SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Leqvio® (inclisiran) **(J1306) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: SUBQ: Initial: 284 mg as a single injection, again at 3 months, and then every 6 months thereafter

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

❑ Must be prescribed by or in consultation with a Cardiologist, Endocrinologist or Lipid Specialist

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- ❑ Medication will be used as adjunct to low-fat diet
- ❑ Provider has **COMPLETED** Sections I, IIa or IIb (if applicable) and III below

Section I. Diagnoses: (select one below)

❑ Diagnosis: Primary Hyperlipidemia

NOTE: This is not associated with atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH) and may be referred to as combined hyperlipidemia, hypercholesterolemia (pure, primary), dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels.

- ❑ Member must meet **ALL** the following:
  - ❑ Member is 18 years of age or older
  - ❑ Member has a coronary artery calcium or calcification score ≥ 300 Agatston units
  - ❑ Member has a baseline low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL (prior to treatment with antihyperlipidemic therapy)
  - ❑ Member meets **ONE** of the following:
    - ❑ Member meets **ALL** the following:
      - ❑ Member has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product])
      - ❑ Member has tried one high-intensity statin therapy above along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks
      - ❑ Member's LDL-C level after this treatment regimen remains ≥ 100 mg/dL
    - ❑ Member has been determined to be statin intolerant and meets all clinical criteria in section IIb below
- ❑ Provider has completed section III

❑ Diagnosis: Atherosclerotic Cardiovascular Disease

- ❑ Member is 18 years of age or older and has Atherosclerotic Cardiovascular Disease (ASCVD) confirmed by at least **ONE** of the following:
  - ❑ Acute Coronary Syndrome
  - ❑ History of myocardial infarction
  - ❑ Stable or unstable angina
  - ❑ Peripheral arterial disease presumed to be of atherosclerotic origin
  - ❑ Member has undergone coronary or other arterial revascularization procedure in the past
  - ❑ History of Stroke
  - ❑ History of Transient ischemic attack
- ❑ Provider has completed sections IIa or IIb & III

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❑ Diagnosis: Heterozygous familial hypercholesterolemia (HeFH)

- ❑ Member is 10 years of age or older and has heterozygous familial hypercholesterolemia (HeFH) as confirmed by the following:
  - ❑ Member meets **ONE** of the following:
    - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL (prior to treatment with antihyperlipidemic therapy)
    - ❑ Member has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene
    - ❑ Member has been diagnosed with heterozygous familial hypercholesterolemia by meeting **ONE** of the following diagnostic criteria thresholds:
      - ❑ Provider attests member's Dutch Lipid Network criteria score was > 5
      - ❑ Provider attests that Simone Broome criteria met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia
- ❑ Provider has completed sections IIa or IIb & III

❑ Diagnosis: Homozygous familial hypercholesterolemia (HoFH)

- ❑ Member is 10 years of age or older and has homozygous familial hypercholesterolemia (HoFH) as confirmed by the following:
  - ❑ Member meets **ONE** of the following:
    - ❑ Member has genetic confirmation of two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 gene locus
    - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) level > 500 mg/dL **AND** meets **ONE** of the following:
      - ❑ Member has had clinical manifestations of homozygous familial hypercholesterolemia before the age of 10 (e.g., xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma)
      - ❑ Members parents both have had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (i.e., both parents have had an untreated LDL-C level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL
    - ❑ Member has a treated LDL-C level ≥ 300 mg/dL **AND** meets **ONE** of the following:
      - ❑ Member has had clinical manifestations of homozygous familial hypercholesterolemia before the age of 10 (e.g., xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma)
      - ❑ Members parents both have had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (i.e., both parents have had an untreated LDL-C level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL
- ❑ Provider has completed sections IIa or IIb & III

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Section IIa. FOR ALL DIAGNOSIS: Skip to Section IIb **IF** member is unable to tolerate statin therapy

- ❑ Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks:
  - ❑ High intensity statin therapy with atorvastatin (generic Lipitor) ≥ 40 mg daily
  - ❑ High intensity statin therapy rosuvastatin (generic Crestor) ≥ 20 mg daily
  - ❑ Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
  - ❑ Low intensity statin therapy (member unable to tolerate moderate intensity therapy
- ❑ Member must meet **ONE** of the following:
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 55 mg/dL in those with a diagnosis of ASCVD with Type 2 Diabetes Mellitus
- ❑ Please provide member's LDL levels below:

  LDL baseline: _____**LDL post-treatment:** _____

Section IIb. FOR ALL DIAGNOSIS: Contraindication to statin therapy

- Select below if the member is unable to tolerate low, moderate, and high intensity statin therapy as evidenced by intolerable and persistent symptoms to **TWO** different statins (i.e., more than 2 weeks); Please provide previously attempted statin name, strength & therapy initiation date below:

Drug Name: _____ **Strength:** _____ **Date started:** _____

Drug Name: _____ **Strength:** _____ **Date started:** _____

- ❑ Member is unable to tolerate statin therapy due to the occurrence of at least **ONE** of the following symptoms:
  - ❑ Myalgia (muscle symptoms without CK elevations)
  - ❑ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)
  - ❑ Member has experienced rhabdomyolysis or muscle symptoms with CK elevations > 10 times upper limit of normal
  - ❑ Member has a labeled contraindication to **ALL** statins as documented in medical records
- ❑ Re-initiation of statin therapy has been attempted and failed

Section III. Prerequisite Therapy:

- ❑ Member must meet **ONE** of the following:
  - ❑ Member has tried and failed at least 90 days of therapy with Repatha® **(verified by claims, chart notes, and/or labs)**
  - ❑ Member has a contraindication or intolerance to Repatha® **(verified by chart notes and/or labs)**

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider attests member has experienced a positive clinical response to PCSK9 therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels) and continues to have need of requested medication

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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.****