



Request for Prior Authorization
PCSK9 INHIBITORS

(PLEASE PRINT - ACCURACY IS IMPORTANT)

Form with fields for IA Medicaid Member ID #, Patient name, DOB, Patient address, Provider NPI, Prescriber name, Phone, Prescriber address, Fax, Pharmacy name, Address, Phone, Pharmacy NPI, Pharmacy fax, NDC.

Prior authorization is required for PCSK9 Inhibitors. Payment for non-preferred PCSK9 Inhibitors will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent, when available for the submitted diagnosis. Payment will be considered under the following conditions: 1) Patient is 18 years of age or older (or, for Homozygous Familial Hypercholesterolemia (HoFH), patient is 13 years of age or older); and 2) Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); and 3) Is to be prescribed as an adjunct to a low fat diet; and 4) A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and 5) Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program; and 6) Is prescribed by a lipidologist, cardiologist, or endocrinologist. 7) The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors. 8) Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced. 9) Lost or stolen medication replacement requests will not be authorized. 10) Goal is defined as a 50% reduction in untreated baseline LDL-C. 11) Is prescribed for one of the following diagnoses: Heterozygous Familial Hypercholesterolemia (HeFH), Clinical Atherosclerotic Cardiovascular Disease (ASCVD), or HoFH. The required trials (excluding the statin trial) may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Quantity Limits:

Praluent/Repatha for HeFH or ASCVD: One syringe/pen/autoinjector per fill (requires refill every 14 days)
Repatha for HoFH only: One three-pack per month

Initial Requests (please see below for renewal requests):

HeFH or ASCVD Drug and Dose Requested:

Preferred: [] Praluent 75mg every 2 weeks for 8 weeks (4 doses)
Non-Preferred: [] Repatha 140mg every 2 weeks for 8 weeks (4 doses)

HoFH Drug and Dose Requested:

[] Repatha 420mg (3x140mg autoinjectors) every month for 3 months

Is patient on a low fat diet: [] Yes [] No

Has patient experienced >= 50% reduction in untreated baseline LDL-C with current therapies?

[] Yes [] No

Attach baseline (prior to pharmacologic therapy) and current lipid profiles.

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Statin to be used as adjunct to PCSK9 inhibitor: _____ **Dose:** _____

Has patient been counseled on importance of abstinence from tobacco? Yes No

Is patient a current smoker or tobacco user: Yes No

If yes, has patient been encouraged to enroll in smoking cessation program? Yes No

Prescriber Specialty: Lipidologist Cardiologist Endocrinologist Other: _____

Prescriber and dispensing pharmacy will educate patient on proper storage and administration?

Yes No

Heterozygous Familial Hypercholesterolemia (HeFH)

- 1) Total cholesterol > 290mg/dL or LDL-C > 190mg.dL; *and*
 - a) Presence of tendon xanthomas; *or*
 - b) In first or second degree relative, one of the following: documented tendon xanthomas, MI at age ≤ 60 years, or total cholesterol > 290mg/dL; *or*
 - c) Confirmation of diagnosis by gene or receptor testing (attach results); *and*
- 2) Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications.

Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), plus ezetimide (Zetia) 10mg daily, plus cholestyramine daily.

Total cholesterol: _____ **Date obtained:** _____

LDL-C: _____ **Date obtained:** _____

Presence of tendon xanthomas: Yes No

Any of the following present in first degree relative:

Documented tendon xanthomas MI at age ≤ 60 years Total cholesterol > 290mg/dL

Diagnosis confirmed by gene or receptor testing? Yes (attach results) No

Statin 1 trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Statin 2 trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Plus concurrent ezetimibe (Zetia) trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Plus concurrent cholestyramine trial:

Drug name & dose: _____ Trial dates: _____

Failure reason: _____

Medical or contraindication reason to override trial requirements: _____

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Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

- 1) History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; *and*
- 2) Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications.

Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), plus ezetimide (Zetia) 10mg daily, plus cholestyramine daily.

History of any of the following: MI Angina
 Coronary or other arterial revascularization Stroke TIA PVD of atherosclerotic origin

Statin 1 trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Statin 2 trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Plus concurrent ezetimibe (Zetia) trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Plus concurrent cholestyramine trial:

Drug name & dose: _____ Trial dates: _____

Failure reason: _____

Medical or contraindication reason to override trial requirements: _____

Homozygous Familial Hypercholesterolemia (HoFH) – Repatha only

- 1) Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; or
- 2) Confirmation of diagnosis by gene or receptor testing (attach results); and 3) Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications.

Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), plus ezetimide (Zetia) 10mg daily, plus cholestyramine daily.

Total cholesterol: _____ Date obtained: _____

LDL-C: _____ Date obtained: _____

Triglycerides within reference range? Yes No (attach results)

Diagnosis confirmed by gene or receptor testing? Yes (attach results) No

Statin 1 trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Statin 2 trial:

Dose: _____ Trial dates: _____

Failure reason: _____

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PCSK9 INHIBITORS**
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Plus concurrent ezetimibe (Zetia) trial:

Dose: _____ Trial dates: _____

Failure reason: _____

Plus concurrent cholestyramine trial:

Drug name & dose: _____ Trial dates: _____

Failure reason: _____

Medical or contraindication reason to override trial requirements: _____

Renewal Requests:

HeFH or ASCVD (Praluent or Repatha)

Lipid profile required at week 8, week 24, and every 6 months thereafter (attach results).

Yes Most recent date obtained: _____ LDL-C: _____ No

Preferred: Praluent:

- LDL-C at goal – continue therapy at 75mg every 2 weeks for 24 weeks
- LDL-C not at goal – increase dose to 150mg every 2 weeks for 8 weeks (4 doses) and repeat LDL-C in 8 weeks
 - If repeat LDL-C at goal – continue therapy at 150mg every 2 weeks for 24 weeks
 - If repeat LDL-C not at goal – discontinue treatment

Non-Preferred: Repatha:

- LDL-C at goal – continue therapy at 140mg every 2 weeks for 24 weeks
- LDL-C not at goal – discontinue treatment

Patient continues therapy with a maximally tolerated statin dose and remains at goal? Yes No

Current Statin: Drug name: _____ Dose: _____

Patient has continued compliance with a low fat diet? Yes No

HoFH (Repatha only)

Lipid profile required after 3 months (third dose) and every 6 months thereafter (attach results).

Yes Most recent date obtained: _____ LDL-C: _____ No

- LDL-C at goal – continue therapy at 420mg every month for 6 months
- LDL-C not at goal – discontinue treatment

Patient continues therapy with a maximally tolerated statin dose and remains at goal? Yes No

Patient has continued compliance with a low fat diet? Yes No

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission
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IMPORTANT NOTE: In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.