Initial Approval: October 14, 2015

CRITERIA FOR PRIOR AUTHORIZATION

PCSK9 Inhibitors

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drugs require prior authorization:
alirocumab (Praluent®)
evolocumab (Repatha®)

CRITERIA FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH) (must meet all of the following):

- Patient must have a diagnosis of homozygous familial hypercholesterolemia. This must be evidenced by:
  - Genotyping; or
  - Clinical diagnosis based on a history of untreated LDL-C > 500 mg/dl and one of the following:
    - Xanthoma prior to the age of 10 years
    - Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents
- Patient must be at least 13 years old
- Must be used as adjunct to diet
- Must be used as adjunct to other LDL-lowering therapy (maximally tolerated stable therapy, or patient must have a contraindication or allergic reaction to other therapy)
- Must be prescribed by or in consultation with a cardiologist or lipidologist
- Prescribed drug is evolocumab (Repatha®)
  - Dose must not be greater than 140 mg every 14 days

CRITERIA FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) (must meet all of the following)**:**

- Patient must have a diagnosis of heterozygous familial hypercholesterolemia. This must be evidenced by:
  - Genotyping; or
  - Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria
- Must be at least 18 years old
- Must be used as adjunct to diet
- Must be used as adjunct to maximally tolerated stable, daily statin therapy (or patient must have a contraindication or allergic reaction to statins)*
- Must be prescribed by or in consultation with a cardiologist or lipidologist
- Prescribed drug is:
  - Evolocumab (Repatha®)
    - Dose must not be greater than 140 mg every 14 days
  - Alirocumab (Praluent®)
    - Dose must not be greater than 150 mg every 14 days

Prior Authorization Criteria – Updated January 2021

CRITERIA FOR PRIMARY HYPERLIPIDEMIA (must meet all of the following):

- Patient must have a diagnosis of clinical atherosclerotic cardiovascular disease (diagnosis of CVD, MI, unstable angina, or previous ACS) and require additional lowering of LDL-cholesterol
- Must be at least 18 years old
- Must be used as adjunct to diet
- Must be used as adjunct to maximally tolerated stable, daily statin therapy (or patient must have a contraindication or allergic reaction to statins)*
- Must be prescribed by or in consultation with a cardiologist or lipidologist
- Prescribed drug is:
    - Evolocumab (Repatha®)
        - Dose must not be greater than 140 mg every 14 days
    - Alirocumab (Praluent®)
        - Dose must not be greater than 150 mg every 14 days

LENGTH OF INITIAL APPROVAL: 3 months

CRITERIA FOR RENEWAL (must meet all of the following):

- Documentation that lipid lowering has occurred
- Documentation of continued adjunct diet changes and pharmacotherapy from initial approval
- Prescribed drug is:
    - Evolocumab (Repatha®)
        - Dose must not be greater than 140 mg every 14 days
    - Alirocumab (Praluent®)
        - Dose must not be greater than 150 mg every 14 days

LENGTH OF RENEWAL APPROVAL: 6 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

(Note: The DUR Board authorized this addition during the DUR Board meeting on July 10, 2019)

*Notes:

- Clinical atherosclerotic cardiovascular disease includes, but is not limited to, a diagnosis of cardiovascular disease (CVD) or a previous acute coronary syndrome (ACS) (e.g., myocardial infarction, ischemic stroke, unstable angina)
- For HeFH and Primary Hyperlipidemia patients who require adjunct therapy for High LDL Levels (LDL-C > 160 mg/dl), a trial of a stable statin therapy and failure of multiple statins at maximum dose must be employed
    - Stable statin therapy is defined as the patient being at a stable dose for at least 4 weeks
    - Combination therapy with covered alternative agent(s) is required if maximum statin dosage did not achieve efficacious level (e.g. ezetimibe, bile acid sequestrants, or other antilipemic agent or therapy)

- Baseline lab prior to any treatment and labs after all previous treatments showing inadequate control on statins
- For intolerance to statins, trial and failure of 2 statins at lower dose must be utilized. Specific intolerance must be documented and temporally related to statin treatment.
  - If intolerance is due to muscle pain, attach creatinine kinase labs checking for rhabdomyolysis.

- For Repatha®, requests of 420mg every 28 days, clinical justification must be provided as to why the 140mg every 14 day dosing regimen was not sufficient/indicated.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
_____	_____
DATE	DATE