Managing Dyslipidemia in Primary Care with Restricted Access to Lipid-Modifying Therapy

John T. Lynch, MPH; Catherine E. Cooke, PharmD, BCPS, PAHM; Jonathan Rosen, MD; Sanjay Gandhi, PhD; Michael F. Bullano, PharmD

**Background:** Many patients with dyslipidemia do not achieve goal low-density lipoprotein cholesterol levels. The barriers to achieving goal include inadequate assessment of cardiovascular risk status, medication cost, formulary restrictions, patient lack of adherence, and inadequate counseling time. Removing barriers may improve goal attainment and reduce the risk for cardiovascular events.

**Objective:** To identify opportunities to improve dyslipidemia management in primary care by examining low-density lipoprotein cholesterol goal attainment in patients with unrestricted or restricted access to lipid-modifying therapy.

**Method:** A total of 5936 adult patients from a primary care practice with a low-density lipoprotein measurement were categorized by coronary heart disease risk into 1 of 4 lipid-modifying therapy groups: unrestricted (fluvastatin, lovastatin, pravastatin, or simvastatin monotherapy); restricted (atorvastatin, rosuvastatin, or simvastatin/ezetimibe fixed-dose combination); other (lipid-modifying combination statin therapy or a nonstatin lipid-modifying therapy); and no lipid-modifying therapy. The primary outcome was low-density lipoprotein cholesterol goal attainment by lipid-modifying therapy group. Logistic regression identified associated demographic and clinical factors.

**Results:** In this cohort, 78.1% of the patients achieved low-density lipoprotein cholesterol goal levels. Overall goal attainment rates were lower in the high and very high coronary heart disease risk categories, at 52.6% and 31.6%, respectively. For patients at elevated coronary heart disease risk (high or very high), the rates of low-density lipoprotein cholesterol goal attainment were 14 to 16 percentage points higher for patients receiving restricted lipid-modifying therapy compared with patients receiving unrestricted lipid-modifying therapy (high coronary heart disease risk: 68% vs 52%, respectively; very high coronary heart disease risk: 42% vs 28%, respectively). Increasing age, male sex, and use of restricted lipid-modifying therapy were significantly associated with improved low-density lipoprotein cholesterol goal attainment. Of the 1298 patients who were not at low-density lipoprotein cholesterol goal attainment. Of the 1298 patients who were not at low-density lipoprotein cholesterol goal attainment, 54.1% were not receiving any lipid-modifying therapy. For each coronary heart disease risk category, there was a significantly higher percent utilization of unrestricted lipid-modifying therapy compared with restricted lipid-modifying therapy ($P < .001$).

**Conclusion:** A significant number of patients at elevated risk for coronary heart disease remain untreated or have low-density lipoprotein cholesterol levels above target. Removing barriers to the use of restricted lipid-modifying agents in patients at risk for heart disease provides an opportunity to improve low-density lipoprotein cholesterol levels.
Managing Dyslipidemia with Restricted Access to Lipid-Modifying Therapy

The National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III guidelines and 2004 update stress the importance of achieving low-density lipoprotein cholesterol (LDL-C) goals in patients with dyslipidemia.1,2 Patients at higher coronary heart disease (CHD) risk have lower LDL-C goals and require more aggressive lipid-modifying therapy to achieve these goals than patients at lower CHD risk. Reducing LDL-C with lipid-modifying therapy in patients at higher CHD risk yields greater relative benefits in reducing the risk of CHD events compared with such treatment in patients at lower CHD risk.1,3

Despite awareness of the importance of appropriately managing patients with dyslipidemia, evaluations of current practice reveal that only about 40% to 75% of all patients with dyslipidemia achieve goal LDL-C levels.4,5 The likelihood of goal attainment is inversely associated with cardiovascular (CV) risk.5,6 Reported rates of LDL-C goal attainment range from 50% to 98% in patients at lower CHD risk,5,7,8 and from 10% to 70% in patients at higher CHD risk.5,8,9 Only about 20% to 30% of patients at very high risk achieve goal LDL-C levels.10

Several barriers to achieving goal LDL-C levels have been reported in the literature, including patient, physician, and system barriers.11-14 A study of primary care providers in the United States identified barriers to initiating statin therapy, such as concerns about cost, patient adherence, and lack of adequate counseling time.11 In a managed care organization (MCO), cost and adherence were also of concern and were found to be inversely related.12 Non-Medicaid MCO patients with higher copayments were more likely to discontinue statin therapy sooner than those with lower copayments.12

