Updated: 02/2019
PARP Approved: 03/2019

Prior Authorization Criteria

PCSK9 Inhibitors

All requests for PCSK9 inhibitors require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for PCSK9 inhibitors all of the following criteria must be met:

- For non-formulary agents, the member has had a trial and failure of a formulary agent or submitted a clinical reason for not having a trial of a formulary agent†
- The medication is being prescribed by a qualified specialist or there is documentation the PCSK9 inhibitor is being prescribed in consultation with a qualified specialist (cardiologist, endocrinologist, lipid specialist)
- Documentation of adherence or counseling to lipid-lowering lifestyle interventions, including exercise and a low fat, low cholesterol diet
- Documentation of lipid panel results at baseline (pre-treatment), current LDL level with treatment for at least one month, and goal LDL level are provided
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- The member will not be taking the requested PCSK9 inhibitor concurrently with another PCSK9 inhibitor
- The member will be obtaining the medication from a qualified network specialty pharmacy

Coverage may be provided with a diagnosis of **heterozygous familial hypercholesterolemia (HeFH)** and the following criteria is met:

- Documentation of HeFH confirmed as **definite** with one of the following:
    - A score of > 8 using the Dutch Lipid Clinic Network criteria (all points added to calculate the total score must be documented)
    - The Simon-Broome criteria. Clinical evidence and laboratory results must be provided to support the diagnosis
    - Genetic testing confirming a point mutation in LDLR, APOB, PCSK9, or LDLRAP1 genes
- Pertaining to the member's current lipid-lowering treatment regimen:
    - The member has had an adequate trial of at least two statins at the maximally tolerated dose
        - The member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 6 months unless the member is new to the plan. If new to the plan, documentation from the prescribing physician and/or the patient's pharmacy demonstrates adherence to therapy over the past 6 months
        - For Praluent (alirocumab) only, the member must be taking a PCSK9 inhibitor concurrently with a maximally tolerated statin
- Documented therapeutic failure, intolerance, or contraindication to Zetia (ezetimibe*) in combination with statin therapy for at least 8 weeks

- Documentation, within the past month, that the member's LDL-C is >100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD) or >55mg/dl (with extreme risk designation) while adherent to a maximally tolerated dose of statin therapy in combination with Zetia (ezetimibe*)

Coverage may be provided with a diagnosis of **Clinical Atherosclerotic Cardiovascular Disease (ASCVD) requiring additional lowering of LDL-cholesterol OR reduction of risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease (Repatha (evolocumab) only)** and the following criteria is met:

- Documentation of a diagnosis of clinical atherosclerotic cardiovascular disease defined as one of the following:
    - Acute Coronary Syndrome
    - History of Myocardial Infarction
    - Stable or unstable Angina
    - Coronary revascularization
    - Other arterial revascularization
    - Stroke
    - Transient Ischemic Attack
    - Peripheral Arterial Disease
- The member will be taking a PCSK9 inhibitor concurrently with a maximally tolerated statin
- Pertaining to the member's current lipid-lowering treatment regimen:
    - The member has had an adequate trial of at least two statins at the maximally tolerated dose
    - The member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 6 months, unless new to the plan. If new to the plan, documentation from prescribing physician and/or patient's pharmacy demonstrates adherence to therapy over the past 6 months
- Documentation, within the past month, that the member's LDL-C is > 70 mg/dL or >55mg/dl (with extreme risk designation) while adherent to a maximally tolerated dose of statin therapy
- If the member has ASCVD and requires < 25% additional LDL-C lowering:
    - Documented therapeutic failure, intolerance, or contraindication to Zetia (ezetimibe*) in combination with statin therapy for at least 8 weeks

Coverage may be provided with a diagnosis of **homozygous familial hypercholesterolemia (HoFH)-Repatha (evolocumab) only** and the following criteria is met:

- Documented diagnosis of HoFH (clinical documentation and laboratory results must be provided to support the diagnosis) confirmed by:
    - An untreated LDL-C >500 mg/dL or a treated LDL-C ≥ 300 mg/dL with one of the following:
        - Presence of cutaneous or tendon xanthoma before 10 years of age

