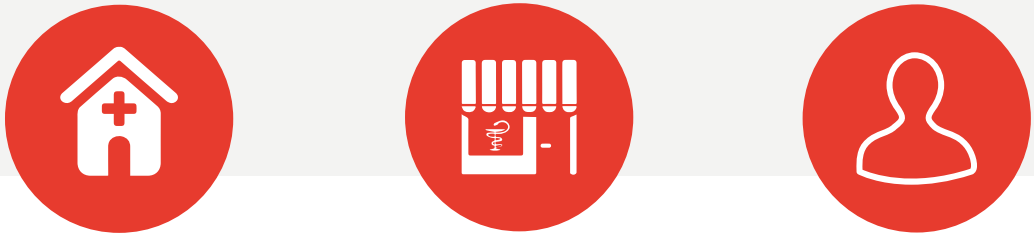
THE REPATHA® SPECIALTY PHARMACY GUIDEBOOK



Repatha® (evolocumab) injection 140 mg/mL

Table of Contents

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.

Important Safety Information

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

Please see additional Important Safety Information on the last page.

Repatha*Ready*® provides personalized support programs for practices and patients that include insurance verification and prescription triage, as well as working with the specialty pharmacy to complete prior authorization, ship Repatha®, and follow up with refill reminders.

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Specialty Pharmacy Overview

Specialty pharmacies play a key role in a patient's Repatha® Access

Specialty pharmacies focus on medications that require special handling or administration, such as injectable drugs. Physicians and patients may choose to fill Repatha® prescriptions at specialty pharmacies.

Specialty pharmacies can help patients *start* and *stay* on track with their therapy by:

- Conducting insurance verification
- Coordinating with the physician's office to help navigate the PA process
- Filling the prescription, facilitating financial assistance, and collecting patient payment
- Shipping Repatha® directly to a patient's home
- Reminding patients when to administer and refill Repatha®

The Repatha® Access Specialist (RAS) can help support your office and patient through the Repatha® fulfillment process.

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Key Steps in the Repatha® Specialty Pharmacy Pathway

1 Prescription Intake

- Select specialty pharmacy
- Submit intake form
- Confirm receipt of Rx
- Verify coverage
- Determine PA requirements and specialty pharmacy restrictions (if any)

See page 6 for more details.

2 Prior Authorization (PA) Submission

- Communicate PA requirements to HCP
- Support PA process
- Complete PA
- Provide supporting documentation
- Submit to specialty pharmacy or payer

See page 8 for more details.

3 Appeal

- Facilitates appeals and tracks status
- Decide to pursue appeal
- Submit appeal documentation to the specialty pharmacy or payer

See page 9 for more details.

4 Financial Assistance

- Provide financial assistance options based on patient request*
- Collect out-of-pocket costs
- Educate about Repatha® and the patient's condition

* Commercial patients can go to Repatha.com or call 1-844-REPATHA to sign up for the copay card.

See page 10 for more details.

Please see Important Safety Information on the last page.

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Key Steps in the Repatha® Specialty Pharmacy Pathway *(cont'd)*

5 Prescription Shipment and Delivery

- Coordinate Repatha® delivery
- Ship Repatha® to patient (typically overnight)

See page 11 for more details.

6 Patient Follow-up

- Confirm Repatha® delivery
- Provide additional education and/or training (if needed)
- May provide reminders to refill Repatha®

See page 11 for more details.

Helpful tips

Intake form

- Ensure Intake Form is filled out completely
- Include a copy of the patient's pharmacy benefit card
- Obtain the Repatha® Specialty Pharmacy Intake Form from your Amgen representative or online at **RepathaFinder.com**

PA form

- Fill out all forms completely and legibly
  - PA forms and documentation should be clean, clear, and concise
  - Your preferred specialty pharmacy or the patient's payer may help identify payer-specific PA requirements
- Provide a legible summary page containing PA requirements and required documentation in a legible and easily identifiable form
  - Provide only the documentation required

Appeal process

- Ensure that payer requirements are met
  - Each payer may have its own appeal requirements
  - The payer's denial letter will outline specifics regarding the appeal process and required documentation
  - The Letter of Appeal and Letter of Medical Necessity may be included with your response. A template letter is available at **RepathaHCP.com**
- Follow up with a phone call to the payer after the appeal is submitted
  - There may be multiple levels of appeal including peer-to-peer review

Please see Important Safety Information on the last page.

