Drug Name: Repatha

Date: 09-2017

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Prescriber Restrictions:	• Prescriber must be a lipid specialist (either a **lipidologist** or a **cardiologist**) with expertise in treating high lipids.
Age Restrictions:	• Patient must be at least 18 years of age.
Required Medical Information:	• **Homozygous Familial Hypercholesterolemia (HoFH) or Heterozygous Familial Hypercholesterolemia (HeFH)**: o Documentation 3 months prior to therapy with at least ONE high-intensity or maximum tolerated statin PLUS ezetimibe (adherence will be assessed based on Neighborhood's pharmacy claims system); and o LDL is greater than or equal to 160 mg/dL despite adherence to therapy with high-intensity or maximum tolerated statin PLUS ezetimibe; and o Baseline LDL-C level and current LDL-C level must be provided (within the last 30 days) reflecting use of high-intensity or maximum tolerated statin PLUS ezetimibe; and o Diagnosis of HoFH is confirmed by one of the following: ▪ LDL-R DNA Sequencing Test or APOB (hypercholesterolemia) Mutation Analysis; *or* ▪ A Dutch Lipid Clinic Network Criteria score equal to or greater than 8; *or* ▪ A confirmed diagnosis per Simon-Broome Diagnostic Criteria for definite familial hypercholesterolemia; *or* ▪ Baseline pretreatment LDL ≥ 190mg/dL.

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Required Medical Information (continued):	• **Diagnosis of atherosclerotic cardiovascular disease (ASCVD)**: o Documentation submitted includes patient's complete medical history and co-morbidities; and o For patients with a confirmed clinical diagnosis of ASCVD requiring additional lowering of a low-density lipoprotein (LDL) cholesterol: ▪ Documentation has been submitted that the patient is receiving and will continue to receive maximally tolerated doses of stains; *and* ▪ Patient has a history of acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin; and o Documentation submitted of two fasting lipid panel lab reports within the past 12 month with abnormal LDL cholesterol levels (greater than 70); and o Documented claim history or chart notes show consistent therapy (at least 3 months) with atorvastatin 80 mg OR Crestor (Rosuvastatin) 40mg with inadequate response OR a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing one of these therapies to manage their medical condition; and ▪ Note: If the patient is of Asian descent, then document should be provided, as Crestor 20 mg is the maximum dose for this population. o If the request indicates that the patient is "statin intolerant," documentation was provided of agents tried, including descriptions of the side effects, duration of therapy, "wash out," re-trial, and then change in agents, or change in dose of agents; and o Documentation submitted includes an attestation that the patient is following a "heart healthy" diet; and o Documentation submitted indicates the patient is a non-smoker or is actively quitting smoking.
Renewal Criteria	• Documentation of current LDL-C level (within the past 30 days) must be recorded; and • Documentation has been submitted that indicates that the medication has obtained clinical benefit from the medication, including repeat fasting lipid panel lab report; and • Documentation of a greater than or equal to 50% reduction in LDL-C compared to baseline; and • The patient's claim history shows consistent therapy (e.g. monthly fills).
Note(s):	Repatha 420 mg is only approvable for the diagnosis of HoFH. Medical director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
Coverage Duration:	**Initial**: 3 months **Continuation of therapy**: 6 months