Remboursement de Repatha[MD] par les assureurs privés : Conseils pour remplir les formulaires de demande d'autorisation spéciale pour les assureurs privés

Les suggestions et les conseils suivants ont été rassemblés afin d'aider votre clinique à remplir les formulaires de demande d'autorisation spéciale pour les patients à qui l'on a prescrit Repatha[MD] et qui sont couverts par un régime privé. Ces conseils pourraient vous être utiles pour consigner les renseignements demandés au sujet des critères de remboursement et des antécédents, en fonction du diagnostic et des traitements antérieurs de chaque patient.

Repatha[MD] est remboursé par la majorité des régimes d'assurance privés au Canada dans l'hypercholestérolémie familiale hétérozygote et la maladie cardiovasculaire athéroscléreuse, et par la plupart des régimes d'assurance provinciaux canadiens dans l'hypercholestérolémie familiale hétérozygote[1-9]*.

Veuillez vous assurer de préciser l'indication principale dans laquelle le traitement est prescrit[10] :

- pour prévenir les événements cardiovasculaires : comme traitement d'appoint au régime alimentaire et au traitement de référence pour réduire le risque d'infarctus du myocarde, d'accident vasculaire cérébral ou de revascularisation coronarienne chez les patients adultes atteints d'une maladie cardiovasculaire athéroscléreuse, ou
- pour réduire le taux élevé de cholestérol des lipoprotéines de basse densité (C-LDL) chez les patients atteints d'hyperlipidémie primaire (y compris d'hypercholestérolémie familiale hétérozygote). Voir les indications de Repatha[MD] ci-après.

Si le patient a reçu un diagnostic d'hypercholestérolémie familiale hétérozygote et de maladie cardiovasculaire athéroscléreuse, l'hypercholestérolémie familiale hétérozygote est le plus souvent documentée comme étant la cause sous-jacente de la maladie cardiovasculaire athéroscléreuse. **La majorité des assureurs acceptent les diagnostics probables d'hypercholestérolémie familiale hétérozygote** déterminés à l'aide des critères de Simon-Broome ou du Dutch Lipid Clinic Network.

Un taux de C-LDL ≥ 2 mmol/L prouvé par des analyses de laboratoire récentes (au cours des 3 derniers mois).

- Joindre les rapports des résultats de laboratoire à toutes les demandes d'autorisation, car la plupart des assureurs exigent des **résultats d'analyses de laboratoire récentes (au cours des 3 derniers mois)** indiquant que le patient présente un **taux de C-LDL ≥ 2 mmol/L** malgré le traitement en cours.

* À l'heure actuelle, 90 % des principaux assureurs privés remboursent Repatha[MD]; la couverture varie en fonction de chaque régime.

C-LDL = cholestérol des lipoprotéines de faible densité

REPÈREPatha[MD]
PROGRAMME DE SOUTIEN AUX PATIENTS
VOTRE PARTENAIRE DE SOINS, SUR TOUTE LA LIGNE

Pr Repatha[MD]
(évolocumab)

Remboursement de Repatha[MD] par les assureurs privés : Conseils pour remplir les formulaires de demande d'autorisation spéciale pour les assureurs privés

Fournir les **antécédents complets concernant le traitement hypolipidémiant**.

Fournir un résumé des traitements hypolipidémiants antérieurs reçus par le patient.

- Ne pas oublier de documenter les intolérances, les différents essais, ainsi que les expositions répétées ou les contre-indications à des hypolipidémiants utilisés précédemment, comme les statines et l'ézétimibe.

De nombreux assureurs exigent une vérification du taux de C-LDL avant d'autoriser un renouvellement.

Il faut s'assurer que le **taux de C-LDL du patient a été vérifié** de 1 à 3 mois avant la date d'expiration de l'assurance, laquelle varie selon le régime d'assurance du patient (la plupart sont d'une durée de 6 mois ou de 1 an).