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1 Prescription Intake

Selecting a specialty pharmacy

The first step in the specialty pharmacy pathway is selecting a specialty pharmacy. Any pharmacy can fill Repatha® prescriptions unless a specific specialty pharmacy is mandated by the patient's payer.

If you need help getting started with a pharmacy, you can find a list at: **RepathaFinder.com**

The prescription intake form

Most specialty pharmacies use prescription intake forms to help get the process started. This helps the pharmacy begin the PA.

Although some specialty pharmacies may have their own intake form, Amgen has created an SP Intake Form specifically for Repatha®, which can be accessed in person from an Amgen sales representative, a RAS, or online at: **RepathaHCP.com/Resources**

Any pharmacy can fill Repatha®.

(unless the patient's payer designates a mandated specialty pharmacy)

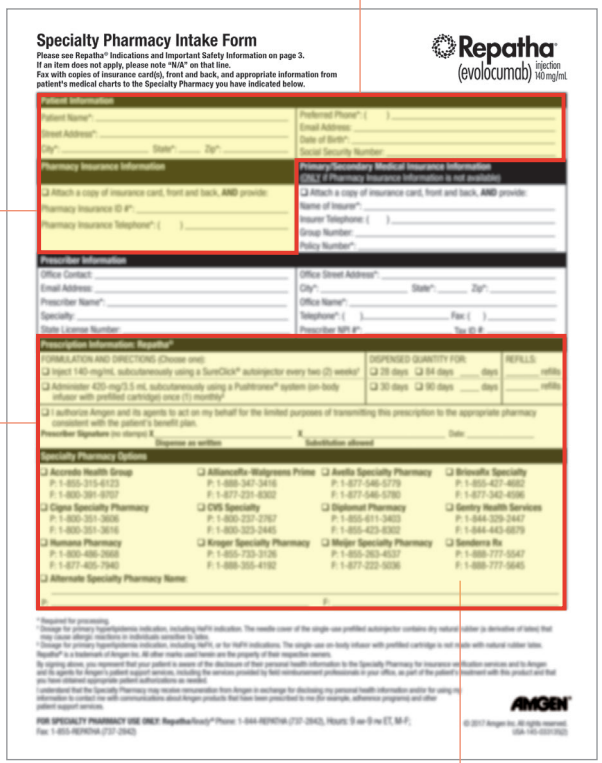
1 Prescription Intake *(cont'd)*

Make sure to include the patient's pharmacy insurance information to avoid a delay in prescription fill.

A copy of the front and back of the patient's pharmacy insurance card

Valid patient contact information

Relevant primary and secondary ICD-10 codes, along with the treatment history


Specialty Pharmacy Intake Form

Please see Repatha® Indications and Important Safety Information on page 3.
If an item does not apply, please note "N/A" on that line.
Fax with copies of insurance card(s), front and back, and appropriate information from patient's medical charts to the Specialty Pharmacy you have indicated below.

