



Montana Healthcare Programs Physician Administered Drug Coverage Criteria

LEQVIO® (inclisiran)

I. Medication Description

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)

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Must be prescribed by, or in consult with, a cardiologist, endocrinologist or lipidologist.
- Member has an LDL-cholesterol equal to or greater than 70mg/dl.
- Member has diagnosis of either:
 - Heterozygous familial hypercholesterolemia (HeFH)
 - Atherosclerotic cardiovascular disease (ASCVD)
- Member must have trialed at least TWO high-intensity statins for at least 12-weeks AND will continue receiving maximally tolerated high-intensity statin therapy unless ineffective or contraindicated.
- Member has trialed ezetimibe for at least 12-weeks and has been ineffective or contraindicated.
- Member will not be using this in combination with Juxtapid®, Repatha®, or Praluent®.

IV. Renewal Coverage Criteria

Member must meet the following criteria:

- Member has been adherent to Leqvio®
- Member has been adherent to statin at maximally tolerated dose.
- Member has experienced a positive clinical response as defined by a reduction in LDL-C.
- Annual specialist consult provided if prescriber not a specialist.

V. Quantity Limitations

284mcg SQ initially, again at 3-months, then every 6-months.

VI. Coverage Duration

Initial approval duration: 9 months

Renewal approval duration: 1 year