Repatha[MD] est remboursé dans l'hypercholestérolémie familiale hétérozygote selon les listes de médicaments provinciales suivantes :

- British Columbia Pharmacare (autorisation spéciale)
- Programme de médicaments de l'Ontario (LU CODE 527)
- Alberta Drug Benefit List (autorisation spéciale)
- RAMQ† (médicament d'exception)
- Liste de médicaments du Régime d'assurance-médicaments de la Saskatchewan pour l'hypercholestérolémie familiale hétérozygote (médicament d'exception)
- Formulaire des Régimes de médicaments du Nouveau-Brunswick (médicament d'exception)
- Manitoba Drug Benefits and Interchangeability Formulary (médicament d'exception)
- Nova Scotia Pharmacare Formulary (médicament d'exception)

Des questions? Composez sans frais le 1-888-Repatha (1-888-737-2842)

† RAMQ est le sigle officiel de la Régie de l'assurance maladie du Québec. Veuillez consulter la *Liste des médicaments* à l'adresse : https://www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/2020/liste_med_2020_03_04_fr.pdf.

C-LDL = cholestérol des lipoprotéines de faible densité

REPÈREPatha[MD]
PROGRAMME DE SOUTIEN AUX PATIENTS
VOTRE PARTENAIRE DE SOINS, SUR TOUTE LA LIGNE

Pr Repatha[MD]
(évolocumab)

Repatha[MD] (évolocumab) est indiqué :

- comme traitement d'appoint au régime alimentaire et au traitement de référence (y compris au traitement d'intensité modérée ou élevée par une statine, seule ou en association avec un autre traitement hypolipidémiant) pour réduire le risque d'infarctus du myocarde, d'accident vasculaire cérébral ou de revascularisation coronarienne chez les patients adultes atteints d'une maladie cardiovasculaire athéroscléreuse;

- pour réduire le taux élevé de cholestérol des lipoprotéines de faible densité (C-LDL) chez les patients adultes atteints d'hyperlipidémie primaire (y compris d'hypercholestérolémie familiale [HF] hétérozygote) comme traitement d'appoint au régime alimentaire et au traitement par une statine, seul ou en association avec d'autres traitements hypolipidémiants, chez les patients qui ont besoin d'une réduction additionnelle de leur taux de C-LDL; ou comme traitement d'appoint au régime alimentaire, seul ou en association avec d'autres traitements hypolipidémiants qu'une statine, chez les patients pour qui les statines sont contre-indiquées.

Veuillez consulter la monographie du produit à l'adresse www.amgen.ca/Repatha_PM_Fre.pdf pour connaître les contre-indications, les mises en garde, les précautions, les effets indésirables, les interactions, la posologie et les conditions d'utilisation clinique. Il est aussi possible de se procurer la monographie du produit en appelant l'Information médicale d'Amgen au 1-866-502-6436.

Références : 1. British Columbia PharmaCare. Consulté le 12 juillet 2020 au www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-evolocumab. **2.** Alberta Drug Benefit List. Consulté le 21 avril 2020 au idbl.ab.bluecross.ca/idbl/load.do. **3.** Régime d'assurance-médicaments de la Saskatchewan. Consulté le 21 avril 2020 au formulary.drugplan.ehealthsask.ca/SearchFormulary/BG/596951. **4.** Manitoba Drug Benefits and Interchangeability Formulary, Bulletin #106, 2 mars 2020. Consulté le 21 avril 2020 au www.gov.mb.ca/health/mdbif/docs/bulletins/bulletin106.pdf. **5.** Programme de médicaments de l'Ontario. Consulté le 21 avril 2020 au https://www.ontario.ca/fr/page/resultats-des-medicaments-pris-en-charge/?q=evolocumab. **6.** Régie de l'assurance maladie du Québec. *Liste des médicaments,* 30 septembre 2020. Consulté le 3 novembre 2020 au https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-09-30-fr.pdf. **7.** Formulaire des régimes de médicaments du Nouveau-Brunswick, novembre 2020. Consulté le 6 novembre 2020 au https://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/fr/RegimeMedicamentsN-B/RegimeMedicamentsN-B.pdf. **8.** Nova Scotia Pharmacare Formulary, octobre 2020. Consulté le 3 novembre 2020 au novascotia.ca/dhw/pharmacare/documents/formulary.pdf. **9.** Amgen Canada, lettre en dossiers. **10**. Monographie de Repatha[MD] (évolocumab). Amgen Canada Inc., 11 juin 2019.

