Clinical Policy Title:	inclisiran
Policy Number:	RxA.773
Drug(s) Applied:	Leqvio®
Original Policy Date:	04/05/2022
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Heterozygous Familial Hypercholesterolemia and Atherosclerotic Cardiovascular Disease (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. ASCVD as evidenced by a history of any one of the following conditions (i-vii):
      i. Myocardial infarction;
      ii. Acute coronary syndromes;
      iii. Coronary artery disease;
      iv. Stable or unstable angina;
      v. Coronary or other arterial revascularization;
      vi. Stroke;
      vii. Transient ischemic attack;
      viii. Peripheral arterial disease;
   b. HeFH as confirmed by both of the following (i and ii):
      i. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was ≥ 190 mg/dL;
      ii. HeFH diagnosis is confirmed by one of the following (a or b):
         a) World Health Organization (WHO)/Dutch Lipid Network Criteria with score of > 8 points;
         b) Diagnosis per Simon Broome criteria;
2. Member meets one of the following (a, b, or c);
   a. Member has taken a statin for at least 4 months and has failed to achieve LDL-C goal;
   b. Member has inability to tolerate at least two high-intensity statins due to adverse events;
   c. Statins are contraindicated;
3. Member has been adherent to ezetimibe used concomitantly with a statin for at least 4 months unless contraindicated;
4. Documentation of recent (within the last 60 days) LDL-C of one of the following (a or b):
   a. If member has ASCVD (i or ii):
      i. ≥ 70 mg/dL;
      ii. ≥ 55 mg/dL, and member is at very high risk;
   b. If member has HeFH: ≥ 100 mg/dL;
5. Treatment plan does not include coadministration with Juxtapid®, Repatha®, or Praluent®.

Approval Duration

All Lines of Business (except Medicare): 9 months

II. Continued Therapy Approval

A. Heterozygous Familial Hypercholesterolemia and Atherosclerotic Cardiovascular Disease (must meet all):
1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. If member is statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;
3. Member is responding positively to therapy as evidenced by lab results within the last 3 months showing an LDL-C reduction since initiation of Leqvio® therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Turgeon RD, Barry AR, Pearson GJ. Familial hypercholesterolemia. Can Fam Physician. 2016;62(1):32-37. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4721838/. Accessed August 28,2024.
2. Lambert CT, Sandesara P, Isiadinso I, et al. Current treatment of familial hypercholesterolaemia. Eur Cardiol. 2014;9(2):76-81. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6159444/. Accessed August 28,2024.
3. Fh diagnosis, management and family screening. The Family Heart Foundation. Available at: https://thefhfoundation.org/diagnostic-criteria-for-familia-hypercholesterolemia2. Accessed August 28,2024.
4. Chou R, Dana T, Blazina I, et al. Table 1, statin dosing and acc/aha classification of intensity. Available at: https://www.ncbi.nlm.nih.gov/books/NBK396417/table/ch1.t1/. Accessed August 28,2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/05/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1.b.i: Updated to include new lab values criteria Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was ≥ 190 mg/dL. 2. Initial Approval Criteria, I.A.1.b.ii: Updated to include diagnosis criteria HeFH diagnosis is confirmed by one of the following (a or b). 3. Initial Approval Criteria, I.A.6: Updated to include new documentation criteria Documentation of recent (within the last 60 days) LDL-C of one of the following (a or b): a. If member has ASCVD (i or ii): i. ≥ 70 mg/dL; ii. ≥ 55 mg/dL, and member is at very high risk; b. If member has HeFH: ≥ 100 mg/dL; 4. References were reviewed and updated.	06/01/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period.	8/28/2024	9/13/2024

5. Updated approval duration verbiage. 6. References were reviewed and updated.		