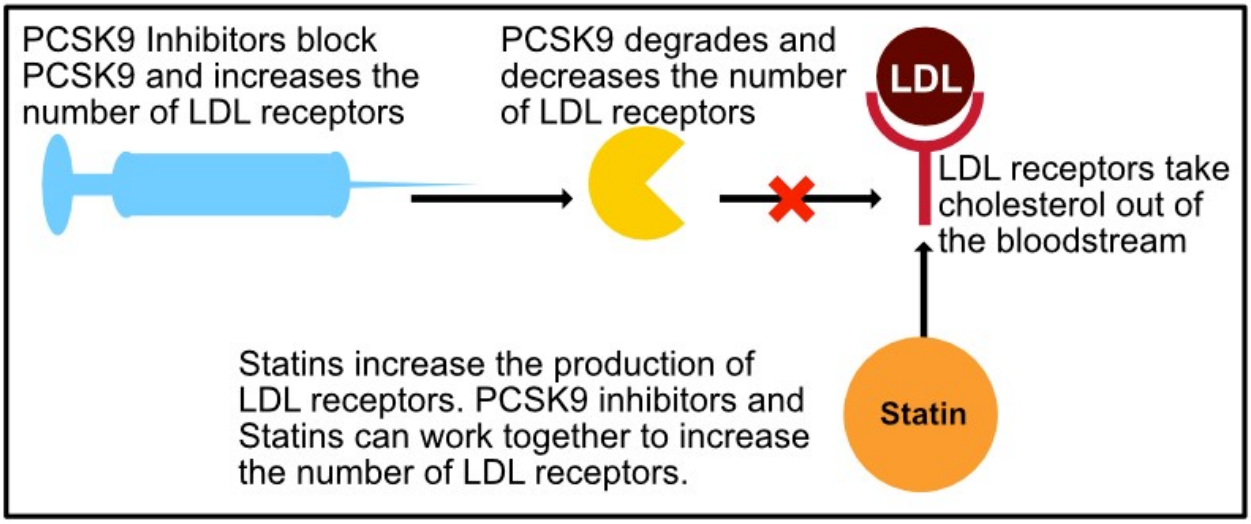
## New LDL lowering medications approved by the FDA.

This summer, the FDA approved two medications from a new class of drugs called the PCSK9 Inhibitors. These medications lower LDL by 40-60% but have not demonstrated the ability to reduce cardiovascular events. Clinical trials are ongoing to determine if the addition of PCSK9 Inhibitors to Statin therapy will improve outcomes. The medications are well tolerated but very expensive.
This summer, the FDA approved two new medications for lowering LDL cholesterol:
• Praluent (alirocumab) 75-120mg subcutaneously every 2 weeks
• Repatha (evolucumab) 140mg subcutaneously every 2 weeks or 420mg monthly

The PCSK9 Inhibitors are human monoclonal antibodies that inactivate a protein called *Proprotein convertase subtilisin kexin type 9*. Inhibition of PCSK9 results in a reduction of LDL cholesterol levels by 40-60%. When added to a statin, the LDL lowering is even greater.

**How PCSK9 Inhibitors work**




PCSK9 Inhibitors are approved for use in addition to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or patients with clinical atherosclerotic cardiovascular disease such as heart attacks or strokes, who require additional lowering of LDL cholesterol.

The approval of these medications is based on their ability to lower LDL cholesterol.
***It is not known if these medications will reduce cardiovascular events***.
Ongoing clinical trials are evaluating the clinical outcomes of LDL lowering with PCSK9 inhibitors. The first of these studies is expected to be completed in 2017.

Side effects: nasopharyngitis, itching, flu, injection site reactions, and allergic reactions.

Cost is currently between $14,000 - $15,000 per patient per year.

**Recommended reading:**

Everett BM, Smith RJ, Hiatt WR. (2015, October 22). Reducing LDL with PCSK9 Inhibitors - the Clinical Benefit of Lipid Drugs. NEJM, 373(17), 1588-1590.

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**Source**: *Hot Clinical Topics* Newsletter by the Indian Health Service (IHS) Division of Diabetes Treatment and Prevention (DDTP)