Inclisiran (Leqvio) – PA Criteria

HCPC: J1306

Leqvio is an Antilipemic Small Interfering Ribonucleic Acid (siRNA) Agent indicated for hypercholesterolemia and atherosclerotic cardiovascular disease (ASCVD) as an adjunct to diet and maximally tolerated statin therapy in adults. It is given via a subcutaneous (SQ) injection by a healthcare professional every 6 months and is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Individual has a diagnosis of **one** of the following:
    - Heterozygous familial hypercholesterolemia as evidenced by mutation in the LDLR, ApoB, PCSK9 or ARH adapter protein gene
    - History of clinical ASCVD as indicted by **one** of the following:
      - Acute coronary syndrome
      - Coronary artery disease (CAD)
      - History of myocardial infarction (MI)
      - Stable or unstable angina
      - Coronary or other arterial revascularization
      - Stroke
      - Transient ischemic attack (TIA)
      - Peripheral arterial disease (PAD)
    - ASCVD risk ≥20%
  - Individual meets **one** of the following regarding statin therapy
    - Individual is currently taking high intensity statin therapy (high intensity statin is defined at atorvastatin ≥40mg or rosuvastatin ≥20mg) and has been compliant with therapy for ≥3 months
    - Individual is statin intolerant based on **one** of the following
      - Inability to tolerate at least two statins, with at least one started at the lowest daily starting dose
      - Development of statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin
    - Individual has a contraindication to statin therapy including but not limited to active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy
  - Individual meets **one** of the following regarding ezetimibe therapy
    - Individual is currently taking at a dose of 10mg daily and has been compliant with therapy for ≥3 months
    - Individual has had a trial and inadequate response to ezetimibe therapy
    - Individual is intolerant of ezetimibe as documented by provider
  - Individual meets **one** of the following regarding proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor therapy
    - Individual has had a trial and inadequate response to PCSK9 therapy as indicated by LDL reduction of ≤50% from baseline
    - Individual is intolerant of PCSK9 therapy
    - Documentation is provided that individual is LDLR negative
  - Documentation is provided indicating baseline lipid panel and comprehensive metabolic panel (CMP) were completed prior to starting therapy with Leqvio
  - Therapy will not be used in combination with Praluent, Repatha, Juxtapid or Evkeeza
  - Individual is ≥18 years of age
  - Approval duration: 1 year

- **Continuation of Therapy (must meet all):**
  - Individual continues to use with high intensity statin (unless requirement previously waived for contraindication/therapy failure)
  - Individual has had a positive response to therapy as indicated by a reduction in total LDL-C
  - Approval duration: 1 year