Praluent® (alirocumab), the first of a new class of drugs to treat high cholesterol, has been approved. A second, Repatha™ (evolocumab), has also been approved. The new drugs have been shown to have a potent effect on LDL (low-density lipoprotein) cholesterol, but definitive studies about their effect on clinical outcomes won’t be complete until 2017. Current cholesterol treatment is dominated by low-cost generic statins. The new entrants—known as PCSK9 inhibitors—are injectables.

- **Praluent**: $40 per day
- **Praluent for 28 days**: $1,120
- **Praluent for a year**: $14,600
- **The U.S. wholesale acquisition cost of Praluent is $40 per day.** Because these are maintenance medications, people will take them for years, amplifying cost concerns.

Praluent is indicated for patients with a relatively rare hereditary condition called heterozygous familial hypercholesterolemia and for those with established coronary artery disease who need additional cholesterol lowering to reduce their heart risk.

In 2013, when statins were the primary treatment, the American College of Cardiology (ACC) and the American Heart Association (AHA) released cholesterol treatment guidelines that were far less specific than earlier recommendations that physicians treat patients to reach a target goal. These newer guidelines are based on risk stratification and recommend treating high-risk patients with high potency cholesterol-lowering therapy. That could complicate treatment choices with these new drugs.

**Key question is the rate of uptake:** Which patients will receive prescriptions for the new drugs?

 CVS Health has developed clear guidelines around how to appropriately manage utilization of these agents. 

 CVS Health has engaged providers to review the management challenges and to reach consensus on how to implement management criteria.

 CVS Health will carefully assess patterns of prescribing to evaluate appropriateness of use and help support our clients’ clinical and budgetary goals.

**The Management Challenge**

As noted by CVS Health Research Institute experts in the Journal of the American Medical Association (JAMA), current guidelines could inadvertently limit the ability of payors to manage utilization of these high-cost agents. In order to help payors manage their pharmacy benefit:

- **73.5 Million** have high cholesterol
- **8 to 10 Million** have established coronary artery disease and need additional cholesterol lowering
- **620,000** have familial hypercholesterolemia

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<table>
<thead>
<tr>
<th>Condition</th>
<th>Number</th>
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<tbody>
<tr>
<td>High cholesterol</td>
<td>73.5 Million</td>
</tr>
<tr>
<td>Familial hypercholesterolemia</td>
<td>620,000</td>
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