Repatha® Pushtronex® System Discontinuation
FREQUENTLY ASKED QUESTIONS (FAQ) for HCPs

Q: How do I transition my patients from the Repatha® Pustronex system?

- For your patients who do not have a latex allergy, we recommend switching them to the Repatha® SureClick prefilled autoinjector, the #1 prescribed device for Repatha®.

Q: What should I do for my latex allergy patients who are currently using the Pushtronex® System?

- A small quantity of Pushtronex® system has been reserved for patients with a latex allergy through certain wholesalers. These patients may still be able to fill their Pushtronex® prescription. If they are unable to do so, these patients are encouraged to transition to the prefilled syringe that is not made with natural rubber latex, available January 6, 2025. A SureClick® autoinjector that is not made with natural rubber latex will be available in April 2025 in limited quantity, with full inventory expected by summer 2025. Amgen will stop all drop shipments of Pushtronex® system on December 18, 2024.

Q: Who should I contact if I have further questions about transitioning my patients from Pushtronex® system?

- Please direct your patients to [1-844-Repatha] for further assistance.

Q: How many presentations of Repatha® are there in the US?

- Historically, there have been 3 device presentations of Repatha® in the US:
  - 140 mg/mL single-dose prefilled SureClick® autoinjector
  - 140 mg/mL single-dose prefilled syringe
  - 420 mg/3.5 mL single-dose Pushtronex® System (on-body infusor with prefilled cartridge) (discontinued)

  The SureClick® autoinjector is the #1 prescribed Repatha® device.

- As of January 6, 2025, a new device will be available for patients with latex allergies:
  - 140 mg/mL single-dose prefilled syringe not made with natural rubber latex (140 mg/mL single-dose prefilled SureClick® prefilled autoinjector not made with natural rubber latex will be available in limited quantity April 2025, with full inventory expected by summer 2025.)

Q: Are there differences between the devices in terms of adverse event / side effects?

- The side effect profile of Repatha® was not differentiated based on the device or administration. Adverse events in the Repatha® clinical study groups, including 140 mg and 420 mg dosing groups, were balanced across treatment arms in short- and long-term studies.[1-5]

Q: Why has Amgen decided to discontinue the Repatha® Pushtronex® System? When does that go into effect?

- Repatha® Pushtronex® System is discontinued, to be followed by the discontinuation of the prefilled syringe mid-2025. This decision was made globally to uphold the high standards that Amgen has set to enable the most optimal patient experience. At this time, any patients without HoFH or a latex allergy should transition to the single-dose prefilled Repatha® SureClick® autoinjector, 140 mg administered every 2 weeks or the single-dose prefilled syringe, 140 mg administered every 2 weeks. A new prescription will be needed for the new device presentation.

Q: Is Amgen discontinuing Pushtronex® System globally?

- Yes. In addition to the U.S. this presentation will be discontinued in all countries where it is available, including Canada, Germany, Japan, and Australia.

Q: Were there safety or quality issues with the Pushtronex® System?

- There are no concerns about the drug product quality, efficacy, or patient safety for any of the three Repatha® device presentations.

Q: What should patients do with their existing Repatha® Pushtronex® System device?

- Patients who are currently in possession of the Repatha® Pushtronex® System device can continue to take their medicine as directed by their health care professional.

SureClick® Autoinjector

Q: Why is Amgen focused on transitioning patients to the Repatha® SureClick® autoinjector?

- The overwhelming majority of patients are prescribed the Repatha® SureClick® autoinjector.
- Injection with Repatha® SureClick® on an annualized basis takes approximately 6.5* minutes for the Repatha® SureClick® autoinjector for the 140 mg every 2-week administration vs. 60 minutes with the Repatha® Pushtronex® System for the 420 mg once a month administration.
- Through Amgen® SupportPlus services patients can access supplemental administration support, reminders, cost, and co-pay support information (for eligible, commercially insured patients).
- For patients with fear of needles, the needle in the Repatha® SureClick® autoinjector is hidden which may make it more patient friendly compared to the Prefilled Syringe. Additionally, a caregiver may administer the SureClick® autoinjector if available.

Q: Is the Repatha® SureClick® autoinjector appropriate for all patients?

- The labeled indication and drug product for the devices is the same. There are no patient population or indication differences, except that historically the prefilled syringe and SureClick® autoinjector contained dry natural rubber (a derivative of latex). This is why Amgen is introducing a prefilled syringe not made with natural rubber latex into the market, followed by a SureClick® autoinjector next year that will not be made with natural rubber latex.

HoFH Patients

Q: Now that the Repatha® Pushtronex® system is going off the market, how can my HoFH patients continue receiving their Repatha® 420 mg monthly dose?