MCOs use preferred drug lists (PDLs) to have an impact on prescribing. In one study of Medicaid recipients, significant decreases (range, 65%-97%) were found in the proportion of statin prescriptions filled for off-PDL (ie, restricted) medicines after the adoption of a Medicaid PDL.11 Physicians have difficulty assigning CHD risk status and following guideline-recommended interventions.11 Other studies have confirmed that physicians are unaware of national guidelines for statin use.12 When physicians underestimate CHD risk status, drug therapy restrictions may result in undertreatment of patients with dyslipidemia, especially those at higher CHD risk.

Removing barriers to achieving nationally recommended LDL-C goals in patients at increased CHD risk may reduce the risk of CV events. The objective of our study was to identify opportunities to improve dyslipidemia management in primary care by examining LDL-C goal attainment in patients with unrestricted and restricted access to lipid-modifying therapy.

**KEY POINTS**

- Despite widespread awareness of the importance of lipid management in patients with dyslipidemia, many patients do not achieve target cholesterol levels.
- Previous studies have reported barriers to achieving goal LDL-C levels, which involve patients, physicians, and the healthcare system as a whole.
- This study included 5936 patients with medical and pharmacy coverage who had an LDL-C measurement and were either receiving different types of lipid-modifying therapies or no therapy.
- Pharmacy coverage restricted the initial lipid-modifying therapy with a step-edit on atorvastatin, rosuvastatin, and simvastatin/ezetimibe fixed-dose combination.
- Cholesterol goal attainment was unaffected by the type of lipid-modifying therapy used by patients at low risk, but in patients at higher risk, more patients reached LDL-C goal with one of the drugs included in the restricted coverage category.
- This finding has implications to payers’ drug coverage decisions and clinicians’ prescribing decisions.

**Methods**

**Study Population**

Patients were retrospectively identified from the largest primary care group practice in Connecticut, which serves approximately 320,000 patients. In addition to the internal patient care database, this primary care practice routinely receives data on hospitalizations, emergency department visits, and pharmacy claims for their patients insured by a regional MCO.

To be eligible for inclusion in this study, patients had to be insured by the regional MCO, have at least 1 office visit to the primary care group practice, and have at least 1 LDL-C measurement during 2007. LDL-C values reported from the laboratory were calculated by using a formula that includes total cholesterol, high-density lipoprotein cholesterol (HDL-C), and triglycerides; patients had to have these additional lipid parameters available for CHD risk stratification. Patients were excluded if they were younger than age 18 years on January 1, 2007, or if they had no associated pharmacy claims data.

**Data Collection**

Data from the primary care practice and managed care claims databases during 2007 were combined to create individual patient profiles. These patient profiles...
Coronary Heart Disease Risk Status

Patients were stratified into CHD risk categories of low, moderate, high, and very high using a modified NCEP ATP III approach (see Appendix at www.AHDBonline.com). International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes, Current Procedural Terminology, version 4 (CPT-4) codes, and pharmacy claims data were used to stratify patients by hierarchy into the highest risk category.

Patients were considered to be at high CHD risk (goal LDL-C <100 mg/dL) if they had any ICD-9-CM codes for myocardial infarction, other ischemic heart disease, angina pectoris, symptomatic carotid artery disease, peripheral arterial disease, abdominal aortic aneurysm, or diabetes mellitus; any CPT-4 claims for coronary artery bypass graft or percutaneous transluminal coronary angioplasty; or any pharmacy claims for antidiabetic agents. Patients identified as having high CHD risk (clinical CHD) were considered to be at very high CHD risk (goal LDL-C <70 mg/dL) if they also had claims indicating diabetes, intermediate coronary syndrome, or dysmetabolic syndrome X (metabolic syndrome). Patients with diabetes must also have had other comorbid codes within the high CHD risk category to be classified as having very high CHD risk.

The remaining patients with at least 2 risk factors were considered to be at moderate risk (goal LDL-C <130 mg/dL). Risk factors included age ≥45 years for men or age ≥55 years for women, HDL-C <40 mg/dL, and hypertension as defined by ICD-9-CM codes or by pharmacy claims for an antihypertensive medication. Patients who did not meet the criteria for very high, high, or moderate CHD risk categories were placed into the low CHD risk category (goal LDL-C <160 mg/dL category).

