HIGHMARK WHOLECARE

Updated: 03/2022
PARP Approved:03/2022

Prior Authorization Criteria

Leqvio (inclisiran)

All requests for Leqvio (inclisiran) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests the following criteria must be met in addition to the diagnosis specific criteria below:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- The prescribed medication is age appropriate based upon FDA-approved labeling.
- The medication is being prescribed by or in consultation with a qualified specialist (e.g. cardiologist, endocrinologist, lipid specialist)
- Documentation of lipid panel results at baseline (pre-treatment), current LDL level with treatment for at least one month, and goal LDL level are provided.
- Pertaining to the member's current lipid-lowering treatment regimen:
    - The member has had an adequate trial of at least two statins at the maximally tolerated dose or documentation of intolerance or contraindication to statin therapy
    - The member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 3 months unless the member is new to the plan. If new to plan, documentation from the prescribing physician and/or the patient's pharmacy demonstrates adherence to therapy over the past 3 months
    - Documented therapeutic failure, intolerance, or contraindication to both of the following:
        - ezetimibe in combination with statin therapy (unless intolerance or contraindication to statin therapy) for at least 8 weeks
        - A PCSK9 inhibitor for at least 3 months (PCSK9 inhibitors require a prior authorization)
    - Documentation, within the past month, that the member's LDL-C is >100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD)) or >55mg/dl (with extreme risk designation) while adherent to a maximally tolerated dose of statin therapy in combination with ezetimibe
    - The member will be taking a Leqvio (inclisiran) concurrently with a maximally tolerated statin (if statin tolerant)

Coverage may be provided with a diagnosis of **heterozygous familial hypercholesterolemia (HeFH)** and the following criteria is met:

- Documentation of HeFH confirmed as **definite** with one of the following:
    - A score of > 8 using the Dutch Lipid Clinic Network criteria (all points added to calculate the total score must be documented)
    - The Simon-Broome criteria. Clinical evidence and laboratory results must be provided to support the diagnosis

- Genetic testing confirming a point mutation in LDLR, APOB, PCSK9, or LDLRAP1 genes
- An untreated low-density lipoprotein cholesterol (LDL-C) level ≥190mg/dl (5 mmol/L) and a family history of elevated cholesterol or premature coronary artery disease (CAD)

Coverage may be provided with a diagnosis of **Clinical Atherosclerotic Cardiovascular Disease (ASCVD) requiring additional lowering of LDL-cholesterol** and the following criteria is met:

- Documentation of a diagnosis of clinical atherosclerotic cardiovascular disease defined as one of the following:
  - Acute Coronary Syndrome
  - History of Myocardial Infarction
  - Stable or unstable Angina
  - Coronary revascularization
  - Other arterial revascularization
  - Stroke
  - Transient Ischemic Attack
  - Peripheral Arterial Disease
  - Other documented atherosclerotic disease may be considered if documentation provided
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation the member is adherent to statin treatment in combination with Leqvio (inclisiran) (if statin tolerant)
  - LDL-C drawn after treatment initiation demonstrates improvement while on maximized therapy
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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LEQVIO (INCLISIRAN)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Baseline LDL-C: _____ Date:_____
Current LDL-C: _____ Date:_____
Goal LDL-C: _____
% Reduction in LDL-C required to reach goal: _____ Date: _____

Extreme Risk – Does the member have any of the following:

1. Progressive ASCVD, including unstable angina, that persists after achieving an LDL-C <70 mg/dL ☐ Yes ☐ No
2. Established clinical cardiovascular disease with diabetes, stage 3 or 4 chronic kidney disease (CKD), or heterozygous familial hypercholesterolemia (HeFH) ☐ Yes ☐ No
3. A history of premature ASCVD (<55 years of age for males, <65 for females) ☐ Yes ☐ No

☐ **Heterozygous Familial hypercholesterolemia (HeFH)**

Has the diagnosis been confirmed as "definite" by one of the following? ☐ Yes ☐ No

☐ Dutch Lipid Network criteria, please list total score and factors contributing to the total:_____

_____

☐ Simon Broome criteria, please list factors leading to definite diagnosis: _____

_____

☐ Previous genetic confirmation of one mutant alleles in the LDLR, Apo-B, PCKS9 or LDLRAP1 gene locus

☐ An untreated low-density lipoprotein cholesterol (LDL-C) level 190mg/dl (5 mmol/L) and a family history of elevated cholesterol or premature coronary artery disease (CAD)

☐ **Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**

Has the patient been diagnosed with one of the following: ☐ Yes ☐ No

- ☐ Acute Coronary Syndrome
- ☐ History of Myocardial Infarction
- ☐ Stable or unstable Angina
- ☐ Other arterial revascularization
- ☐ Stroke
- ☐ Transient Ischemic Attack
- ☐ Peripheral Arterial Disease
- ☐ Coronary revascularization
- ☐ Other vascular disease, please attach documentation

Will the requested drug be used in combination with a statin? ☐ Yes ☐ No

If no please explain why: _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No

Please describe:

Diagnosis: ☐ Heterozygous FH ☐ Clinical ASCVD ☐ Other: _____

Current LDL-C on Leqvio (inclisiran): _____ **Date lab drawn:** _____

Is the member continuing to take a statin in combination with Leqvio (inclisiran) ? ☐ Yes ☐ No (statin intolerant) ☐ No (other reason please provide: _____)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date