Not All Expensive Drugs Are Equal

By Josh Bloom — August 31, 2015

You could see this coming a mile away.

As we wrote in June [1], the approval of one (now two [2]) cholesterol-lowering drugs that are very different from statins the current standard of care was going to open up a new front in the ongoing war between pharmacy benefits managers, and doctors and their patients.

It was inevitable. and also unprecedented, since the two new drugs, Amgen’s Repatha, and Sanofi/Regeneron's Praluent, have a profound effect in lowering cholesterol especially LDL (bad) cholesterol.

But the new drugs are not pills. They are antibodies one class of drugs that are called biologics protein drugs that are derived from living organisms. Biologics must be injected, since they cannot withstand the environment in the stomach. This is inevitable with protein drugs. The body treats them just like other proteins, such as those derived from food. They are rapidly broken down into the amino acid components that make up all proteins.

Biologics are more difficult to make and purify than pills, and their costs reflect this. And most of them still have patent protection, which almost always means higher prices.

But, the real issue here is who should use them, and who should pay for them. Compared to statins, such as Lipitor all of which, except one, have generic copies they do not cost $20 per month. Their price tag will be about $1,000 per month.

Further complicating this matter is the fact that statins are pretty good drugs.

Lipitor, for example, is effective in reducing cholesterol, and has been shown to be effective in both primary and secondary [3] (after a cardiovascular event has occurred) prevention of cardiovascular disease and stroke.
Therefore, in addition to the cost of the new drugs, an obvious question is whether the statins are "good enough," or whether the antibody drugs will be shown to be so superior in preventing cardiovascular morbidity and mortality that they will become the new standard of care.

Pharmacy benefit managers do not want this. The new drugs are not approved for most of the people who are currently taking statins. Rather, the approval is for patients with hereditary high cholesterol who do not attain desired LDL levels from the maximum tolerated dose of statins, and those who already have cardiovascular disease and require additional LDL lowering.

But, cardiologists are so excited by the magnitude of LDL reduction that many of them want to use the drug off-label for patients who have elevated cholesterol and respond well to statins. This is where it gets messy.

Even messier: Neither of the new drugs has been shown to prolong life or reduce cardiovascular disease. This is extrapolated from the known cardioprotective effects of the statins. The antibodies, just like statins before trials showed reduced disease and deaths, have effectively been approved based on a biomarker LDL cholesterol.

For example, Dr. Harlan Krumholz, a cardiologist at Yale said, We are in a period of exuberant enthusiasm about these drugs. We could just be performing cosmetic surgery on a lab value.

Clinical data based on defined endpoints will not be available until 2017, so what to do before that is hotly debated.

The comparison of Repatha and Praluent with the best known "expensive drug" Gilead's Sovaldi, a breakthrough cure for hepatitis C is inevitable. But it's not a valid one.

Why? Sovaldi, which is listed at $1,000 per pill $84,000 for a full course (although it really sells for about half that) is a one-time expense. Then the hepatitis C infection is gone for good. But, Repatha and Praluent are taken chronically. After about four years of use, these drugs will surpass the cost of Sovaldi.

This is all unknown territory. No one can predict how it will play out. But whatever the result, it's going to be a precedent-settling battle, and probably an ugly one at that.

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