Praluent (Alirocumab) / Repatha (Evolocumab)

EXCEPTION DRUG STATUS (EDS) REQUEST FORM

FAX: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	**Fax Number:** **Phone Number:**
Prescriber Address:	**Prescriber License Number (NOT Billing Number):**

Patient's First Name:	**PHIN:**	**MH Registration Number:**
Patient's Last Name:	**Patient's Date of Birth:**	
Requested Medication Name and Strength: ◯ **Praluent (alirocumab) – Strength: _____** ◯ **Repatha (evolocumab) – Strength: _____**	**Expected Dosing:**	**Expected Therapy Duration:**

Exception Drug Status (EDS) approval is granted only upon demonstration that the patient meets the specified EDS criteria. Please provide the following details to support the meeting of EDS criteria by the patient.

Diagnosis/Indication:	

Patient's Baseline Information (Prior to Treatment Initiation)

☐ **Definite or probable diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)** confirmed by:
- ☐ Simon Broome criteria
- ☐ Dutch Lipid Network criteria
- ☐ Genetic testing

☐ **Unable to reach Low Density Lipoprotein Cholesterol (LDL-C) target (ie. LDL-C<2.0 mmol/L for secondary prevention) or at least 50% reduction in LDL-C from untreated baseline**:

Treated Baseline LDL-C: _____ Date: _____

Current LDL-C: _____ Date: _____

☐ Confirmed adherence to high dose statin (ie. 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 (inability to tolerate at least 2 statins with at least one started at the lowest daily dose); AND**

For each statin (2 statins in total), total dose reduction is attempted for intolerable symptom (myopathy) or biomarker abnormality (creatine kinase (CK) >5 times the upper limit of normal) resolution rather than discontinuation of statin altogether; **AND**

For each statin (2 statins in total), intolerable symptoms (myopathy) or abnormal biomarkers (CK >5 times the upper limit of normal) 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 (ie. active liver disease, unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal); **AND**

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

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

Patient's Drug History - Please complete the attached Statin and Ezetimibe Medication History Chart.

Statin Medication History (for all requests):

Name of Statin	***Dosing Regimen***	***Start Date***	***End Date or Currently On***	***Patient Response: (Reason for discontinuation, details of intolerance or failure at maximum tolerated dose must be provided)***	***Dose reduction attempted***	***Rechallenge***
				❑ Intolerable myopathy ❑ Biomarker abnormality (CK level = _____) ❑ Other – please detail:	❑ Yes ❑ No If not, why not?	❑ Yes ❑ No If not, why not?
				❑ Intolerable myopathy ❑ Biomarker abnormality (CK level = _____) ❑ Other – please detail:	❑ Yes ❑ No If not, why not?	❑ Yes ❑ No If not, why not?

Ezetimibe History (for all requests):

Dosing Regimen	***Start Date***	***End Date or Currently On***

RENEWAL Coverage

☐ Patient is adherent to therapy;

☐ Patient has achieved a reduction of at least 40% from baseline (4-8 weeks after initiation);

☐ Patient continues to have a significant reduction in LDL-C (with continuation of medication) of at least 40% from baseline since the initiation of treatment. LDL-C should be checked periodically with continued treatment (ie. every 6 months)

LDL-C (pre-therapy): _____ Current LDL-C: _____Date: _____

Prescriber Signature and Date:

Date:		**Prescriber Signature:**	