Pr Repatha[MD] (évolocumab)

REPÈRERepatha[MD]
PROGRAMME DE SOUTIEN AUX PATIENTS
VOTRE PARTENAIRE DE SOINS, SUR TOUTE LA LIGNE

RÉVISÉ PAR CCPP

MEMBRE DE MÉDICAMENTS NOVATEURS CANADA

AMGEN®
Cardiovasculaire

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.

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.

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.

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.

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.

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.

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.

Repatha®
(evolocumab)

REPATHA[MD] est remboursé par la RAMQ* (Médicament d'exception) pour la HFHe et par la majorité des régimes privés pour la HFHe et la MCVAS

CRITÈRES DE LA RAMQ (MÉDICAMENT D'EXCEPTION) RELATIVEMENT AUX PATIENTS ATTEINTS D'HFHe

Diagnostic : HFHe chez l'adulte confirmée par génotypage ou phénotypage

Le phénotypage est défini par une concentration de C-LDL > 4,9 mmol/L chez l'adulte avant le début d'un traitement et par au moins un des éléments suivants :

- Antécédents familiaux d'HFHe confirmée par génotypage chez un parent du 1er degré
- Présence chez un parent du 1er degré d'une mutation du gène du récepteur des LDL, du gène ApoB ou du gène PCSK9 responsable de l'hypercholestérolémie familiale
- Présence de xanthomes chez le patient ou chez un parent du 1er ou du 2e degré
- Présence d'arcs cornéens chez un parent du 1er degré de moins de 45 ans
- Antécédents familiaux de taux de C-LDL > 4,9 mmol/L chez un parent adulte du 1er degré ou ≥ 4 mmol/L chez un parent du 1er degré de moins de 18 ans
- Antécédents familiaux de taux de cholestérol total > 7,5 mmol/L chez un parent adulte du 1er ou du 2e degré ou > 6,7 mmol/L chez un parent du 1er degré de moins de 16 ans

Traitement actuel : Dose optimale d'une statine + ézétimibe, qui n'a pas permis d'obtenir une maîtrise adéquate de la cholestérolémie, à moins d'une intolérance grave ou d'une contre-indication.

Par maîtrise adéquate du cholestérol, on entend :

- Chez les patients n'ayant pas de MCVAS, une diminution d'au moins 50 % du taux de C-LDL par rapport à la valeur de départ, c.-à-d. avant l'instauration d'un traitement hypolipidémiant
- Chez les patients ayant une MCVAS, un taux de C-LDL < 2,0 mmol/L

La demande initiale est autorisée pour une période maximale de 4 mois.

Pour les demandes subséquentes, le médecin doit fournir la preuve d'un effet bénéfique du traitement, soit une diminution d'au moins 40 % du taux de C-LDL par rapport à la valeur de départ mesurée **avant l'instauration du traitement par l'évolocumab**. Les demandes subséquentes sont autorisées pour une période maximale de 12 mois.

Les autorisations pour l'évolocumab sont données à raison d'une dose maximale de 140 mg toutes les deux semaines ou de 420 mg une fois par mois.

* RAMQ est le sigle officiel de la Régie de l'assurance maladie du Québec. Veuillez consulter la *Liste des médicaments* à l'adresse : https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-09-30-fr.pdf.

C-LDL = cholestérol des lipoprotéines de faible densité; HFHe = hypercholestérolémie familiale hétérozygote; MCVAS = maladie cardiovasculaire athéroscléreuse

Référence : Régie de l'assurance maladie du Québec. *Liste des médicaments,* 30 septembre 2020. Consulté le 3 novembre 2020 au https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste-med-2020-09-30-fr.pdf.

Pr Repatha[MD] (évolocumab)

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.

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.

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.

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.

Repatha® (evolocumab)