COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

Proprotein convertase subtilisin kexin type 9 (PCSK9) or ATP Citrate Lyase (M4V)

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

MEMBER INFORMATION

Last Name:

First Name:

Medicaid ID Number:

Date of Birth: ___ – ___ – ____

Gender: ☐ **Male** ☐ **Female**

Is the Member Over 18 Years of Age? ☐ **Yes** ☐ **No**

PRESCRIBER INFORMATION

Last Name:

First Name:

NPI Number:

Phone Number: ___ – ___ – ____

Fax Number: ___ – ___ – ____

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

☐ Cardiologists ☐ Lipidologists ☐ Endocrinologists ☐ Other: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

 Revised: 11/25/2020 | Effective: 01/01/2021

Member's Last Name:

Member's First Name:

CRITERIA

1. For what indication(s) is the drug being prescribed? Check all that apply.
   - ☐ To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
   - ☐ As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) to reduce low-density lipoprotein cholesterol (LDL-C).
   - ☐ As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.
   - ☐ The member has had prior treatment 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 **and** is in one of the three groups identified by NLA (i.e., extremely high risk ASCVD members with LDL-C ≥ 70 mg/dL, very high risk atherosclerotic cardiovascular disease [ASCVD] members with LDL-C ≥ 100 mg/dL, and high risk members with LDL-C ≥ 130 mg/dL.
   - ☐ Other: _____
2. Is this request for a new start or continuation of therapy? (If **New Start**, skip to diagnosis section.)
   - ☐ New Start ☐ Continuation
3. Was this drug previously authorized for this member and are they stable on the medication? (If **No**, skip to diagnosis section.)
   - ☐ Yes ☐ No
4. How long has the member been receiving treatment with these medications?
   - ☐ 3 to 5 months (or first renewal request after initial authorization)
   - ☐ 6 months or more (or second and subsequent renewal requests)
5. **For PCSK9S Praluent® or Repatha® therapy only**: Has the member achieved at least a 30% reduction in LDL-C since the beginning of treatment with Praluent® or Repatha®?
   ACTION REQUIRED: If **Yes**, please attach clinical notes and laboratory results that support reduction in LDL-C after initiation of therapy.
   - ☐ Yes ☐ No
6. **For ATP Citrate Lyase (M4V) Nexletol® or Nexlizet™ therapy only**: Has the member achieved at least a 15% to 20% reduction in LDL-C since the beginning of treatment with Nexletol® or Nexlizet™?
   ACTION REQUIRED: If **Yes**, please attach clinical notes and laboratory results that support reduction in LDL-C after initiation of therapy.
   - ☐ Yes ☐ No

(Form continued on next page.)

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Member's Last Name: | **Member's First Name:**

7. Does the member continue to benefit from treatment as measured by either continued decrease in LDL-C levels **or** maintenance of optimum LDL-C levels?
   ACTION REQUIRED: If **Yes**, please attach clinical notes and laboratory results that support continued benefit of Praluent® or Repatha® therapy.
   ☐ Yes ☐ No
8. Is the member unable 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 member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue, and all of the following:
   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 [e.g., polymyalgia rheumatica], steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
   e. The member has been diagnosed with statin-induced rhabdomyolysis

   ☐ Yes ☐ No

   If **Yes** to any, give details: _____

DIAGNOSIS AND LAB VALUES FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH)

9. Has genetic testing confirmed the presence of two 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
10. 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).
    ☐ Untreated LDL-C > 500 mg/dL **and** cutaneous or tendon xanthoma before age 10 years
    ☐ Untreated LDL-C > 500 mg/dL **and** untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
    ☐ Treated LDL-C ≥ 300 mg/dL **and** cutaneous or tendon xanthoma before age 10 years
    ☐ Treated LDL-C ≥ 300 mg/dL **and** untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
    ☐ None of the above

(Form continued on next page.)

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Member's Last Name: | | | | | | | | | | | | |

Member's First Name: | | | | | | | | | | | | |

11. Does the member have a history of clinical ASCVD or a cardiovascular event listed below? Indicate which ones.
    - ☐ Acute coronary syndromes
    - ☐ Myocardial infarction
    - ☐ Stable or unstable angina
    - ☐ Transient ischemic attack (TIA)
    - ☐ Stroke of presumed atherosclerotic origin
    - ☐ Coronary or other arterial revascularization procedure (e.g., percutaneous transluminal coronary angioplasty [PTCA], coronary artery bypass graft [CABG])
    - ☐ Peripheral arterial disease of presumed atherosclerotic origin
    - ☐ Findings from a computerized tomography (CT) angiogram or catheterization consistent with clinical ASCVD
12. What is the member's pre-treatment LDL-C level (i.e., prior to starting PCSK9 or M4V therapy)?

    _____ mg/dL.
13. Is the member diagnosed with homozygous familial hypercholesterolemia (HoFH) and at least 13 years of age?
    ☐ Yes ☐ No

DIAGNOSIS AND LAB VALUES FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH)

14. Does the member have a **definite** diagnosis of heterozygous familial hypercholesterolemia (HeFH) as defined by the Dutch Lipid Clinic Network criteria (total score greater than 8)?
    ACTION REQUIRED: If **Yes**, please provide a copy of the lab repot 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
15. Does the member have a definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria?
    ☐ Yes ☐ No

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the SA process.
Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

The completed form may be: **FAXED TO 800-932-6651**, phoned to 800-932-6648, or mailed to:
Magellan Medicaid Administration / ATTN: MAP
11013 W. Broad Street, Glen Allen, VA 23060

Virginia Medicaid Pharmacy Services Portal: http://www.virginiamedicaidpharmacyservices.com

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