

Clinical Information:

****This drug requires supportive documentation (genetic testing, chart notes, lab/test results, etc). If this is an on-line request, supportive documentation for all answers must be attached with this request.**

What is your patient's diagnosis or reason for treatment?

- Homozygous Familial Hypercholesterolemia (HoFH)
 Heterozygous Familial Hypercholesterolemia (HeFH)
 Other Hyperlipidemia not associated with Homozygous Familial Hypercholesterolemia (HoFH) and is referred to as combined hyperlipidemia, hypercholesterolemia (pure, primary), dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels
 other (please specify):

Is documentation being provided that the patient has had genetic testing confirming homozygous familial hypercholesterolemia? 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 1 (LDLRAP1) gene. Please note: Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying 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 genetic test confirmation) Is documentation being provided that the patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than 400 mg/dL? Note: Untreated refers to prior to therapy with any antihyperlipidemic agent. Please note: Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying 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 untreated LDL-C greater than 400mg/dL) Is documentation being provided that the patient has a treated LDL-C level of at least 300 mg/dL? 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 (that is, Repatha [evolocumab subcutaneous injection], Praluent [alirocumab subcutaneous injection]), or Juxtapid (lomitapide capsules). Please note: Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying 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 10 years or older) Has the patient tried one high-intensity statin therapy (that is, atorvastatin at least 40 mg daily; rosuvastatin at least 20 mg daily [as a single entity or as a combination product])? Yes No

(if yes) Has the patient tried one high-intensity statin along with ezetimibe (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 level after this treatment regimen remain at least 70 mg/dL? Yes No

Did the patient have clinical manifestations of homozygous familial hypercholesterolemia before the age of 10 years? Note: Clinical manifestations of homozygous familial hypercholesterolemia are cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma. Yes No

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

(if 10 years or older, no high-intensity statin, high-intensity statin plus ezetimibe, or LDL less than 70 mg/dL) Has the patient experienced 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 10 years or older, no rhabdo OR no high-intensity statin, high-intensity statin plus ezetimibe, or LDL less than 70 mg/dL) Has the patient experienced 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 patient's skeletal-muscle related symptoms occur while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination product)? Yes No

(if yes) Did the patient's skeletal-related muscle symptoms resolve upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin) after receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination product)? Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia. Yes No

(if 10 years or older) Is documentation being provided to confirm the patient is known to have two LDL-receptor negative alleles?
Please note: Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying 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 2 LDL-receptor negative alleles) Has the patient tried one PCSK9 inhibitor for at least 8 continuous weeks? Note: Examples of PCSK9 inhibitors include Repatha (evolocumab subcutaneous injection) and Praluent (alirocumab subcutaneous injection). Yes No

(if yes) Did the patient's LDL-C level after this PCSK9 inhibitor therapy remain at least 70 mg/dL? Yes No

Is the requested dosing up to 15 mg/kg administered by intravenous infusion no more frequently than once every 4 weeks? Yes No

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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