Fax completed form to: (855) 840-1678
If this is an URGENT request, please call
(800) 882-4462 (800.88.CIGNA)

Leqvio
(inclisiran)

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.*		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Patient Name:		
Office Phone:			* Cigna ID:	* Date of Birth:	
Office Fax:			* Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		

Urgency:
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

Medication requested:
☐ Leqvio 284 mg/1.5 mL syringe ☐ other (please specify):

ICD10:

Directions for use: Quantity:

Where will this medication be obtained?
☐ Physician's office stock
☐ Retail Pharmacy:
☐ Home Health / Home Infusion vendor (name):
CPT Code(s):
☐ Other *(please specify)*:

Facility and/or doctor dispensing and administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Where will this drug be administered?
☐ Patient's Home ☐ Physician's Office
☐ Hospital Outpatient ☐ Other (please specify):

NOTE: Per some Cigna plans, infusion of medication MUST occur in the least intensive, medically appropriate setting.
Is this patient a candidate for re-direction to an alternate setting (such as alternate infusion site, physician's office, home) with assistance of a Specialty Care Options Case Manager? ☐ Yes ☐ No (provide medical necessity rationale):

Is the requested medication for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient? ☐ Yes ☐ No

What is the patient's diagnosis or reason for treatment?
PLEASE NOTE: A patient may have a diagnosis that pertains to more than one indication, therefore, consider review under different approval conditions, if applicable (for example, a patient with heterozygous familial hypercholesterolemia may have established cardiovascular disease, a patient with hypercholesterolemia may have heterozygous familial hypercholesterolemia).

☐ Established Cardiovascular Disease
☐ Heterozygous Familial Hypercholesterolemia (HeFH)
☐ Homozygous familial hypercholesterolemia (HoFH)
☐ Hypercholesterolemia
☐ All other indications or diagnoses

Clinical Information:

Is the requested medication being used concurrently with Lerochol (lerodalcibep-liga subcutaneous injection), Repatha (evolocumab subcutaneous injection) or Praluent (alirocumab subcutaneous injection)? ☐ Yes ☐ No

Is the patient currently receiving Leqvio? ☐ Yes ☐ No

(if Currently receiving) Has the patient had prior approval through the Cigna Coverage Review Department for this product? - Please note: If the patient is currently receiving the requested therapy but has not previously received approval of Leqvio for this specific indication through the Cigna Coverage Review Department, review under criteria for Initial Therapy (answer "No" to this question). If the patient is restarting therapy with Leqvio, Initial Therapy criteria must be met (answer "No" this question). ☐ Yes ☐ No

(if Currently receiving) According to the prescriber, has the patient experienced a response to therapy? Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels. ☐ Yes ☐ No

(if Currently receiving) According to the prescriber, has the patient experienced a response to therapy? Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels. ☐ Yes ☐ No

(if yes) According to the prescriber, does the patient have a family history of early atherosclerotic cardiovascular disease (ASCVD) or elevated low-density lipoprotein cholesterol (LDL-C) or total cholesterol (TC) in a parent?

(if no untreated LDL-C at least 150 mg/dL OR no family hx of early ASCVD or elevated LDL-C/TC in parent) Is documentation being provided to show the diagnosis has been confirmed by genetic testing OR prescriber confirming the diagnosis by Dutch Lipid Network criteria (score was great then 5) or Simon Broome criteria (patient met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia)? PLEASE NOTE: Medical documentation specific to your response must be attached to this case or your request may be denied. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information. Note: Examples include pathogenic variants at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. ☐ Yes ☐ No

(if HeFH and 18+ yrs old) Is documentation being provided to show the patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (that is, prior to treatment with antihyperlipidemic agents) OR the diagnosis has been confirmed by genetic testing OR prescriber confirming the diagnosis by Dutch Lipid Network criteria (score was great then 5) or Simon Broome criteria (patient met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia)? PLEASE NOTE: Medical documentation specific to your response must be attached to this case or your request may be denied. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information. Note: Examples include pathogenic variants at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. ☐ Yes ☐ No

(if Established Cardiovascular Disease) Does one of the following apply to the patient?
☐ Previous myocardial infarction or history of an acute coronary syndrome
☐ Angina (stable or unstable)
☐ Past history of stroke or transient ischemic attack
☐ Peripheral arterial disease
☐ Undergone a coronary or other arterial revascularization procedure in the past (Please Note: Examples of coronary or other arterial revascularization procedures include coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures.)
☐ Coronary artery disease
☐ None of the above

(if HoFH) Is documentation being provided that the diagnosis has been confirmed by genetic testing OR an untreated low-density lipoprotein (LDL-C) level greater than 400 mg/dL OR a treated low-density lipoprotein (LDL-C) level greater than 300 mg/dL? PLEASE NOTE: Medical documentation specific to your response must be attached to this case or your request may be denied. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.
☐ Yes - The diagnosis has been confirmed by genetic testing. Note: Examples include pathogenic variants at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene.
☐ Yes - The patient has an untreated LDL-C level greater than 400 mg/dL. - Please Note: Untreated refers to prior therapy with any antihyperlipidemic agents
☐ Yes - The patient has a treated LDL-C level of 300 mg/dL or greater. - Please Note: Treated refers to after therapy with at least one antihyperlipidemic agent. Some examples of antihyperlipidemic agents include statins (for example, atorvastatin, rosuvastatin, lovastatin, simvastatin, pravastatin), ezetimibe, a PCSK9 inhibitor (for example, Praluent [alirocumab subcutaneous injection]), Evkeeza (evinacumab-dgnb intravenous infusion), and Juxtapid (lomitapide capsules).
☐ No

