Managed Care Commentary: MCOs face new challenges

By Cary Sennett, MD, PhD

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The management of hypercholesterolemia continues to be a topic of active research—reflecting, no doubt, the enormous burden of cost and illness that cardiovascular disease (CVD) represents; the importance of hypercholesterolemia as a risk factor; and the gap between current risk and minimum risk in the US population.

This research is providing new insights to guide clinical management. To begin with, we appreciate how complex are the physiologic systems that govern serum cholesterol—and are challenged to consider interventions to address multiple components of those systems to achieve desired results. More recently, we have come to understand that historical targets for low-density lipoprotein (LDL) cholesterol—especially in patients with (or at high risk for) CVD—may not be low enough. Finally, we have recognized the expansion of the therapeutic armamentarium—in particular, the efficacy of a cholesterol absorption inhibitor, such as ezetimibe, in combination with a statin, as a means by which to achieve LDL cholesterol control.

These findings suggest that cholesterol control targets are moving—lower levels seem to lead to better outcomes and seem increasingly achievable. This has real implications for managed care organizations (MCOs). The challenges these imply are even more noteworthy, given evidence that many patients are not managed even to current National Cholesterol Education Program goals.

There is, in these findings, great opportunity for MCOs to improve care. At the same time, there are very real issues on the financial front. Expansion of the group of patients at high risk for CVD increases the number of individuals eligible for (what is usually costly) pharmaceutical therapy. Furthermore, the lowering of targets for control will increase the intensity (and the cost) of that therapy.

While the use of higher doses of statins may have little effect on cost, the addition of new agents (like ezetimibe) that act synergistically could increase cost quite significantly.

How many patients will be prescribed ezetimibe is difficult to know. But with "usual care" achieving target less than 50% of the time (data elsewhere in this supplement)—and with a clear physiologic rationale for intervention elsewhere in the cholesterol pathway—the likelihood that ezetimibe plus a statin will become the standard of care is very high. Although that should lead to significantly better control—and better clinical outcomes—it seems certain that it will lead to higher costs in the short run. Whether the intriguing results from Sweden, that suggest lower health care costs for CVD, will persist and generalize remains to be seen. For the moment, it seems only that it will exacerbate a health care cost problem that is already formidable.

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How can MCOs respond? I think they need to lay out—and communicate to their networks and to their members—rational protocols for cholesterol management. In addition, they need to consider what mechanisms they have to encourage and enable their adoption and use. Those protocols must map out treatment paths for patients with hypercholesterolemia that drive toward targets but assure that medications are added rationally and cost-effectively.

Statins will remain the first-line therapy—ideally with diet and exercise. Guidelines will need to consider when to advance statin therapy and when to add other agents. There will be enthusiasm, no doubt, to add ezetimibe—early and often. MCOs will need to provide guidance to assure that potentially cost-effective alternatives (bile acid sequestrants, niacin) are appropriately considered.

This will mean education and judicious use of incentives. Pharmacy benefits should provide members with incentives to move along the most cost-effective treatment path. Perhaps no aspect of care, though, is more amenable to measurement-based systems to influence physician decisions. The outcome of cholesterol management is measurable (and obtainable relatively inexpensively from laboratory datasets), and the cost of achieving those outcomes is readily obtainable from claims data.

The opportunity for feedback—or value-based incentives—is clear. In combination with education (of members and physicians), the potential to rationalize but also to improve care should be clear as well. ■

Aggressive lipid lowering superior to usual care in a real-world setting: The ALLIANCE study

NEW ORLEANS—In a real-world setting of managed care or Veterans Administration hospitals, more patients with coronary heart disease randomized to an aggressive lipid-lowering regimen achieved their low-density lipoprotein (LDL) cholesterol target levels compared with patients receiving usual care. The aggressive treatment group also had fewer cardiac events. The Aggressive Lipid-Lowering Initiation Abates New Cardiac Events (ALLIANCE) study enrolled 2442 patients for 4 years. The aggressive treatment group received 10 to 80 mg of atorvastatin daily, titrated to achieve an LDL cholesterol level of <80 mg/dL, or up to the maximum dose. No concomitant lipid-lowering drugs were allowed.

The usual care group was treated with cholesterol-lowering therapies (eg, drugs, weight loss, exercise, and diet modification) according to standard clinical practice. They were allowed atorvastatin after its approval in 1997.

The primary end point of the trial was the time to the composite end point of cardiac death, nonfatal myocardial infarction (MI), resuscitated cardiac arrest, cardiac revascularization, or unstable angina requiring hospitalization. Principal investigator Donald B. Hunninghake, MD, professor of medicine and pharmacology at the University of Minnesota, said atorvastatin allowed 72% of patients to reach their recommended LDL cholesterol goals of <100 mg/dL compared with only 40% of patients on usual care. From an initial baseline LDL cholesterol level of 147 mg/dL, the atorvastatin group achieved a final level of 95 mg/dL versus 111 mg/dL for the usual care group ($P < .0001$).

Patients taking atorvastatin experienced 47% fewer nonfatal MIs ($P = .0002$) and a 17% reduction in overall negative cardiovascular outcomes, including cardiac death, MIs, strokes, and hospitalizations, compared with patients randomized to usual care over the course of the trial ($P = .02$).

Dr Hunninghake said that this trial shows that LDL cholesterol reductions can also be achieved outside of a clinical trial. He emphasized that the 16-mg/dL difference in LDL cholesterol levels between the 2 groups "resulted in very significant benefit." He predicted that this strategy could substantially lower the total burden of coronary disease in this country.

Lower costs when LDL goals attained—Swedish study

In another study presented at the meeting, Jan Stållhammar, MD, and colleagues from the Karolinska Institute in Stockholm, Sweden, showed that 70% of the 9789 patients receiving lipid-lowering therapy in 29 primary care centers in Sweden between 1993 and 2003 did not achieve their LDL cholesterol target based on a review of their medical records. The population included both primary and secondary prevention patients.

Coauthor Linus Jönsson, an internist at the St. Göran Hospital and a researcher at Stockholm Health Economics, said, "There is a trend here to a lower cost of care especially for inpatient care related to cardiovascular disease for those patients who had attained the treatment goal."

Dr Jönsson said charts indicated many patients did not have a cholesterol measurement after the initiation of treatment, so they could not even be included in the study.

A similar lack of monitoring and treatment adjustments may play a role for those patients in the study who did not reach their LDL cholesterol goal. ■