ATRIO HEALTH PLANS

Dyslipidemia Step Therapy

Leqvio (inclisiran) J1306 is non-preferred Preferred products are Part D PCSK9 inhibitors (Praluent, Repatha, No PA required)

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:

- ☐ Patient has Heterozygous Familial Hypercholesterolemia (HeFH) verified by:
  - ☐ Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene OR
  - ☐ WHO/Dutch Lipid Clinic Network criteria with score of greater than eight points; OR
- ☐ History of clinical atherosclerotic cardiovascular disease (ASCVD) including one or more of the following:
  - ☐ Acute coronary syndrome;
  - ☐ Coronary artery disease (CAD);
  - ☐ History of myocardial infarction (MI);
  - ☐ Stable or unstable angina;
  - ☐ Coronary or other arterial revascularization;
  - ☐ Stroke;

☐ Transient ischemic attack (TIA);

☐ Peripheral arterial disease (PAD);

☐ Patient meets ONE of the following:

☐ Patient is on high intensity statin therapy or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher); OR

☐ Patient is statin intolerant based on ONE of the following:

☐ Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by adverse effects associated with statin therapy that resolve or improve with dose reduction or discontinuation; OR

☐ Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin; OR

☐ Patient has a contraindication for statin therapy including but not limited to active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy; AND

☐ Patient is on ezetimibe in addition to statin therapy (only applies to Patients on statin therapy);

☐ Patient has achieved suboptimal lipid lowering response despite at least 90 days of compliant lipid lowering therapy and lifestyle modifications as defined:

☐ For Patients where initial LDL-C is known:

☐ Less than 50% reduction in LDL-C; OR

☐ For Patients where initial LDL-C is unknown:

☐ ASCVD and LDL-C remains greater than or equal to 70 mg/dL; OR

☐ No history of ASCVD and LDL-C remains greater than or equal to 100 mg/dL.

- **Leqvio (inclisiran) may NOT be approved when used in combination with Praluent or Repatha**

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient continues to use in combination with maximally tolerated statin therapy (unless contraindication or patient is statin intolerant); AND

☐ Patient has achieved LDL-C reduction.

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Dyslipidemia Therapy PA

Drug Name(s):

LEQVIO	**INCLISIRAN**
PRALUENT	**ALICROCUMAB**
REPATHA	**EVOLOCUMAB**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 12 months

FDA Indications:

Leqvio

- Hyperlipidemia, Primary; including heterozygous familial hypercholesterolemia; Adjunct

Off-Label Uses:

N/A

Step Therapy Indications:

Praluent, Repatha

- Disorder of cardiovascular system, In patients with established cardiovascular disease; Prophylaxis
- Familial hypercholesterolemia - homozygous, Adjunct to LDL-C-Lowering Therapies
- Primary heterozygous familial hypercholesterolemia, Alone or in combination with other lipid-lowering therapies
- Primary heterozygous familial hypercholesterolemia, In combination with other LDL-C-lowering therapies (Repatha Only)
- Primary hypercholesterolemia, Alone or in combination with other lipid-lowering therapies

Age Restrictions:

N/A

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/34F37E/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/110ABE/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933501&contentSetId=100&title=Inclisiran&servicesTitle=Inclisiran&brandName=Leqvio&UserMdxSearchTerm=Leqvio&=null#

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