# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors – Repatha Drug Quantity Management Policy – Per Days

- Repatha® (evolocumab subcutaneous injection [single-use prefilled syringes, single-dose prefilled SureClick® autoinjector, and Pushtronex® system] – Amgen)

**REVIEW DATE:** 09/21/2022

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## OVERVIEW

Repatha, a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor antibody, is indicated for the following uses:[1]

- **Established cardiovascular (CV) disease**, in adults to reduce the risk of myocardial infarction (MI), stroke, and coronary revascularization.
- **Primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH])**, in adults as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies to reduce LDL-C.
- **HeFH, in pediatric patients ≥ 10 years of age**, as an adjunct to diet and other LDL-C lowering therapies.
- **Homozygous familial hypercholesterolemia (HoFH)**, as an adjunct to other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients ≥ 10 years of age, to reduce LDL-C.

The safety and effectiveness of Repatha have not been established in pediatric patients with HeFH or HoFH who are < 10 years of age.[1]

## Dosing

- **Adults with established CV disease or primary hyperlipidemia:** The recommended dose is either 140 mg every 2 weeks (Q2W) or 420 mg once monthly by subcutaneous (SC) injection.[1] If switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.
- **Pediatric patients ≥ 10 years of age with HeFH:** The recommended dose is either 140 mg Q2W OR 420 mg once monthly by SC injection. If switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.
- **Adults and pediatric patients ≥ 10 years of age with HoFH**: The initial recommended dose is 420 mg once monthly by SC injection. The dose can be increased to 420 mg Q2W if a clinically meaningful response is not achieved in 12 weeks. Patients on lipid apheresis may initiate treatment with 420 Q2W to correspond with their apheresis schedule.

The LDL-lowering effect of Repatha may be measured as early as 4 weeks after initiation.

Repatha can be self-administered. For doses of 420 mg, the dose can be administered over 5 minutes by using the single-dose on-body infuser with prefilled cartridge, or by giving three injections consecutively (140 mg each) within a 30 minutes using the single-dose prefilled autoinjector or single-dose prefilled syringe.

## Availability

Repatha is available as a single-dose prefilled syringe (1 pack) or single-dose prefilled SureClick® autoinjector (1-, 2-, or 3-pack) containing 140 mg/mL.[1] It is also available as a single-dose Pushtronex® system (on-body infuser with prefilled cartridge) containing 420 mg/3.5 mL (1 pack).

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling and waste, and to address potential order entry error of Repatha. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

**Automation:** None.

**Drug Quantity Limits**

| Product | Strength and Form | Retail Maximum Quantity per 28 Days* | Home Delivery Maximum Quantity per 84 Days |
|---|---|---|---|
| Repatha® (evolocumab subcutaneous injection) | 140 mg/1 mL prefilled syringe | 2 mL (2 syringes) | 6 mL (6 syringes) |
| | 140 mg/1 mL SureClick® auto-injector | 2 mL (2 auto-injectors) | 6 mL (6 auto-injectors) |
| | 420 mg/3.5 mL Pushtronex® | 3.5 mL (1 Pushtronex unit) | 10.5 mL (3 Pushtronex units) |

*This is enough drug for patients to follow the recommended dosing schedule of 140 mg every two weeks or 420 mg once monthly. For coverage of additional quantities, a coverage review is required.

## CRITERIA

Repatha 140 mg/mL pen or syringe

1. If the patient has a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) and is using a dose of 420 mg per month, approve 3 pens or syringes (6 mL) per 28 days at retail or 9 pens or syringes (18 mL) per 84 days at home delivery.
2. If the patient has a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) and is using a dose of 420 mg every 2 weeks, approve 6 pens or syringes (12 mL) per 28 days at retail or 18 pens or syringes (36 mL) per 84 days at home delivery.

Repatha Pushtronex 420 mg/3.5 mL

1. If the patient has a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) and is using a dose of 420 mg every 2 weeks, approve 2 Pushtronex units (7 mL) per 28 days at retail or 6 Pushtronex units (21 mL) per 84 days at home delivery.

## REFERENCES

1. Repatha® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen, September 2021.