Outcome Measures

The primary outcome measure was the percentage of patients achieving LDL-C goals. In accordance with the NCEP ATP III guidelines and the 2004 update, LDL-C goals were defined as <160 mg/dL for the low CHD risk category, <130 mg/dL for the moderate CHD risk category, <100 mg/dL for the high CHD risk category, and <70 mg/dL for the very high CHD risk category. For patients with more than 1 LDL-C value, the most recent value was utilized. An analysis was conducted in patients who had not achieved goal LDL-C values to identify opportunities to improve dyslipidemia management in this practice.

Dyslipidemia Treatment Patterns

The use of lipid-modifying therapy was determined from the pharmacy claims and grouped based on the mechanistic types of lipid-modifying therapy and expected patterns of therapy (eg, monotherapy or combination therapy). Types of lipid-modifying therapy included statins (atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, or simvastatin); simvastatin/ezetimibe fixed-dose combination; fibrates (fenofibrate or gemfibrozil); niacin; cholesterol absorption inhibitors (ezetimibe); and bile acid sequestrants (cholestyramine or colestipol).

Patients receiving a statin as monotherapy or the simvastatin/ezetimibe fixed-dose combination were further classified into “unrestricted” and “restricted” categories.

The unrestricted and restricted lipid-modifying therapy categories were based on a step-therapy program instituted by the regional MCO during the study examination period (ie, 2007). As part of the program, patients were required to “step through” (ie, cumulative pharmacy fills for at least a 90-day supply) therapy with either lovastatin or simvastatin. After this trial, patients would become “eligible” to receive atorvastatin, rosuvastatin, or simvastatin/ezetimibe fixed-dose combination therapy under their prescription benefit.

For circumstances in which patients were prescribed a restricted medication and elected not to follow the step-therapy program, they would pay the full cost of their restricted lipid-modifying therapy medication out of pocket. Accordingly, the restricted statin lipid-modifying therapy group included patients receiving atorvastatin or rosuvastatin or simvastatin/ezetimibe fixed-dose combination.

The unrestricted statin group contained patients who were receiving fluvastatin, lovastatin, pravastatin, or simvastatin monotherapy.

Patients observed taking more than 1 lipid-modifying therapy type (ie, multipill combination therapy) or a non–statin-containing lipid-modifying therapy were categorized into the “other” group.

The last group—no lipid-modifying therapy—included patients who had no prescription claims observed for any lipid-modifying therapy type. For patients who switched therapy, the most recent prescription was used to categorize into a lipid-modifying therapy group.
Statistical Analysis

Descriptive statistics were used to report sample characteristics, treatment patterns, and NCEP ATP III LDL-C goal attainment rates. Categorical variables are reported as frequencies and percentages, and continuous variables are reported as mean ± standard deviation. Chi-square tests were used to compare LDL-C goal attainment among the lipid-modifying therapy groups, and demographic and clinical factors associated with LDL-C goal attainment were evaluated using logistic regression. Statistical significance was set at an accepted alpha (P < .05). All statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC) and Stata version 8.1 (Stata Corporation, College Station, TX).

Results

Member Demographics

A total of 5936 patients met the study inclusion criteria, which represented 17% of the patients seen in this large group practice who were also insured by the regional MCO (Figure 1). The baseline characteristics of these patients are presented in Table 1. In this primary care setting, the majority of patients were categorized as having low CHD risk (58.6%). A total of 2458 patients (41.4%) were at an elevated CHD risk: 24.6% at moderate, 14.9% at high, and 1.9% at very high CHD risk. Hypertension was the most common risk factor, found in 45.3% of patients. Diabetes was present in 12.2% of the cohort, which automatically placed these patients into high or very high CHD risk categories.

Of the 1626 patients who received statin monotherapy or a simvastatin/ezetimibe fixed-dose combination, 986 and 658 patients were categorized as unrestricted and restricted lipid-modifying therapy, respectively (Table 2). This equates to an approximate 60/40 split in the 1626 patients receiving statin-based therapy. Unrestricted lipid-modifying therapy utilization was higher than restricted lipid-modifying therapy for each CHD risk category. Of note, 3849 patients (64.8%) were not treated with any lipid-modifying therapy; most of them were in the low CHD risk category (n = 2739).