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Patient Information

Pharmacy Insurance Information

Primary/Secondary Medical Insurance Information
ONLY if Pharmacy Insurance information is not available

Prescriber Information

Prescription Information: Repatha®

Specialty Pharmacy Options

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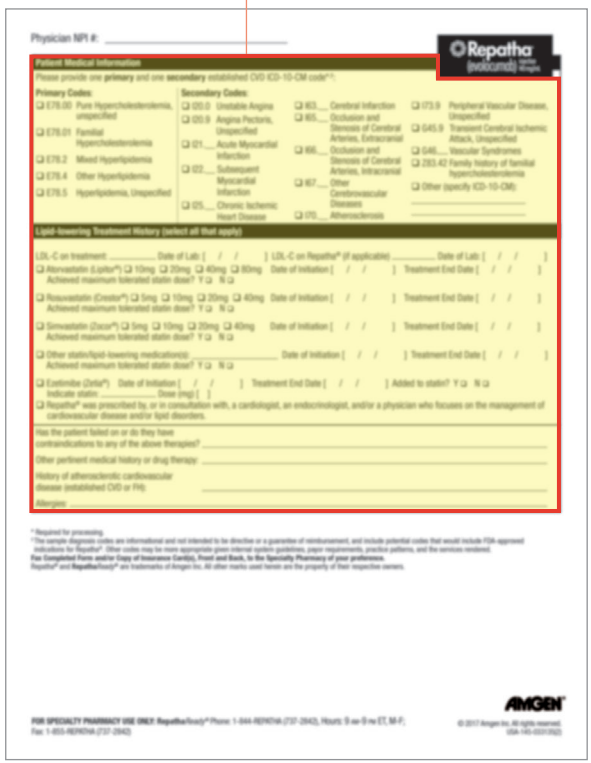
Physician NPI #:

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Patient Medical Information

Please provide one **primary** and one **secondary** established CVD ICD-10-CM code*†:

Primary Codes:

Secondary Codes:

Lipid-lowering Treatment History (select all that apply)

AMGEN

Prescriber's signature

Selected specialty pharmacy

Important Safety Information

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.

Please see additional Important Safety Information on the last page.

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2 Prior Authorization (PA) Submission

The PA submission

A payer may require that an office submit additional information to obtain authorization before a patient can access Repatha®. If a PA is required, the payer may or may not cover Repatha® until a PA approval is obtained.

Each payer may have its own PA requirements. When the specialty pharmacy conducts insurance verification, it will:

- Obtain the PA form and identify documentation specifics for a patient
- Fill and forward forms to the physician's office for completion and signatures
- Track the status of the PA through approval or denial

Payers may require supporting documentation along with the PA form, such as medical chart notes, lab results, and prescription records.

Types of information typically requested on a Repatha® PA

Diagnostic Evidence

- Diagnosis type and related ICD-10 codes
- Medical history, labs, and/or assessments confirming the diagnosis
- Patient age

Treatment History

- Current and previous treatment regimens, including lipid profiles
- Detailed treatment experience
- Specialty of the prescriber or the consulting physician

If a patient's PA is denied, a specialty pharmacy MAY help a physician pursue an appeal on behalf of a patient.

3 Appeal

The Appeal

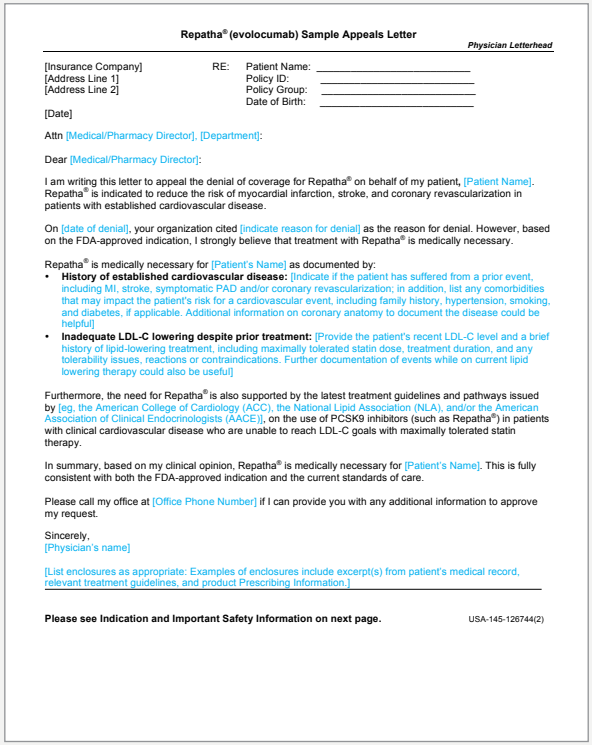
If a patient's PA submission is denied, an appeal can be filed to request that the payer reconsider the initial decision. Either the provider or the patient can initiate an appeal.