    - Both parents have documented elevated LDL-C before lipid-lowering treatment (pre-treatment) consistent with a diagnosis of heterozygous familial hypercholesterolemia [e.g. untreated LDL-C >190 mg/dL]
    - Previous history of genetic confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus
- The member will be taking Repatha (evolocumab) concurrently with other lipid lowering therapies as indicated in the FDA approved labeling
- Repatha (evolocumab) will not be used concomitantly with Juxtapid (lomitapide) or Kynamro (mipomersen)
- Pertaining to the member's current lipid-lowering treatment regimen:
    - The member has had an adequate trial of at least two statins at the maximally tolerated dose
    - The member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 6 months, unless new to the plan. If new to the plan, documentation from prescribing physician and/or patient's pharmacy demonstrates adherence to therapy over the past 6 months
- Documented therapeutic failure, intolerance, or contraindication to Zetia (ezetimibe*), in combination with statin therapy for at least 8 weeks
- Documentation, within the past month, that the member's LDL-C is > 100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD) or >55mg/dl (with extreme risk designation) while adherent to lipid lowering therapies

- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - The member is adherent to PCSK9 inhibitor therapy as evidenced by consistent pharmacy claims
    - Documentation the member is adherent to statin treatment in combination with Praluent (alirocumab) or Repatha (evolocumab).
        - If Repatha (evolocumab) is being used for HeFH, documentation of statin adherence is not required
    - LDL-C drawn after treatment initiation with a PCSK9 inhibitor demonstrates improvement while on maximized therapy
    - The member has been adherent to statin therapy as evidenced by consistent pharmacy claims except when the member is using Repatha (evolocumab) for a diagnosis of heterozygous familial hypercholesterolemia (HeFH)
- **Reauthorization Duration of Approval:** 12 months

*(ezetimibe) requires prior authorization
+Formulary Repatha (evolocumab) NDCs include

- 72511-0750-01
- 72511-0770-01

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or

peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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PCSK9 INHIBITORS
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE: _____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Baseline LDL-C: _____ **Date:**_____
Current LDL-C: _____ **Date:**_____
Goal LDL-C: _____
% Reduction in LDL-C required to reach goal: _____ **Date:** _____

Will member be utilizing lipid-lowering lifestyle interventions, including exercise and a low fat, low cholesterol diet?
☐ **Yes** ☐ **No**

Extreme Risk – Does the member have any of the following:

1. Progressive ASCVD, including unstable angina, that persists after achieving an LDL-C <70 mg/dL ☐ Yes ☐ No
2. Established clinical cardiovascular disease with diabetes, stage 3 or 4 chronic kidney disease (CKD), or heterozygous familial hypercholesterolemia (HeFH) ☐ Yes ☐ No

A history of premature ASCVD (<55 years of age for males, <65 for females) ☐ Yes ☐ No

☐ **Heterozygous Familial hypercholesterolemia (HeFH)**

Has the diagnosis been confirmed as "definite" by one of the following? ☐ Yes ☐ No

☐ Dutch Lipid Network criteria, please list total score and factors contributing to the total:_____

_____

☐ Simon Broome criteria, please list factors leading to definite diagnosis: _____

_____

☐ Previous genetic confirmation of one mutant alleles in the LDLR, Apo-B, PCKS9 or LDLRAP1 gene locus

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PCSK9 INHIBITORS
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

☐ **Homozygous Familial hypercholesterolemia (HoFH)**

Has the diagnosis been confirmed by any of the following (check all that apply)? ☐ Yes ☐ No

- ☐ Untreated LDL-C levels consistent with heterozygous FH in both parents [untreated LDL-C >190mg/dL]
- ☐ Presence of cutaneous or tendon xanthoma before 10 years of age
- ☐ Previous genetic confirmation of two mutant alleles in the LDLR, Apo-B, PCKS9 or LDLRAP1 gene locus

☐ **Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**

Has the patient been diagnosed with one of the following: ☐ Yes ☐ No

- ☐ Acute Coronary Syndrome
- ☐ History of Myocardial Infarction
- ☐ Stable or unstable Angina
- ☐ Other arterial revascularization
- ☐ Stroke
- ☐ Transient Ischemic Attack
- ☐ Peripheral Arterial Disease
- ☐ Coronary revascularization

Will the requested drug be used in combination with other lipid lowering therapy (please specify dose/frequency)?
☐ None ☐ Statin ☐ Zetia (ezetimibe) ☐ Other (please list):_____

_____

If the requested drug will not be used in combination with a statin please explain:

_____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Diagnosis: ☐ Heterozygous FH ☐ Homozygous FH ☐ Clinical ASCVD ☐ Other: _____

Current LDL-C on PCSK9 inhibitor: **Date lab drawn:**

Is there documentation of improvement shown while on PCSK9 inhibitor therapy? ☐ Yes ☐ No

If No, please explain clinical rationale for continued use of a PCSK9 inhibitor in the "supporting information" section

Has the patient been adherent to the PCSK9 inhibitor? ☐ Yes ☐ No

Has the patient been adherent to the adjunct lipid-lowering therapy? ☐ Yes ☐ No

Will the patient continue to take the PCSK9 with lipid-lowering therapy? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date