ALASKA MEDICAID
Prior Authorization Criteria

# Leqvio®
# (Inclisiran)

## FDA INDICATIONS AND USAGE[1]

Leqvio® is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C). The effect of Leqvio® on cardiovascular morbidity and mortality has not been determined

## APPROVAL CRITERIA[1,2,3,4,5,6]

1. Patient's age is to FDA label **AND**;
2. Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist **AND**;
3. Patient has diagnosis of one of the following (a or b):
    a. HeFH, and member meets 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) Family history of myocardial infarction (heart attack) in first-degree relative less than 60 years of age
            b) Family history of myocardial infarction (heart attack) in second-degree relative less than 50 years of age
            c) Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
            d) Family history of familial hypercholesterolemia (HeFH or HoFH) in first- or second-degree relative
            e) Family history of tendinous xanthoma (lipid deposits in tendons) or arcus cornealis (lipid deposits in the outer part of the cornea) in first- or second-degree relative
            f) Patient has genetic mutation in the LDL receptor, ApoB, or PCSK9 gene
            g) Patient has physical signs of HeFH (i.e., tendon xanthomas, corneal arcus and age less than 45 years)
            h) Dutch Lipid Clinic Network diagnostic criteria for familial hypercholesterolemia score is greater than 8 (i.e., definite familial hypercholesterolemia)
            i) Simon Broome diagnostic criteria for familial hypercholesterolemia corresponds to definite familial hypercholesterolemia
    b. Atherosclerotic cardiovascular disease (ASCVD) as confirmed by **one** of the following:
            a) Acute coronary syndromes

   b) History of myocardial infarction
   c) Coronary or other arterial revascularization
   d) Stroke
   e) Transient ischemic attack
   f) Peripheral arterial disease presumed to be of atherosclerotic origin **AND**;
4. Current (within the last 12 months) labs have been submitted indicating LDL lab values
   a. Patients with ASCVD failed to achieve goal LDL-C <70mg/dl
   b. Patients with HeFH failed to achieve goal LDL-C <100mg/dl **AND**;
5. Patient has tried and failed at least two high potency statins (i.e. rosuvastatin or atorvastatin), one of which in combination with ezetimibe, after a trial of at least 12 weeks each at the maximum tolerated dose, or has a intolerance or contraindication to use. If stable on high-potency statin in combination with ezetimibe additional trials of statins will not be required **AND**;
6. Patient has tried and failed to achieve LDL goal using PCSK9 inhibitor for a period of at least 12 weeks with or without a statin or contraindication to use **AND**;
7. Leqvio® is being administered by a healthcare professional.

## DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient will be concurrently using with a PCSK9 inhibitor.

## CAUTIONS[1]

- Common adverse reactions in clinical trials (≥ 3%): injection site reaction, arthralgia, urinary tract infection, diarrhea, bronchitis, pain in extremity, and dyspnea.
- Leqvio® should only be injected subcutaneously into the abdomen, upper arm, or thigh.

## DURATION OF APPROVAL

- Initial Approval: 6 months
- Reauthorization 12 months with chart notes indicating at least 10% reduction in LDL-C

## QUANTITY LIMIT[1]

- Initiate dosing with 284mg administered as a single subcutaneous
- injection initially, again at 3 months, and then every 6 months
- HCPCS – J1306 max of 284

**REFERENCES / FOOTNOTES:**

1. Leqvio [package insert]. East Hanover, NJ; Novartis, Inc.; December 2021. Accessed December 2021.
2. Ray KK, Wright RS, Kallend D, et al. Two phase 3 trials of inclisiran in patients with elevated LDL cholesterol. N Engl J Med. 2020; 382: 1507-1519.
3. Raal FJ, Kallen D, Ray KK, et al. Inclisiran for the treatment of heterozygous familial hypercholesterolemia. N Engl J Med. 2020; 382: 1520-1530.
4. Cannon CP. Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. N Engl J Med 2015; 372:2387–2397.
5. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol. 2017 Oct 3;70(14):1785-1822.
6. Robinson JG, Jayanna MB, Brown AS, et al. Enhancing the Value of PCSK9 Monoclonal Antibodies by Identifying Patients Most Likely to Benefit, Journal of Clinical Lipidology (2019),