(if untreated LDL-C at least 400 mg/dL OR treated LDL-C of at least 300 mg/dL) Did the patient have clinical manifestations of homozygous familial hypercholesterolemia (HoFH) before the age of 10 years? Please Note: Clinical manifestations of homozygous familial hypercholesterolemia (HoFH) are cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma. ☐ Yes ☐ No

(if no) Did at least one parent of the patient have untreated low-density lipoprotein cholesterol (LDL-C) levels or total cholesterol levels consistent with familial hypercholesterolemia? Please Note: An example of familial hypercholesterolemia is an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL and/or an untreated total cholesterol level greater than 250 mg/dL. ☐ Yes ☐ No

(if HeFH or HoFH) Has the patient tried one high-intensity statin therapy (that is, atorvastatin 40 mg or greater daily; rosuvastatin 20 mg or greater daily [as a single-entity or as a combination product]) for at least 8 weeks continuously? ☐ Yes ☐ No

(if yes) Does the patient's low-density lipoprotein cholesterol (LDL-C) level after this treatment remain greater than or equal to 70 mg/dL? ☐ Yes ☐ No

(if not tried high-intensity statin therapy for 8+ weeks OR LDL-C less than 70 mg/dL) Has the patient been determined to be statin intolerant by experiencing statin-related rhabdomyolysis? Please Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal) along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a 0.5 mg/dL or greater increase in Scr or doubling of the Scr]) and/or myoglobinuria (myoglobin present in urine). ☐ Yes ☐ No

(if no) Has the patient been determined to be statin intolerant by experiencing skeletal-related muscle symptoms? Please Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, tenderness). ☐ Yes ☐ No

(if no rhabdo) Did the skeletal-related muscle symptoms occur while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products)? ☐ Yes ☐ No

(if no rhabdo) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) did the skeletal-related muscle symptoms resolve upon discontinuation of each respective statin therapy (atorvastatin AND rosuvastatin)? Please Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia. ☐ Yes ☐ No

(if Established Cardiovascular Disease) Has the patient tried ONE high-intensity statin therapy (that is, atorvastatin 40 mg daily or higher; rosuvastatin 20 mg daily or higher [as a single entity or as a combination product]) for at least 8 continuous weeks? ☐ Yes ☐ No

(if yes) Does the patient's low-density lipoprotein cholesterol (LDL-C) level remain greater than or equal to 55 mg/dL? ☐ Yes ☐ No

(if no) Has the patient been determined to be statin intolerant by experiencing statin-related rhabdomyolysis? Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage, which can include signs of acute renal injury (noted by substantial increases in serum creatinine [SCr] levels [a 0.5 mg/dL or greater increase in SCr or doubling of the SCr] and/or myoglobinuria [myoglobin present in urine]). ☐ Yes ☐ No

(if no) Has the patient been determined to be statin intolerant by experiencing skeletal-related muscle symptoms? Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness). ☐ Yes ☐ No

(if yes) Did the skeletal related muscle symptoms occur while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination products)? ☐ Yes ☐ No

(if yes) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products), did the skeletal-related muscle symptoms resolve upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin)? Note: Examples of skeletal muscle symptoms include myopathy and myalgia. ☐ Yes ☐ No

(if Hypercholesterolemia) Is documentation provided that the patient has a coronary artery calcium or calcification score greater than or equal to 300 Agatston units [may require prior authorization]? Please note: Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. Medical documentation specific to your response to this question must be attached to this case or your request could be denied. ☐ Yes ☐ No

(if no) Does the patient have diabetes? ☐ Yes ☐ No

(if Hypercholesterolemia) Has the patient tried ONE high-intensity statin therapy (that is, atorvastatin 40 mg daily or higher; rosuvastatin 20 mg daily or higher [as a single entity or as a combination product])? ☐ Yes ☐ No

(if yes) Was the high-intensity statin therapy (that is, atorvastatin 40 mg or greater daily; rosuvastatin 20 mg or greater daily [as single-entity or as a combination product]) given with ezetimibe (as a single-entity or as a combination product) for at least 8 weeks continuously? ☐ Yes ☐ No

(if yes) Does the patient's low-density lipoprotein cholesterol (LDL-C) level after this treatment remain greater than or equal to 70 mg/dL? ☐ Yes ☐ No

(if no) Has the patient been determined to be statin intolerant by experiencing statin-related rhabdomyolysis? Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage, which can include signs of acute renal injury (noted by substantial increases in serum creatinine [SCr] levels [a 0.5 mg/dL or greater increase in SCr or doubling of the SCr] and/or myoglobinuria [myoglobin present in urine]). ☐ Yes ☐ No

(if no) Has the patient been determined to be statin intolerant by experiencing skeletal-related muscle symptoms? Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness). ☐ Yes ☐ No

(if yes) Did the skeletal related muscle symptoms occur while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination products)? ☐ Yes ☐ No

(if yes) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products), did the skeletal-related muscle symptoms resolve upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin)? Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia. ☐ Yes ☐ No

(if initial or no previous auth from Cigna for this indication) Has the patient tried Repatha (evolocumab subcutaneous injection)?
☐ Yes
☐ No - The preferred product is Repatha.

(if yes) Has the patient experienced inadequate efficacy or significant intolerance according to the prescriber?
☐ Yes
☐ No - The preferred product is Repatha.

Additional Pertinent Information:

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature:_____ **Date:**_____

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