Leqvio (inclisiran)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Approval: 6 months Continuation Approval: 1 year

Medications	Quantity Limit
Leqvio (inclisiran) 284 mg/1.5 mL prefilled syringe	1 syringe per 6 months*

*Initiation of therapy: May approve one additional prefilled syringe within the first six months of initiating therapy.

APPROVAL CRITERIA

Initial requests for Leqvio (inclisiran) may be approved when the following criteria are met:

I. Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response. Medication samples/coupons/discount cards are excluded from consideration as a trial;

AND

II. Individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
   A. Individual has Heterozygous Familial Hypercholesterolemia (HeFH) verified by (Singh 2015; WHO 1999):
      1. Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; **OR**
      2. WHO/Dutch Lipid Clinic Network criteria with score of greater than eight points;

   OR

   B. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD) including **one or more** of the following (AHA/ACC 2018):
      1. Acute coronary syndrome;
      2. Coronary artery disease (CAD);
      3. History of myocardial infarction (MI);
      4. Stable or unstable angina;
      5. Coronary or other arterial revascularization;
      6. Stroke;
      7. Transient ischemic attack (TIA);
      8. Peripheral arterial disease (PAD);

OR

   C. Individual has primary hyperlipidemia;

AND

III. Individual meets one of the following:
   A. Individual 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) (AHA/ACC 2018);

   OR

   B. Individual is statin intolerant based on one of the following:
      1. 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 (NLA 2022); **OR**
      2. Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin;

   OR

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

AND

III. Individual has achieved suboptimal lipid lowering response despite at least 90 days of compliant lipid lowering therapy and lifestyle modifications as defined (AHA/ACC 2018):
   A. For individuals where initial LDL-C is known:
      1. Less than 50% reduction in LDL-C; **OR**
   B. For individuals where initial LDL-C is unknown:
      1. ASCVD and LDL-C remains greater than or equal to 70 mg/dL; **OR**
      2. No history of ASCVD and LDL-C remains greater than or equal to 100 mg/dL.

Continuation requests for Leqvio (inclisiran) may be approved when the following criteria are met:

I. Individual continues to use in combination with maximally tolerated statin therapy (unless contraindication or individual is statin intolerant); **AND**
II. Confirmation of LDL-C reduction has been provided.

Leqvio (inclisiran) may not be approved for the following:

I. In combination with Praluent or Repatha; **OR**
II. When the above criteria are not met and for all other indications.

Key References:

1. Cheeley MK, Saseen JJ, Agarwala A, et. al. NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. *J Clin Lipidol*. 2022. https://doi.org/10.1016/j.jacl.2022.05.068.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 13, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ ADA/AGS/APhA/ASPC/NLA/ PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019;73:e285–350.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. *Curr Atheroscler Rep*. 2015; 17(2):482.
7. World Health Organization. Familial hypercholesterolemia—report of a second WHO Consultation. Geneva, Switzerland: World Health Organization, 1999. Available at: http://whqlibdoc.who.int/hq/1999/WHO_HGN_FH_CONS_99.2.pdf?ua=1. Accessed: July 17, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.