LDL-C Goal Attainment

A total of 4638 patients (78.1%) met their LDL-C goal levels. As CHD risk increased, the percentage of patients achieving goal LDL-C decreased (low, 90.8%; moderate, 67.1%; high, 52.6%; very high, 31.6%). A similar pattern of decreasing goal attainment with increasing CHD risk was found in patients in the other lipid-modifying therapy group (low, 84.7%; moderate, 64.0%; high, 58.1%; very high, 31.3%).

For all CHD risk categories except the lowest, goal achievement increased as drug therapy progressed from

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients N (%)</th>
</tr>
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<tbody>
<tr>
<td>Age (yrs), mean ± SD [range]</td>
<td>44.9 ± 13.5 [18-92]</td>
</tr>
<tr>
<td>Men, any age</td>
<td>2984 (50.3)</td>
</tr>
<tr>
<td>Men ≥45 yrs</td>
<td>2169 (36.5)</td>
</tr>
<tr>
<td>Women, any age</td>
<td>2952 (49.7)</td>
</tr>
<tr>
<td>Women ≥55 yrs</td>
<td>996 (16.8)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Diabetes or on antidiabetic medication</td>
<td>724 (12.2)</td>
</tr>
<tr>
<td>Hypertension or on antihypertensive therapy</td>
<td>2688 (45.3)</td>
</tr>
<tr>
<td>CHD risk status</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>3478 (58.6)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1461 (24.6)</td>
</tr>
<tr>
<td>High</td>
<td>883 (14.9)</td>
</tr>
<tr>
<td>Very high</td>
<td>114 (1.9)</td>
</tr>
</tbody>
</table>

*Data on ethnicity not collected. Total patients = 5936. LDL-C indicates low-density lipoprotein cholesterol.
For patients at elevated CHD risk (high or very high), the rates of LDL-C goal attainment were 14 to 16 percentage points higher for patients receiving restricted lipid-modifying therapy compared with patients receiving unrestricted lipid-modifying therapy (high CHD risk: 68%-52%; very high CHD risk: 42%-28%).

Factors in the multivariable logistic regression model that were significantly associated with improved LDL-C goal attainment were increasing age (odds ratio, 1.04; 95% confidence interval [CI], 1.02-1.06), male sex (odds ratio, 1.37; 95% CI, 1.07-1.76), and use of restricted lipid-modifying therapy (odds ratio, 1.46; 95% CI, 1.14-1.86). Patients at moderate (odds ratio, 0.34; 95% CI, 0.25-0.48), high (odds ratio, 0.17; 95% CI, 0.12-0.23), and very high (odds ratio, 0.05; 95% CI, 0.03-0.09) CHD risk were less likely to achieve LDL-C goal when compared with patients at low risk (data not shown).

**Patients Not at LDL-C Goal**

As CHD risk increased, the percentage of patients not achieving goal LDL-C increased (low, 9.2%; moderate, 32.9%; high, 47.4%; very high, 68.4%). Further examination of the 1298 patients who were not at LDL-C goal revealed that 702 (54.1%) patients were not

### Table 2 Lipid-Modifying Therapy Utilization, by CHD Risk Group

<table>
<thead>
<tr>
<th>Therapy group, by CHD risk category, N (%)</th>
<th>Low risk (N = 3478)</th>
<th>Moderate risk (N = 1461)</th>
<th>High risk (N = 883)</th>
<th>Very high risk (N = 114)</th>
<th>All patients (N = 5936)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No therapy</td>
<td>2739 (78.8)</td>
<td>799 (54.7)</td>
<td>298 (33.7)</td>
<td>13 (11.4)</td>
<td>3849 (64.8)</td>
</tr>
<tr>
<td>Unrestricted therapies&lt;sup&gt;a&lt;/sup&gt;</td>
<td>392 (11.3)</td>
<td>312 (21.4)</td>
<td>228 (25.8)</td>
<td>36 (31.6)</td>
<td>968 (16.3)</td>
</tr>
<tr>
<td>Restricted therapies&lt;sup&gt;b&lt;/sup&gt;</td>
<td>229 (6.6)</td>
<td>211 (14.4)</td>
<td>185 (21.0)</td>
<td>33 (28.9)</td>
<td>658 (11.1)</td>
</tr>
<tr>
<td>Other lipid therapy&lt;sup&gt;c&lt;/sup&gt;</td>
<td>118 (3.4)</td>
<td>139 (9.5)</td>
<td>172 (19.5)</td>
<td>32 (28.1)</td>
<td>461 (7.8)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Fluvastatin, pravastatin, lovastatin, or simvastatin monotherapy.

