

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. \geq 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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

© 2024 RxAdvance Corporation. All rights reserved. This policy contains the confidential and proprietary information of RxAdvance. Unauthorized reproduction, distribution, modification, display, storage, transmission, or use of this policy or any information contained herein is strictly prohibited.



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: 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. 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). 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):	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

Revised 8/2024 Page 2 of 3 v 2.0.01.1



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