Help your patients start and stay on Repatha®

Below is a list of potential tasks for your patient's progress through the Repatha® prescription process.

Starting on Repatha®

Repatha® prescribed/initial patient discussion (HCP/office staff)

- Coverage information shared
- Copay card (commercial patients only) and suite of services information shared
- Access pathway determined by office (specialty pharmacy, retail, payer, **Repatha***Ready*®)

Case submission (Office staff)

- Patient benefit verification submitted (intake form, eRx)
  - Patient pharmacy benefit card copied and attached, if available
- Prior authorization (PA) requirements received from payer or specialty pharmacy
- Case submitted on ____/____/_____

Completing prior authorization (Office staff)

- Ensure correct PA form for patient pharmacy benefit
- Gather supporting documentation for established CVD/FH diagnosis and maximally tolerated statin utilization
  - Most recent patient LDL test results (some payers prefer within last 4 weeks)
- Cover letter created and attached (template available)
- PA form completed and submitted to pathway on ____/____/_____
  - Supporting documents attached (eg, primary/secondary ICD-10 codes, diagnostic findings, treatment history, lifestyle modifications)
- Response from payer received on ____/____/_____ (approved/denied)

Appeal, if needed (Office staff)

- Payer denial letter received and reviewed
- Gather supporting documentation that directly responds to denial letter and terminology
- Appeal letter/supporting documentation submitted on ____/____/_____
  - If needed, peer-to-peer option with prescribing physician and insurance medical reviewer

Filling Repatha®

Repatha® fulfillment (Pharmacy name)

_____

- Approved on ____/____/_____
- Patient's preferred communication determined
- Pharmacy contacted patient for fulfillment
- Out-of-pocket costs collected
- Medication picked up/shipped on ____/____/_____

Staying on Repatha®

Injection training (844-REPATHA)

- Patient Privacy Notice and Authorization
- Initial injection training by healthcare professional (office)
- Injection support, if needed, from **Repatha***Ready*® Nurses
- Patient follow-ups scheduled (office visit, lipid panel, etc)

Reauthorization due on ____/____/_____

Indications

Prevention of Cardiovascular Events: In adults with established cardiovascular disease, Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization.

Primary Hyperlipidemia (including Heterozygous Familial Hypercholesterolemia): Repatha® is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

Homozygous Familial Hypercholesterolemia: Repatha® is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

The safety and effectiveness of Repatha® have not been established in pediatric patients with HoFH who are younger than 13 years old or in pediatric patients with primary hyperlipidemia or HeFH.

Please see additional Important Safety Information on next page.

Repatha® (evolocumab) injection 140 mg/mL

Important Safety Information

Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®.

Allergic Reactions: Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.

Adverse Reactions in Primary Hyperlipidemia, including HeFH: The most common adverse reactions (> 5% of Repatha®-treated patients and occurring more frequently than placebo) in clinical trials in primary hyperlipidemia (including HeFH) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).

From a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

Adverse Reactions in the Cardiovascular Outcomes Trial: The safety profile of Repatha® in this trial was generally consistent with the safety profile described above in the 12- and 52-week controlled trials involving patients with primary hyperlipidemia (including HeFH). Serious adverse events occurred in 24.8% and 24.7% of Repatha®-treated and placebo-treated patients, respectively. Adverse events led to discontinuation of study treatment in 4.4% of patients assigned to Repatha® and 4.2% assigned to placebo. Common adverse reactions (> 5% of patients treated with Repatha® and occurring more frequently than placebo) included diabetes mellitus (8.8% Repatha®, 8.2% placebo), nasopharyngitis (7.8% Repatha®, 7.4% placebo), and upper respiratory tract infection (5.1% Repatha®, 4.8% placebo).

Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1% in patients assigned to Repatha® compared with 7.7% in those assigned to placebo.

Adverse Reactions in Homozygous Familial Hypercholesterolemia (HoFH): In 49 patients with HoFH studied in a 12-week, double-blind, randomized, placebo-controlled trial, 33 patients received 420 mg of Repatha® subcutaneously once monthly. The adverse reactions that occurred in at least two (6.1%) Repatha®-treated patients, and more frequently than in placebo-treated patients, included upper respiratory tract infection (9.1% versus 6.3%), influenza (9.1% versus 0%), gastroenteritis (6.1% versus 0%), and nasopharyngitis (6.1% versus 0%).

Immunogenicity: Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha.

Please click here to see accompanying full Prescribing Information.

AMGEN®
Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

Repatha® (evolocumab) injection 140 mg/mL