EVOLOCUMAB

Generic	Brand	HICL	GCN	Exception/Other
EVOLOCUMAB	REPATHA SYRINGE, REPATHA SURECLICK, REPATHA PUSHTRONEX	42378		

***********Customer Service/PAC Alert************
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Repatha?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

EVOLOCUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **ONE** of the following diagnoses:
     - Established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)
     - Primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)) as determined by meeting **ONE** of the following:
       - Simon Broome diagnostic criteria (definite)
       - Dutch Lipid Network criteria with a score of 6 or greater

   If yes, **approve for 12 months by GPID for the requested medication with the following quantity limits:**
   - **Repatha 140mg (GPID 39363, 38178): 2mL per 28 days.**
   - **Repatha 420mg (GPID 41834): 3.5mL per 28 days.**

   If no, continue to #7.

CONTINUED ON NEXT PAGE

EVOLOCUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of 8 or greater
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either:
     (1) xanthoma before 10 years of age **OR**
     (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, **approve Repatha 420mg (GPID 41834) for 12 months with a quantity limit of 3.5mL per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **EVOLOCUMAB (Repatha)** requires a diagnosis of established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis), **OR** primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), **OR** homozygous familial hypercholesterolemia (HoFH). In addition, the following criteria must be met:
   - The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment

   For statin tolerant patients, approval also requires:
   - The patient meets **ONE** of the following criteria:
     - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
     - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - The patient will continue statin treatment in combination with Repatha

   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

EVOLOCUMAB

INITIAL CRITERIA (CONTINUED)

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

For patients with established cardiovascular disease, approval also requires:

- The patient is 18 years of age or older

For patients with primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), approval also requires:

- The patient is 18 years of age or older
- The diagnosis is determined by meeting **ONE** of the following:
  - Simon Broome diagnostic criteria (definite)
  - Dutch Lipid Network criteria with a score of 6 or greater

For patients with homozygous familial hypercholesterolemia (HoFH), the diagnosis must be determined by meeting ONE of the following criteria:

- Simon Broome diagnostic criteria (definite)
- Dutch Lipid Network criteria with a score of 8 or greater
- A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - The patient has continued concurrent therapy with a maximally tolerated dose of any statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

EVOLOCUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of established cardiovascular disease **OR** primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH))?

   If yes, **approve for 12 months by GPID for the requested medication with the following quantity limits:**
   - **Repatha 140mg (GPID 39363, 38178): 2mL per 28 days.**
   - **Repatha 420mg (GPID 41834): 3.5mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH)?

   If yes, **approve Repatha 420mg (GPID 41834) for 12 months with a quantity limit of 3.5mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **EVOLOCUMAB (Repatha)** requires a diagnosis of established cardiovascular disease, primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), or homozygous familial hypercholesterolemia (HoFH). In addition, **ONE** of the following must be met:
   - The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - The patient has continued concurrent therapy with a maximally tolerated dose of any statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Repatha.

REFERENCES
- Repatha [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; December 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/11/19
Created: 08/15
Client Approval: 02/19
P&T Approval: 04/18