Pharmacy Pipeline Alert:

PCSK9 Inhibitors

Place in Therapy

The American College of Cardiology (ACC) and American Heart Association (AHA) recommend high intensity statins (atorvastatin or CRESTOR) as first-line treatment of high cholesterol.

- Statins have over 25 years of data to support their efficacy and safety, including data showing they reduce risk of heart attack, stroke, and cardiovascular death.
- High intensity statins reduce LDL cholesterol levels by 40% to 60%.
- Statins may cause side effects such as muscle pain and weakness. About 10% of patients have difficulty tolerating statins.

The ACC and AHA have not yet included PCSK9 inhibitors in their cardiovascular guidelines.

- PCSK9 inhibitors decrease LDL cholesterol by 55% to 60%.

Experts recommend that PCSK9 inhibitors should be treated as an alternative to statins for patients who cannot reach LDL cholesterol goals on statins alone or who are intolerant to more than one statin.

What are PCSK9 Inhibitors?

PCSK9 inhibitors are a new class of specialty drugs that manage high cholesterol by enhancing the liver’s ability to remove LDL (“bad”) cholesterol from the body. They are self-injected by patients once or twice a month.

Two PCSK9 inhibitors have been approved by the FDA for treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease.

- REPATHA (evolocumab)
- PRALUENT (alirocumab)

REPATHA has also been approved for homozygous familial hypercholesterolemia. The PCSK9 inhibitors are very similar with regard to both safety and effectiveness, and study results show patients tolerate them very well.

What makes PCSK9 inhibitors so impactful?

- The PCSK9 inhibitors shift treatment for high cholesterol from traditional drugs (statins) to the realm of high-cost specialty medications.
- The possible patient population for PCSK9 inhibitors is immense, estimated at 3.5 to 15 million total eligible patients in the US.
- PCSK9 inhibitors are priced at over $14,000 per year, compared to $100-$200 annually for high intensity statins which are the current standard of care.
- Patients are likely to remain on PCSK9 inhibitors for life.

What questions remain unanswered?

Do PCSK9 inhibitors decrease the risk of negative health events like heart attack, stroke, or death? The answer to that question has not yet been determined, though clinical trials are in progress. Results are expected in 2017 at the earliest.

How is HealthPartners managing PCSK9 Inhibitors?

HealthPartners negotiated heavily with the PCSK9 inhibitor drug manufacturers to ensure favorable pricing. As an outcome of those negotiations, HealthPartners will include REPATHA on the drug formulary. PRALUENT will be non-formulary.

The HealthPartners Pharmacy & Therapeutics Committee approved thorough clinical criteria to ensure appropriate and safe use for both PCSK9 inhibitors. HealthPartners reviews all PCSK9 inhibitor requests in a daily review group of pharmacists and medical directors. Approvals are initially limited to 3 months, and continued use requires evidence of a clinically significant response to treatment.

What does this mean for clients?

Clients may see an increased pharmacy spend for Cholesterol medications as the uptake of PCSK9 inhibitors accelerates. Clients can be assured that HealthPartners has developed thorough clinical criteria in consultation with cardiology experts to ensure that PCSK9 inhibitors are used appropriately and effectively. HealthPartners pharmacists and medical directors review all requests carefully prior to approval.