



### Repatha® (evolocumab) – New Formulation Approval

- On July 11, 2016, [Amgen announced](#) the [FDA approval](#) of [Repatha \(evolocumab\)](#) Pushtronex™ system (on-body infusor with prefilled cartridge), a hands-free device that delivers 420 mg of Repatha in a single-dose.
- The Pushtronex device adheres to the body, and patients are hands free during administration. Patients are able to perform moderate physical activities (such as walking, reaching or bending) as the 420 mg of Repatha is delivered subcutaneously (SC).
- Repatha is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C); and as an adjunct to diet and other LDL-lowering therapies for the treatment of patients with homozygous familial hypercholesterolemia (HoFH), who require additional lowering of LDL-C.
  - The effect of Repatha on cardiovascular morbidity and mortality has not been determined.
- [Praluent™ \(alirocumab\)](#) was the first PCSK9 inhibitor approved in July 2015. Aside from HoFH, Praluent has the same indications as Repatha.
- Repatha is currently available as a 140 mg/mL solution in a single-use prefilled syringe and as a 140 mg/mL solution in a single-use prefilled SureClick® autoinjector.
- For adults with HeFH or ASCVD, the recommended dose of Repatha is 140 mg SC every 2 weeks or 420 mg SC once a month. For adults with HoFH, the recommended dose is 420 mg SC once a month. The 420 mg dose of Repatha can be administered:
  - over 9 minutes by using the single-use on-body infusor with prefilled cartridge, or
  - by giving 3 injections consecutively within 30 minutes using the single-use prefilled autoinjector or single-use prefilled syringe.
- Praluent is administered every two weeks in a dose of 75 mg – 150 mg depending on LDL-C levels. It is available as a 75 mg/mL or 150 mg/mL single-dose prefilled pen and a single-dose prefilled syringe.
- The wholesale acquisition cost (WAC) of Repatha is \$14,100 annually, whether it is delivered monthly via Pushtronex system or every two weeks via SureClick autoinjector.
- Amgen plans to launch Repatha Pushtronix by August 2016.



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