- Most plans allow multiple levels of appeal, which typically start with a written explanation of why the patient is appropriate for the prescribed medication
- Some plans offer verbal or peer-to-peer review requests

Points to Remember When Filing an Appeal

- Review the payer's denial letter to understand the rationale for denial and to identify the appeal process requirements (documentation, timeframe, etc)
- Review accuracy and completeness of the original PA request (patient information, documentation, etc)
- Consider using a template letter of appeal (see sidebar to right) to create a comprehensive letter of appeal (demographic, diagnostic, and treatment information)
- Include any supporting documentation as required by the payer (the denial letter, letter of medical necessity, patient records/EMR, etc)

A Sample Appeals Letter IS AVAILABLE to help physicians with the process. This letter can be downloaded at: **RepathaHCP.com/Resources**



Repatha® (evolocumab) Sample Appeals Letter

Physician Letterhead

[Insurance Company]
[Address Line 1]
[Address Line 2]

RE: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____

[Date]

Attn [Medical/Pharmacy Director], [Department]:

Dear [Medical/Pharmacy Director]:

I am writing this letter to appeal the denial of coverage for Repatha® on behalf of my patient, [Patient Name]. Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in patients with established cardiovascular disease.

On [date of denial], your organization cited [indicate reason for denial] as the reason for denial. However, based on the FDA-approved indication, I strongly believe that treatment with Repatha® is medically necessary.

Repatha® is medically necessary for [Patient's Name] as documented by:

- **History of established cardiovascular disease:** [Indicate if the patient has suffered from a prior event, including MI, stroke, symptomatic PAD and/or coronary revascularization; in addition, list any comorbidities that may impact the patient's risk for a cardiovascular event, including family history, hypertension, smoking, and diabetes, if applicable. Additional information on coronary anatomy to document the disease could be helpful]
- **Inadequate LDL-C lowering despite prior treatment:** [Provide the patient's recent LDL-C level and a brief history of lipid-lowering treatment, including maximally tolerated statin dose, treatment duration, and any tolerability issues, reactions or contraindications. Further documentation of events while on current lipid lowering therapy could also be useful]

Furthermore, the need for Repatha® is also supported by the latest treatment guidelines and pathways issued by [eg, the American College of Cardiology (ACC), the National Lipid Association (NLA), and/or the American Association of Clinical Endocrinologists (AACE)], **on the use of PCSK9 inhibitors (such as Repatha®) in patients** with clinical cardiovascular disease who are unable to reach LDL-C goals with maximally tolerated statin therapy.

In summary, based on my clinical opinion, Repatha® is medically necessary for [Patient's Name]. This is fully consistent with both the FDA-approved indication and the current standards of care.

Please call my office at [Office Phone Number] if I can provide you with any additional information to approve my request.

Sincerely,
[Physician's name]

[List enclosures as appropriate: Examples of enclosures include excerpt(s) from patient's medical record, relevant treatment guidelines, and product Prescribing Information.]

Please see Indication and Important Safety Information on next page. USA-145-126744(2)

Important Safety Information

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).

Please see additional Important Safety Information on the last page.

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4 Financial Assistance

Financial assistance options

Upon patient request, many specialty pharmacies will work with the patient to help identify potential financial assistance options.

