Updated: 01/2025
DMMA Approved: 01/2025

Request for Prior Authorization for PCSK9 inhibitors, Leqvio (inclisiran), and Evkeeza (evinacumab-dgnb)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for PCSK9 inhibitors, Leqvio (inclisiran), and Evkeeza (evinacumab-dgnb) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

PCSK9 inhibitors, Leqvio (inclisiran), and Evkeeza (evinacumab-dgnb) Prior Authorization Criteria:

For all requests for PCSK9 PCSK9 inhibitors, Leqvio (inclisiran), and Evkeeza (evinacumab-dgnb) all of the following criteria must be met:

- 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.
- For a non-preferred PCSK9, the member has had a trial and failure of a preferred PCSK9 or submitted a clinical reason for not having a trial of a preferred agent if applicable
- The medication is being prescribed by or in consultation with a qualified specialist (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.
- The member will not be taking the requested PCSK9 inhibitor concurrently with another PCSK9 inhibitor
- 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 ezetimibe in combination with statin therapy (unless intolerance or contraindication to statin therapy) for at least 8 weeks
    - If the request is for Leqvio (inclisiran) or Evkeeza evinacumab-dgnb) documentation of therapeutic failure, intolerance, or contraindication to a PCSK9 inhibitor for at least 3 months.
    - 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 the requested medication concurrently with a maximally tolerated statin (if statin tolerant)

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Coverage may be provided with a diagnosis of **heterozygous familial hypercholesterolemia (HeFH)** and the following criteria is met (**PCSK9 and Leqvio)**:

- 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

Coverage may be provided with a diagnosis of **Clinical Atherosclerotic Cardiovascular Disease (ASCVD) requiring additional lowering of LDL-cholesterol OR for reduction of the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease** and the following criteria is met (**PCSK9 and Leqvio)**:

- 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

Coverage may be provided with a diagnosis of **treatment of homozygous familial hypercholesterolemia (HoFH)** and the following criteria is met **(PCSK9 and Evkeeza)**:

- Documented diagnosis of HoFH (clinical documentation and laboratory results must be provided to support the diagnosis) confirmed by one of the following:
  - An untreated LDL-C >500 mg/dL or a treated LDL-C ≥ 300 mg/dL with one of the following:
    - Presence of cutaneous or tendon xanthoma before 10 years of age
    - Both parents have documented elevated LDL-C before lipid-lowering treatment (pre-treatment) consistent with a diagnosis of heterozygous familial hypercholesterolemia [e.g. untreated LDL-C >190 mg/dL]
  - Previous history of genetic confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus

- Repatha (evolocumab) will not be used concomitantly with Juxtapid (lomitapide) or Kynamro (mipomersen)

Coverage may be provided with a diagnosis of **primary hyperlipidemia (**other than those mentioned above) **(PCSK9 and Leqvio)**

- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Documentation the member is adherent to statin treatment in combination with the requested therapy (if statin tolerant)
  - LDL-C drawn after treatment initiation demonstrates improvement while on 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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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PCSK9 INHIBITORS, LEQVIO (INCLISIRAN), AND EVKEEZA (EVINACUMAB-DGNB) 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 Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

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

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a 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)

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

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
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PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)- continued

☐ **Homozygous Familial hypercholesterolemia (HoFH)**
Has the diagnosis been confirmed by any of the following (check all that apply)? ☐ Yes ☐ No
- ☐ Untreated LDL-C levels consistent with heterozygous FH in both parents [untreated LDL-C >190mg/dL]
- ☐ Presence of cutaneous or tendon xanthoma before 10 years of age
- ☐ Previous genetic confirmation of two mutant alleles in the LDLR, Apo-B, PCKS9 or LDLRAP1 gene locus

☐ **Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**
Has the patient been diagnosed with one of the following: ☐ Yes ☐ No
- ☐ Acute Coronary Syndrome
- ☐ Stable or unstable Angina
- ☐ Stroke
- ☐ Peripheral Arterial Disease
- ☐ Other vascular disease, please attach documentation
- ☐ History of Myocardial Infarction
- ☐ Other arterial revascularization
- ☐ Transient Ischemic Attack
- ☐ Coronary revascularization

☐ **Other Primary Hyperlipidemia**

Will the requested drug be used in combination with other lipid lowering therapy (please specify dose/frequency)?
☐ None ☐ Statin ☐ Zetia (ezetimibe) ☐ Other (please list):_____

If the requested drug will not be used in combination with a statin please explain:

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Diagnosis: ☐ Heterozygous FH ☐ Homozygous FH ☐ Clinical ASCVD ☐ Other: _____
Current LDL-C on therapy: _____ **Date lab drawn:** _____

Is there documentation of improvement shown while on therapy? ☐ Yes ☐ No
If No, please explain clinical rationale for continued use of therapy in the "supporting information" section

Has the patient been adherent to the adjunct lipid-lowering therapy? ☐ Yes ☐ No
Will the patient continue to take the requested therapy with lipid-lowering therapy? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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