at least 40% from baseline since initiation of PCSK9 inhibitor. LDL-C should be checked periodically with continued treatment with PCSK9 inhibitors (i.e., every 6 months).

Patients prescribed Repatha® 140 mg every two weeks are limited to 26 prefilled syringes per year. Patients prescribed Repatha® 420 mg every month must use the automated mini-doser and are limited to 12 per year.

LU Authorization Period: 1 year

Reference: Ontario Drug Benefit Program. www.ontario.ca/page/medication-coverage-results/?q=evolocumab. Accessed April 21, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by RAMQ* (Exceptional Medication) for HeFH and by the majority of private drug plans for HeFH and ASCVD

RAMQ (EXCEPTIONAL MEDICATION) CRITERIA FOR HeFH PATIENTS

Diagnosis: HeFH in adults, confirmed by genotyping or phenotyping

Phenotyping defined as LDL-C >4.9 mmol/L in adults prior to initiation of treatment and at least one of the following:

- Family history of HeFH confirmed by genotyping in a first-degree relative
- Presence in a first-degree relative of an LDLR, ApoB or PCSK9 gene mutation that causes familial hypercholesterolemia
- Presence of xanthomas in the patient or in a first- or second-degree relative
- Presence of corneal arcus before the age of 45 years in a first-degree relative
- Family history of LDL-C >4.9 mmol/L in a first-degree adult relative or ≥4 mmol/L in a first-degree relative under 18 years
- Family history of total cholesterol >7.5 mmol/L in a first- or second-degree adult relative or >6.7 mmol/L in a first-degree relative under 16 years

Current treatment: On optimal dose of statin plus ezetimibe, which has not allowed for adequate control of the cholesterolemia, unless there is a serious intolerance or a contraindication.

Adequate control of cholesterol defined as:

- In patients with no ASCVD, at least 50% reduction in LDL-C from baseline, i.e., prior to any lipid-lowering therapy
- In patients with ASCVD, an LDL-C <2.0 mmol/L

The initial request is authorized for a maximum period of 4 months.

For subsequent requests, the physician must provide evidence showing the treatment's beneficial effects, i.e., reduction ≥40% in LDL-C level versus baseline value **prior to initiating treatment with evolocumab**. Subsequent requests are authorized for a maximum duration of 12 months.

Authorizations for evolocumab are given for a maximum dose of 140 mg every 2 weeks or 420 mg every month.

* RAMQ is the official mark of the Régie de l'assurance maladie du Québec. Please consult the *List of Medications* at www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-09-30-en.pdf.

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; LDLR=low-density lipoprotein receptor

Reference: Régie de l'assurance maladie du Québec. List of Medications, September 30, 2020. www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-09-30-en.pdf. Accessed November 3, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the New Brunswick Drug Plan Formulary for HeFH (Exception Drug Status)
and by the majority of private drug plans for HeFH and ASCVD

CLINICAL CRITERIA FOR EXCEPTION DRUG STATUS

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 (<2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) 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 <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 <2.0 mmol/L

See following screen for more criteria

ASCVD=atherosclerotic cardiovascular disease; LDL-C=low-density lipoprotein cholesterol

Reference: New Brunswick Drug Plan Formulary, November 2020. www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf. Accessed November 6, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the New Brunswick Drug Plan Formulary for HeFH (Exception Drug Status)
and by the majority of private drug plans for HeFH and ASCVD

Clinical notes:

1. LDL-C levels must be provided.
2. Intolerance to high-dose statin will be considered if patient has developed documented rhabdomyolysis, myopathy or abnormal biomarkers (i.e., creatine kinase >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.
3. For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim notes:

- Approvals will be for a maximum of 140 mg every 2 weeks or 420 mg monthly
- Initial approval: 6 months
- Renewal approval: 1 year

ASCVD=atherosclerotic cardiovascular disease; LDL-C=low-density lipoprotein cholesterol

Reference: New Brunswick Drug Plan Formulary, November 2020. www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf. Accessed November 6, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the Nova Scotia Pharmacare Formulary (Exception Drug Status) for HeFH
and by the majority of private drug plans for HeFH and ASCVD

CLINICAL ELIGIBILITY CRITERIA

For the treatment of HeFH in adult patients who require additional lowering of 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 (<2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) 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 <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 <2.0 mmol/L.

See following screen for more criteria

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol

Reference: Nova Scotia Pharmacare Formulary, October 2020. novascotia.ca/dhw/pharmacare/documents/formulary.pdf. Accessed November 3, 2020.

Pr Repatha® (evolocumab)

Repatha® is covered by the Nova Scotia Pharmacare Formulary (Exception Drug Status) for HeFH
and by the majority of private drug plans for HeFH and ASCVD

Clinical notes:

1. LDL-C levels must be provided.
2. Intolerance to high-dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e., CK >5xULN) 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 or abnormal biomarkers have been ruled out.
3. For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (i.e., confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding 3xULN).
4. For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.

Claim notes:

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

ASCVD=atherosclerotic cardiovascular disease; CK=creatinine kinase; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein cholesterol; ULN=upper limit of normal

Reference: Nova Scotia Pharmacare Formulary, October 2020. novascotia.ca/dhw/pharmacare/documents/formulary.pdf. Accessed November 3, 2020.

Pr Repatha® (evolocumab)