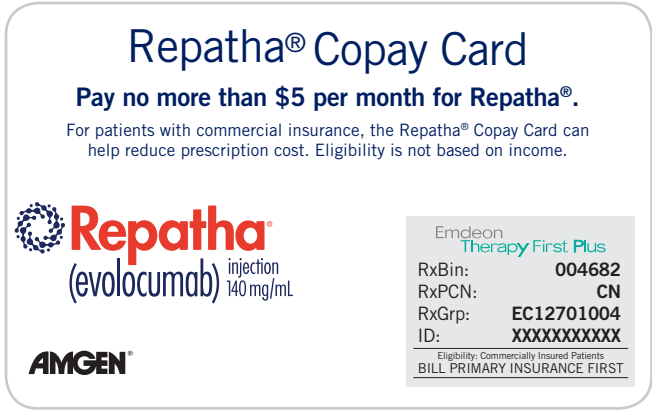
Commercial Insurance	Medicare Part D	Uninsured or Underinsured
Repatha® Copay Card Eligible patients pay no more than $5* per month for Repatha® regardless of income	**Referral to Independent Copay Foundations†** Eligible patients may receive assistance to help them afford the cost of their medicine	**Referral to The Safety Net Foundation** Eligible patients may receive Repatha® at no cost Up to 500% of the federal poverty level income limit

* Please see program details and eligibility criteria below. Applies to deductible, co-insurance, and/or copay for Repatha® (subject to plan design).

† Provided through third-party foundations (501(c)(3), tax-exempt nonprofit organizations). Amgen has no control over independent, third-party programs and provides referrals as a courtesy only.

Repatha® Copay Card details and eligibility information

- The Repatha® Copay Card reduces out-of-pocket costs for Repatha®, including copayments, co-insurance, and prescription deductibles (subject to plan design)
- No income eligibility requirements
- Each patient is responsible for up to the first $5 per month for Repatha®
- The Repatha® Copay Card pays up to an annual maximum
- Once activated, the card must be renewed every 12 months



Eligibility Criteria – Open to patients with a Repatha® (evolocumab) prescription and commercial prescription insurance who are not enrolled in any government-funded healthcare program. Patients may not seek reimbursement for value received from the Repatha® Copay Card from any third-party payers, including a flexible spending account or healthcare savings account. This program is not open to uninsured patients or patients enrolled in any federal, state, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part A, Medicare Part B, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD) or TRICARE®, or where prohibited by law. Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If at any time patients become enrolled under any such federal, state, or government-funded healthcare program, patients will no longer be able to use this card and you must call **1-844-REPATHA** to stop participation. Restrictions may apply. Offer subject to change or discontinuation without notice. **This is not health insurance.** Patients under 18 years of age are not eligible for this program.

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Please see Important Safety Information on the last page.

5 6 Prescription Shipment & Delivery and Patient Follow-up

Patient touchpoints

Once coverage for Repatha® has been confirmed, a specialty pharmacy will have several touchpoints with a patient, including an onboarding call and periodic follow-ups.

The specialty pharmacy will call a patient to:

- Coordinate delivery of the prescription
- Facilitate copay card enrollment for eligible patients
- Collect out-of-pocket costs
- Provide education about Repatha® and the patient's condition
- Confirm Repatha® delivery
- Provide additional education or training, if needed
- Provide refill reminders

Remind patients to expect a call from the specialty pharmacy to arrange delivery, collect copay, and facilitate enrollment in copay card program (for eligible patients), as well as periodic follow-ups.

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Specialty pharmacies can help physicians and their Repatha® patients

- Specialty pharmacies typically offer a broader range of services than retail pharmacies
- Many Repatha® prescriptions are expected to be filled by specialty pharmacies
- Specialty pharmacies can help facilitate the PA process for Repatha® prescriptions
- Repatha® has a network of national specialty pharmacies; however, Repatha® can be filled at any pharmacy
- Specialty pharmacies can help patients identify financial assistance options

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 withw all therapeutic proteins, there is a potential for immunogenicity with Repatha®.

Please click here to see full Prescribing Information.

AMGEN®

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