Field Name	Field Description
Prior Authorization Group Description	**Leqvio**
Drugs	Leqvio (inclisiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 3 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**Initial Authorization** **For All Requests:** • Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". AND the member meets the following for the respective diagnosis:

Revision/Review Date 4/2023	<u>Familial Hypercholesterolemia (FH):</u> • Member has a diagnosis of familial hypercholesterolemia as evidenced by one of the following: o Documentation provided including two fasting lipid panel lab reports with abnormal low density lipoprotein (LDL) levels ≥190 for FH in adults or ≥160 for FH in children. o Results of positive genetic testing for an LDL-C-raising gene defect (LDL receptor, apoB, or PCSK9) • Additionally, if the diagnosis is heterozygous FH (HeFH), both of the following: o Patient has tried and failed ezetimibe at a maximal tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe. o LDL remains ≥100 mg/dL despite maximally tolerated LDL-lowering therapy <u>Hyperlipidemia (Primary OR Secondary Atherosclerotic Cardiovascular Disease [ASCVD] Prevention)</u> • If the diagnosis is primary severe hyperlipidemia (i.e. LDL ≥190 mg/dL) o LDL remains ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy • If the diagnosis is secondary ASCVD prevention o Patient has tried and failed ezetimibe at a maximal tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe. o LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDL-lowering therapy o And ONE of the following: ▪ Documented history of multiple major ASCVD events (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease) ▪ Documented history of 1 major ASCVD event (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease)

	AND multiple high-risk conditions (age ≥ 65 years, history of coronary artery bypass graft or percutaneous coronary intervention, diabetes mellitus, hypertension, chronic kidney disease, current smoker, or congestive heart failure) **<u>Reauthorization for all indications:</u>** • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report and the member has had a reduction in LDL from baseline • The patient's claim history shows consistent therapy (i.e. monthly fills) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**