STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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# Office of Pharmacy Services
# Prior Authorization Criteria
# Effective 11/13/2024
# Leqvio® (*inclisiran*)

## Prior Authorization Request Form

***Leqvio (inclisiran)*** 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).

**CRITERIA FOR APPROVAL:**

1) Patient must meet all age and indication restrictions imposed by the current FDA-approved label; **AND**
2) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL and the goal LDL-C as set by the prescriber after an 8-week trial of either **atorvastatin 40 - 80 mg** OR **rosuvastatin 20 - 40 mg.** Note: If the patient failed to tolerate the first statin, then they must be trialed on the second statin for 8-weeks or until intolerance occurs; **AND**
3) The patient must have a 90-day trial of each preferred PCSK9 inhibitor (Repatha and Praluent) resulting in treatment failure/inadequate response, unless contraindicated.

***NOTE*: "The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization."**

**Approval Duration**: Initial approval will be for 90 days.

**CONTINUATION OF THERAPY CRITERIA:**

1) Demonstrate continued documented compliance; **AND**
2) Documentation of efficacy supported by at least a 40% LDL-C reduction from pre-treatment level is provided.

**Reauthorizations may be approved for 12 months.**