<sup>b</sup>Atorvastatin monotherapy, rosuvastatin monotherapy, or simvastatin/ezetimibe fixed-dose combination.

<sup>c</sup>Fibrates, niacin, ezetimibe, and bile acid sequestrants as monotherapy alone or in multipill combination therapy.

CHD indicates coronary heart disease; LMT, lipid-modifying therapy.
receiving any lipid-modifying therapy, 279 (21.5%) were receiving unrestricted lipid-modifying therapy, 155 (11.9%) were receiving restricted lipid-modifying therapy, and 162 (12.5%) were receiving other lipid-modifying therapy. Among patients not achieving goal with either unrestricted or restricted lipid-modifying therapy (n = 434), many more patients were receiving unrestricted lipid-modifying therapy than restricted lipid-modifying therapy (57.8%-63.2% vs 33.8%-42.2%), and this trend was significant across low, moderate, and high CHD risk categories (P < .001; Figure 3). Patients receiving unrestricted lipid-modifying therapy required, on average, an additional 17.9% reduction in LDL-C levels to achieve goal LDL-C, with the high and very high CHD risk categories requiring the largest reductions, at 22.7% and 21.7%, respectively.

**Discussion**

The intent of our study was to identify targets for quality improvement initiatives. Clearly, the data support attention in the higher CHD risk categories. About half of the patients in the high CHD risk category and two thirds of the patients in the very high CHD risk category did not achieve goal LDL-C levels. These patients represent the largest healthcare burden. They are more likely to suffer adverse CV outcomes and associated costs than patients at lower CHD risk. National guidelines have stressed the importance of aggressively managing this population, yet current practice yields suboptimal results.

Patients at higher CHD risk have lower LDL-C goals, and more difficulty attaining goal LDL-C. In addition to CHD risk status, greater percentage LDL-C reduction and lack of titration have been associated with decreased likelihood of achieving goal. In a study of patients newly initiated on statin therapy, the percentage of LDL-C reduction required to achieve goal was found to independently predict goal attainment. Patients who required at least a 15% reduction in LDL-C level or who were at elevated CHD risk were less likely to achieve goal compared with patients who required less than a 15% reduction or who were low risk. Despite having pharmacy coverage, patients and physicians in our study faced restrictions in choice of lipid-modifying therapy. The restricted lipid-modifying therapy options were atorvastatin, rosuvastatin, and simvastatin/ezetimibe fixed-dose combination. These agents demonstrate superior percentage reductions in LDL-C values versus agents included in the unrestricted lipid-modifying therapy group across various practice settings.

In our study, goal attainment was unaffected by lipid-modifying therapy use in the low CHD risk category, but more patients in the moderate, high, and very high CHD risk categories achieved goal LDL-C if they were receiving restricted lipid-modifying therapy. The disparity in LDL-C goal attainment between restricted and unrestricted lipid-modifying therapy groups was greater in higher CHD risk categories.

Patients in the high and very high CHD risk categories were more likely to achieve LDL-C goal if they were receiving restricted lipid-modifying therapy compared with unrestricted lipid-modifying therapy. In addition, for patients not at LDL-C goal, the use of unrestricted agents was greater in all of the CHD risk categories compared with the use of restricted lipid-modifying therapy. Agents in the unrestricted lipid-modifying therapy group could have been titrated to higher doses or switched to restricted agents with increased LDL-C lowering potential. However, evidence demonstrates that such modifications occur infrequently.

