Iowa Department of Human Services

Request for Prior Authorization
PCSK9 INHIBITORS

FAX Completed Form To
1 (800) 574-2515

Provider Help Desk
1 (877) 776-1567

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
Pharmacy NPI	Pharmacy fax	NDC

Prior authorization is required for PCSK9 Inhibitors. Payment for a non-preferred PCSK9 Inhibitor will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions: 1) Patient meets the FDA approved age for indication; and 2) Dosing follows the FDA approved dose for the submitted diagnosis; and 3) 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 4) Is to be prescribed as an adjunct to a low fat diet; and 5) A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and 6) 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 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), Primary Hyperlipidemia (not associated with ASCVD or HeFH), or HoFH. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Initial requests will be approved for 6 months. Additional requests will be considered under the following conditions: 1) Documentation of positive clinical response to PCSK9 inhibitor therapy (current LDL-C lab provided); and 2) Patient continues therapy with a maximally tolerated statin; and 3) Patient has continued compliance with a low-fat diet.

Preferred

☐ Praluent ☐ Repatha

Strength	Dosage Instructions	Quantity	Days Supply

Initial Requests (please see below for renewal requests):

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.

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

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

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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 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 one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80 mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.

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

High or Medium- Intensity Statin trial:

Dose:_____ Trial dates:_____

Failure reason:_____

Rationale for medium-intensity statin trial:_____

Plus concurrent ezetimibe trial:

Dose:_____ Trial dates:_____

Failure reason:_____

Medical or contraindication reason to override trial requirements:_____

_____

☐ **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 one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80 mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.

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

High or Medium-Intensity Statin trial:

Dose:_____ Trial dates:_____

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Failure reason:_____

Rationale for medium-intensity statin trial:_____

Plus concurrent ezetimibe trial:

Dose:_____ Trial dates:_____

Failure reason:_____

Medical or contraindication reason to override trial requirements:_____

_____

☐ **Primary Hyperlipidemia (not associated with ASCVD or HeFH)**

1) Baseline LDL-C ≥ 190 mg/dL; and

2) Unable to reach goal LDL-C < 100 mg/dL while on high-intensity statin therapy (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80 mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.

LDL-C:_____ Date obtained:_____

High or Medium- Intensity Statin trial:

Dose:_____ Trial dates:_____

Failure reason:_____

Rationale for medium-intensity statin trial:_____

Plus concurrent ezetimibe trial:

Dose:_____ Trial dates:_____

Failure reason:_____

Medical or contraindication reason to override trial requirements:_____

_____

☐ **Homozygous Familial Hypercholesterolemia (HoFH)**

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 one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80 mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.

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

High or Medium-Intensity Statin trial:

Dose:_____ Trial dates:_____

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Failure reason:_____

Rationale for medium-intensity statin trial:_____

Plus concurrent ezetimibe (Zetia) trial:

Dose:_____ Trial dates:_____

Failure reason:_____

Medical or contraindication reason to override trial requirements:_____

_____

Renewal Requests:

Patient continues therapy with a maximally tolerated statin? ☐ Yes ☐ No

Current Statin: Drug name:_____ Dose:_____

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

Documentation of positive clinical response to PCSK9 Inhibitor therapy (provide current LDL-C lab):

_____

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission

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.*