OPTIMA HEALTH COMMUNITY CARE
AND
OPTIMA FAMILY CARE
(MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct**. Incomplete form will delay authorization process**.

Drug Requested: Proprotein Convertase Subtilisin Kexin Type (PCSK9) (Non-Preferred)

DRUG INFORMATON: Complete information below or authorization process will be delayed.

Drug Form/Strength: _____

Dosage Schedule: _____ **Length of Therapy**: _____

CLINICAL CRITERIA: The following criteria **must** be met to qualify to ensure authorization will **NOT** be delayed.

Specialty: Is the drug prescribed by or in consultation with a specialist?

❑ Cardiologists	❑ Lipidologists
❑ Endocrinologists	❑ Other: _____

1. Indications the drug is being prescribed for?
   - ❑ Homozygous familial hypercholesterolemia (HoFH)
   - ❑ Heterozygous familial hypercholesterolemia (HeFH)
   - ❑ Clinical atherosclerotic cardiovascular disease (ASCVD) or history of a cardiovascular event without homozygous/heterozygous familial hypercholesterolemia
   - ❑ Other: _____
2. Has the patient been able to achieve target LDL-C levels using other lipid-lowering interventions? ❑ Yes ❑ No
3. Has the patient had prior treatment history with history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) **AND** ezetimibe for at least three continuous months with failure to reach target LDL-C with clinical ASCVD and (70mg/dL for patients 100mg/dL for patients with HeFH and no history of clinical ACVD)? ❑ Yes ❑ No
4. Is this request for a new start or continuation of Praluent™/Repatha™ therapy? ❑ Yes ❑ No
   a. If New start, skip to diagnosis section. ❑ New Start ❑ Continuation
5. Was Praluent™/Repatha™ previously authorized for this patient and they are stable on the medication? If **NO**, skip to diagnosis section. ❑ Yes ❑ No
6. How long has the patient been receiving treatment with Praluent™/Repatha™?
   a. 3 to 5 months (or first renewal request after initial authorization) ❑
   b. 6 months or more (or second and subsequent renewal requests) ❑

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7. Has the patient achieved an at least 30% reduction in LDL-C since the beginning of treatment with Praluent™/Repatha™? **ACTION REQUIRED: If YES, please attach clinical notes and laboratory results that support an at least 30% reduction in LDL-C after initiation of Praluent™/Repatha™ therapy.** ❑ Yes ❑ No
8. Does the patient continue to receive benefit from Praluent™/Repatha™? **ACTION REQUIRED: If YES, please attach clinical notes and laboratory results that support continued benefit of Praluent™/Repatha™ therapy.** ❑ Yes ❑ No
9. The patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following: ❑ Yes ❑ No
   a. Muscle symptoms resolved after discontinuation of statin; **AND**
   b. Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
   c. Muscle symptoms occurred after switching to an alternative statin; **AND**
   d. Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
   e. The patient has been diagnosed with statin-induced rhabdomyolysis

If YES to any, give details: _____

_____

_____

DIAGNOSIS AND LAB VALUES FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH)

10. Has genetic testing confirmed the presence of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus? **ACTION REQUIRED: If YES, please attach a copy of genetic testing result**. ❑ Yes ❑ No
11. Has the diagnosis of HoFH been confirmed by ANY of the following? **ACTION REQUIRED**: **Please indicate below and provide a copy of the laboratory report with LDL-C level at time of diagnosis and other documentation supporting the presence of xanthoma or family history of HoFH (e.g., chart notes, medical records).** ❑ Yes ❑ No
    - ❑ Untreated LDL-C > 500mg/dL **AND** cutaneous or tendon xanthoma before age 10 years
    - ❑ Untreated LDL-C > 500mg/dL AND untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
    - ❑ Treated LDL-C ≥ 300mg/dL **AND** cutaneous or tendon xanthoma before age 10 years
    - ❑ Treated LDL-C ≥ 300mg/dL **AND** untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
    - ❑ No/none of the above

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12. Does the patient have a history of clinical atherosclerotic cardiovascular disease (ASCVD) or a cardiovascular event listed below? ❑ Yes ❑ No

    ❑ Acute coronary syndromes ❑ Myocardial infarction ❑ Stable or unstable angina

    ❑ Stroke of presumed atherosclerotic origin ❑ Transient ischemic attack (TIA)

    ❑ Coronary or other arterial revascularization procedure (e.g., PTCA, CABG)

    ❑ Peripheral arterial disease of presumed atherosclerotic origin

    ❑ Findings from CT angiogram or catheterization consistent with clinical ASCVD

13. What is the patient's pre-treatment LDL-C level (i.e., prior to starting PCSK9 inhibitor therapy)?

    _____ mg/dL

14. Is age ≥ 13 years if diagnosed with homozygous familial hypercholesterolemia (HoFH)? ❑ Yes ❑ No

DIAGNOSIS AND LAB VALUES FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH)

15. Does the patient have a definite diagnosis of heterozygous familial hypercholesterolemia (HeFH) as defined by the Dutch Lipid Clinical Network criteria (total score greater than 8)? **ACTION REQUIRED: If YES, please provide a copy of the lab report with LDL-C level at time of diagnosis and other documentation supporting clinical/family history and/or physical findings (e.g., chart notes, medical records).**
    ❑ Yes ❑ No

16. Does the patient have a definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria?
    ❑ Yes ❑ No

Use of samples to initiate therapy does not meet step-edit/preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

REVISED/UPDATED: ~~6/29/2017; 8/31/2017; 8/29/2018;~~ **10/26/2018**