A new class of cholesterol drugs. But are they worth it?

By ACSH Staff — July 27, 2015

Since 1987, the year in which the first of the statin-class drugs, Mevacor/lovastatin, was approved, statin drugs have been the standard of care for reducing high cholesterol, especially LDL (bad) cholesterol. Mevacor was eventually left in the dust as new, more potent statins became approved, most notably Pfizer’s Lipitor (atorvastatin), which was approved in 1996, and went on to become the best selling drug ever.

Lipitor has been shown to be effective in both primary and secondary [1] (after a cardiovascular event has occurred) prevention of cardiovascular disease and stroke, although its value in reducing deaths in healthy people (that is, for primary prevention) has been questioned [2].

Now, there is a new option for reducing LDL cholesterol. Regeneron/Sanofi and Amgen each received FDA approval for antibody-based drugs that work by an entirely different mechanism. The antibodies bind to, and inactivate a protein called PCSK9, which is involved in the regulation of circulating LDL in the blood. As we discussed in April [3], inhibition of PCSK9 prevents the degradation of LDL receptors. Since the function of LDL receptors is to remove LDL from the blood, more receptors results in less circulating LDL.

The antibodies work very well [4]. When added to statin therapy, LDL was reduced by 61% approximately twice that of statins alone. But, antibodies are not given orally they are injected. And, whatever pain might come from the injection is insignificant when compared to the pain of paying for these new drugs about $15,000 per year. By contrast, atorvastatin can be purchased for $17 per month at Costco [5]. Quite a difference. Is it worth it?
Dr. Josh Bloom, the director of chemical and pharmaceutical sciences at the American Council on Science and Health, is skeptical: Prices for drugs, especially breakthrough drugs to treat hepatitis C, have been a top news story lately. Gilead's Sovaldi, at $1,000 per pill $84,000 per course has attracted the most attention (although Gilead recently announced [6] that this price would be cut in half). But, it is reasonable to argue that the new LDL drugs Amgen's Repatha (evolocumab), and Sanofi/Regeneron's Praluent (alirocumab) are actually quite a bit more expensive.

Why? He continues, The hep C drugs are a one-time expense. Then the infection is gone for good absent re-exposure to the virus. But, Repatha and Praluent are taken chronically. After about three years of use, these drugs will pass the cost of Sovaldi.

Right now, the PCSK9 drugs are approved only for patients with hereditary high cholesterol who do not attain desired LDL levels from the maximum tolerated dose of statins, and those who have cardiovascular disease and require additional LDL lowering. The drugs are not approved for routine use in healthy patients who are benefitting from statins, although many cardiologists said that they would prescribe the drugs for off-label use [7] for patients who do not meet the approval criteria.

Dr. Bloom thinks that this is a tough call: Keep in mind that no PCSK9 inhibitor has ever been demonstrated to prevent worsening cardiovascular disease or decrease death from heart attack or stroke. This is inferred from the effect of statins, but will not be known until it is proven clinically. In my opinion, it is not unreasonable to wait and see whether clinical trials demonstrate a robust effect on morbidity and mortality from cardiovascular disease before trying these new drugs, especially off-label. This will probably turn into an interesting battle between doctors and healthcare providers.

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