- Amgen does not have a 3-pack of the 140 mg/mL Repatha® SureClick® autoinjector presentation available in the US market.
- For HoFH patients, providers should write a script for a 60-day supply of the Repatha® SureClick® autoinjector to inject 420mg (3 of the 140 mg/mL SureClick® auto-injectors) subcutaneously once a month. Dispense as 3 boxes (3 of the 140 mg/mL SureClick® autoinjectors) refilled 5 times. Note, an exception from the patient's insurance plan may be required.

- For HoFH patients who need the 420mg every 2-week dosing schedule (i.e. Repatha® SureClick® autoinjector 28-day supply) to inject 420mg (3 of the 140 mg/mL SureClick® autoinjectors) subcutaneously every 2 weeks. Dispense as 3 boxes (6 SureClick® autoinjectors) refilled 12 times. Note, an exception from the patient's insurance plan may be required.
- Please refer to the Repatha® Prescribing Information.
- We recognize that the transition for this small subset of patients is more complicated. Therefore, Amgen strongly encourages these patients to sign up for Amgen® SupportPlus to receive further support.

Coverage & Cost

Q: Will Insurance cover once monthly dosing for Repatha® (3x 140mg SureClick® autoinjectors within 30 mins) for HoFH patients?

- Payors will likely ask doctors to submit for an exception for these patients. Amgen Access Specialists can provide live or virtual coverage and access resources to support your patients including educating on payer requirements and necessary documentation for individual patient support.

Q: Will HoFH patients out of pocket cost for Repatha® SureClick® autoinjector be more expensive than Repatha® Pushtronex® system?

- The cost of their Repatha prescription should remain the same as long as they are prescribed and dispensed as directed above. Individual patient insurance coverage varies including out of pocket cost. Please be sure to consult with the particular insurance plan.

Support

Q: How will Amgen support patients who are transitioning off of the Pushtronex® System?

- Amgen intends to support the transition of all existing patients and onboarding new patients to our #1 prescribed device the SureClick® autoinjector, or if they have a latex allergy, the prefilled syringe not made with natural rubber latex.
- We understand patients will need to transition from their current device. Amgen continues to support them through the transition. Resources include:
    - Dedicated transition support line through 844-Repatha (1-844-737-2842) prompt 2. Note, if patients select the option for a callback, they will be contacted promptly when the next line opens during operating hours.
    - Nurse Partner Support

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1 Koren, Lundqvist, Bolognese; et al. Anti-PCSK9 Monotherapy for Hypercholesterolemia: The MENDEL-2 Randomized, Controlled Phase III Clinical Trial of Evolocumab. J AM Coll Cardiol. 2014;63:2531-2540.
2 Robinson, Nedergaard, Rogers; et al. Effect of Evolocumab or Ezetimibe Added to Moderate- or High-Intensity Statin Therapy on LDL-C Lowering in Patients With HypercholesterolemiaThe LAPLACE-2 Randomized Clinical Trial. JAMA. 2014;311:1870-1882.
3 Raal, Stein, Dufour; et al. PCSK9 inhibition with evolocumab (AMG 145) in heterozygous familial hypercholesterolaemia (RUTHERFORD-2): a randomised, double-blind, placebo-controlled trial. Lancet. 2015;385:331-340.
4 Stroes, Colquhoun, Sullivan; et al. Anti-PCSK9 Antibody Effectively Lowers Cholesterol in Patients with Statin Intolerance. J Am Coll Cardiol. 2015;63:2542-2548.
5 Toth, Descamps, Genest; et al. Pooled Safety Analysis of Evolocumab in Over 6000 Patients From Double-Blind and Open-Label Extension Studies. Circulation. 2017;135:1819-1831

**Not inclusive of preparation and time for autoinjector to reach room temperature before injecting*

INDICATIONS

Repatha® is indicated:

• To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease

• As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C

• As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C

• As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of hyperlipidemia.

IMPORTANT SAFETY INFORMATION

• **Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to evolocumab or any of the excipients in Repatha®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.

• **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, have been reported in patients treated with Repatha®. If signs or symptoms of serious hypersensitivity reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.

• **Adverse Reactions in Adults with Primary Hyperlipidemia:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

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. Hypersensitivity reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common hypersensitivity 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 most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: 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 treated with Repatha® compared with 7.7% in patients that received placebo.

• **Adverse Reactions in Pediatric Patients with HeFH:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, headache, oropharyngeal pain, influenza, and upper respiratory tract infection.

• **Adverse Reactions in Adults and Pediatric Patient HoFH:** In a 12-week study in 49 patients, the adverse reactions that occurred in at least two patients treated with Repatha® and more frequently than placebo were: upper respiratory tract infection, influenza, gastroenteritis, and nasopharyngitis. In an open-label extension study in 106 patients, including 14 pediatric patients, no new adverse reactions were observed.

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

Please see full Prescribing Information.