In a recent study of 1654 patients newly initiated with simvastatin therapy, only 45.6% were found to be at LDL-C goal. In those patients who did not achieve LDL-C goal, a majority (85.4%) were not titrated from the initial simvastatin dose or switched to another statin. In a study of high CHD risk patients treated in a primary care setting within a Veterans Administration Medical Center, only 16% of patient visits resulted in an increased statin dose in patients with uncontrolled LDL-C levels. Similar results were found in a study by
Lindgren and colleagues, who examined 1166 patients with uncontrolled LDL-C values at 3 months.\textsuperscript{15} In 87.3% of these patients, there were no changes to the lipid-modifying therapy regimen. Of the 12.7% of patients with changes, approximately 74% had a change in the dose of the original lipid-modifying therapy, and 26% were prescribed a different lipid-modifying therapy. At 12 months, only 7.9% of the original cohort had attained LDL-C goal levels.\textsuperscript{15}

Few patients who are not controlled on their initial regimen achieve goal LDL-C levels.\textsuperscript{12,15} In a prospective study of patients at high CHD risk with uncontrolled LDL-C levels, only 14% attained goal within 6 months.\textsuperscript{25} This low level of goal attainment occurred despite a protocol that instructed the study sites to titrate the prescribed statin as necessary to achieve LDL-C goal <100 mg/dL. Clinical inertia (eg, lack of titration) or patient nonadherence to lipid-modifying therapy can partly explain why even after longer follow-up, LDL-C goal attainment remains elusive. For patients who do have changes to their lipid-modifying therapy regimen, there is an increased risk for nonpersistence. In a study of patients with comorbid hypertension and dyslipidemia, patients who had changes to their lipid-modifying therapy were less likely to persist with their lipid-modifying therapy compared with those who remained on their initial lipid-modifying therapy regimen.\textsuperscript{26}

To effectively manage formulary restrictions, systematic interventions are needed to improve LDL-C goal attainment. One study showed that using an educational intervention improved LDL-C goal attainment rates from 49% to 62%.\textsuperscript{18} After receiving this education, clinicians were more likely to increase the statin dose.\textsuperscript{18} Another study demonstrated that clinical pharmacist involvement improved LDL-C goal attainment rates by 17%, after a therapeutic conversion from one statin to other statins or statin combination products.\textsuperscript{27} Although these programs are effective, they are often only pilot studies and are not sustained for long periods.

Limitations
An overestimation of LDL-C goal attainment might have occurred in this study, because patients were conservatively segmented into CHD risk categories. Data, such as family history of CHD, smoking status, and blood pressure measurements, were unavailable. Without these data, there was no way to determine the complete number of CHD risk factors or to calculate 10-year risk of having a CHD event. These additional data may have categorized patients into higher CHD risk categories, with more aggressive LDL-C goals. The result would likely have been a greater percentage of patients having LDL-C levels not at goal.

In addition, some patients might have received drug samples, and there was no way of accounting for this supply of medication. The impact of samples without any prescription claims could affect lipid-modifying therapy group categorization and rate of LDL-C goal attainment by lipid-modifying therapy group. Similarly, patients who paid cash for their lipid-modifying therapies could have been miscategorized by lipid-modifying therapy group, which could affect the rate of LDL-C goal attainment per lipid-modifying therapy group.

Finally, we did not obtain information on medication adherence. Patients with poor medication adherence are less likely to achieve goal LDL-C values. If the percentage of patients who were nonadherent was different in the various lipid-modifying therapy groups, this could affect the discrepancy in LDL-C goal attainment.

Conclusion
A significant number of patients at elevated risk for CHD remain untreated or have LDL-C levels above target; these patients are either not receiving lipid-modifying therapy or their current regimens are suboptimal. In this study, although patients receiving restricted lipid-modifying therapy agents were more likely to achieve LDL-C goal, the use of these agents was relatively low. These patterns of lipid-modifying therapy use may be helpful to discern approaches to achieve higher LDL-C goal attainment rates. Removing barriers to the use of restricted agents in patients at elevated CHD risk provides an opportunity to achieve goal LDL-C levels aimed at decreasing the risk of subsequent CV disease events.

It is imperative that clinicians have the opportunity to individualize lipid-modifying therapy according to the patient’s CHD risk status and LDL-C goal, with the intent of achieving goal LDL-C with the initial therapy prescribed. To enable clinicians and patients to achieve goals, unrestricted access to initial lipid-modifying therapy regimens that are expected to achieve goal should be a standard formulary strategy for patients at high CHD risk.

