Medical Policy

Leqvio® (inclisiran)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-104
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

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If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov *for additional information.*

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Leqvio® (inclisiran) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Leqvio will be provided for 6 months for initial approval and may be renewed every 12 months.

- Max Units (per dose and over time): 284 mg at months 0, 3 and then every 6 months

Initial

A. Patient is 18 years of age or older; **AND**
B. Patient is not on concomitant PCSK9- or ANGPTL3- inhibitors (i.e., alirocumab, evolocumab, evinacumab, etc.); **AND**
C. Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**

Heterozygous Familial Hypercholesterolemia (HeFH)/Atherosclerotic Cardiovascular Disease (ASCVD)

A. Therapy will be used in conjunction with diet alone or in conjunction with other lipid-lowering therapies unless the patient is unable to tolerate (e.g., statins, ezetimibe); **AND**
    a. Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) (i.e., myocardial infarction, non-hemorrhagic stroke, or peripheral arterial disease) or ASCVD risk; **AND**
        i. Patient can be classified into ONE of the following risk factor groups:
            1. Extremely high risk ASCVD (defined as extensive burden of or active ASCVD, or ASCVD with extremely high burden of adverse poorly controlled risk cardiometabolic risk factors including HeFH or severe hypercholesterolemia (SH) with untreated LDL-C >220 mg/dL) with LDL-C >70 mg/dL
            2. Very high risk ASCVD (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with LDL-C >100 mg/dL
            3. High risk ASCVD with LDL-C >130 mg/dL; **AND**
                a. Less extensive ASCVD and well-controlled risk factors; OR
                b. SH with untreated LDL-C >220 mg/dL with poorly controlled risk factors; **AND**
        ii. Patient has a prior treatment history with the highest available dose or maximally-tolerated dose* of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily), unless contraindicated; **AND**
        iii. Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses* of statins prior to the lipid panel demonstrating suboptimal reduction; **OR**
    b. Patient has a diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping OR by patient having a first-degree relative similarly affected or with premature coronary vascular disease (CVD) or with positive genetic testing for a LDL-C raising gene defect (LDL receptor, apoB, or PCSK9); **AND**
        i. Patient has prior treatment history with the highest available age-appropriate dose or maximally-tolerated dose* of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily), unless contraindicated; **AND**
        ii. Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses* of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**

iii. Used as one of the following:
1. For primary prevention (i.e., patients without ASC//VD) and LDL-C ≥100 mg/dL; **OR**
2. For secondary prevention (i.e., patients with ASCVD) and LDL-C ≥70 mg/dL

*If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, a causal relationship must be established between statin use and muscle symptoms.

- Patient has evidence of pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
  - Muscle symptoms resolve after discontinuation of statin; **AND**
  - Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
  - Muscle symptoms occurred after switching to an alternative statin; **AND**
  - Non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease) have been ruled-out; **OR**
- The patient has been diagnosed with rhabdomyolysis associated with statin use
  - The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal [ULN])

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Patient has had a reduction in LDL-C when compared to the baseline labs (prior to initiating Leqvio); **AND**
C. Patient continues to adhere to diet and/or lipid lowering therapy established prior to the original Leqvio approval; **AND**
D. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, etc.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. LEQVIO (inclisiran) injection, for subcutaneous use. Initial U.S. Approval: 2021
   a. LEQVIO injection is a clear, colorless to pale yellow solution, 284 mg/1.5 mL (189 mg/mL) of inclisiran

CODING

Applicable NDC Codes	
00078-1000-xx	Leqvio 284 mg/1.5 mL single-dose pre-filled syringe

Applicable Procedure Code	
J3490	Unclassified drugs

Applicable ICD-10 Codes	
E78.00	Pure Hypercholesterolemia, unspecified
E78.01	Familial hypercholesterolemia
E78.2	Mixed hyperlipidemia
E78.4	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified
I21	Acute myocardial infarction
I21.0	ST elevation (STEMI) myocardial infarction of anterior wall
I21.1	ST elevation (STEMI) myocardial infarction of inferior wall
I21.2	ST elevation (STEMI) myocardial infarction of other sites
I21.9	Acute myocardial infarction, unspecified
I21.A9	Other myocardial infarction type

EVIDENCE BASED REFERENCES

1. Leqvio [package insert]. East Hanover, NJ; Novartis, Inc.; December 2021. Accessed December 2021.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023: Adopted by MA UM Committee – no changes made.
P&T Committee Endorsement	5/24/2022
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024