Acknowledgment
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Disclosure Statement
Mr Lynch and Dr Rosen receive research grant support from AstraZeneca and Novartis; Dr Cooke receives research grant support from AstraZeneca, Novartis, and Pfizer; Drs Gandhi and Bullano are employees of AstraZeneca LP.

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STAKEHOLDER PERSPECTIVE

Appropriate Medication Selection Key to Cost-Effective Therapy, Patient Adherence

MEDICAL/PHARMACY DIRECTORS: Because of the high cost of treatment and the clinical sequelae of cardiovascular disease, primary and secondary preventive measures are continually on payers’ minds. Cholesterol-lowering drugs are among the top-budgeted therapeutic classes for most payers, making this class a priority category for appropriate utilization management.

In their study, Lynch and colleagues addressed important issues in cholesterol management. Based on their data relevant to low-density lipoprotein cholesterol (LDL-C) goal attainment, particularly in those who are at high and very high risk for coronary heart disease (CHD), better cholesterol management is paramount for the prevention of cardiovascular events. An interesting follow-up to this study would include the doses used and adherence and persistence patterns within the risk groups of patients with CHD.

In the introduction, the authors cite a study showing that high copay cost is inversely related to patient medication adherence. One of the keys to the delivery of and payment for cost-effective therapy is appropriate therapy selection.

In the current study, the largest group of treated
and untreated patients is within the low CHD risk group. In this group, treating patients with more potent and more expensive brand-name statin therapy did not produce better results based on the percentage of patients achieving their goal LDL-C level. In reviewing these data, it appears that the most cost-effective therapy was not selected for the largest group of patients. One can, therefore, understand the rationale for some type of utilization management— in this case step-therapy requirement—for this group of patients.

One alternative to the 90-day supply requirement of a generic, less-potent statin may be the exploration of a step-therapy requirement (or noncoverage) applicable only to the lower doses of the brand-name statins. This may provide more options for patients who initially require greater levels of LDL-C reductions, without wasting money to achieve LDL-C levels that could be achieved, for example, with simvastatin 40 mg/day. This approach may emphasize the importance of appropriate statin and dose selection.

The data presented by Lynch and colleagues highlight the importance of provider education regarding not only initial medication selection but also the need for adequate dose titration that is necessary for LDL-C goal attainment.

PATIENTS: Adherence to cholesterol-lowering therapy has historically been poor. In fact, a recent analysis determined that statin adherence and persistence is worse than adherence to oral antidiabetes medications or angiotensin receptor blockers.1

In addition to providers, patients also need continual education concerning the importance of cholesterol management. All barriers to medication adherence should be addressed to identify solutions, including cost-effective alternatives, when appropriate.


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# Modified NCEP ATP III Criteria for CHD Risk Stratification

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Modified NCEP ATP III criteria</th>
<th>Target LDL-C goal, mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>Presence of CHD event plus 1 of the following: Diabetes mellitus diagnosis or antidiabetic medication therapy Intermediate coronary syndrome Metabolic syndrome diagnosis</td>
<td>&lt;70</td>
</tr>
<tr>
<td>High</td>
<td>Presence of CHD event or CHD risk equivalent: Clinical CHD (MI, ischemic heart disease, angina pectoris, PTCA, CABG) Symptomatic carotid artery disease Peripheral arterial disease Abdominal aortic aneurysm Diabetes mellitus diagnosis or antidiabetic medication therapy Other ischemic disease</td>
<td>&lt;100</td>
</tr>
<tr>
<td>Moderate*</td>
<td>≥2 risk factors: Age: men ≥45yrs or women ≥55 yrs HDL-C &lt;40 mg/dL Hypertension diagnosis (ICD-9-CM 401.xx) or antihypertensive therapy</td>
<td>&lt;130</td>
</tr>
<tr>
<td>Low</td>
<td>≤1 risk factor, as described in “moderate” category</td>
<td>&lt;160</td>
</tr>
</tbody>
</table>

*Patients with diabetes must also have other comorbid codes within the high CHD risk category to be classified as having very high CHD risk.

ATP indicates Adult Treatment Panel; CABG, coronary artery bypass graft; CHD, coronary heart disease; HDL-C, high-density lipoprotein cholesterol; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; LDL-C, low-density lipoprotein cholesterol; MI, myocardial infarction; NCEP, National Cholesterol Education Program; PTCA, percutaneous transluminal coronary angioplasty.