The recent Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk (FOURIER) study demonstrated that Repatha, a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor, can help reduce the risk of a cardiovascular (CV) event among patients with atherosclerotic disease (ASCVD). When added to high- or moderate-intensity statin therapy these drugs help effectively lower levels of low-density lipoprotein (LDL).

The study found that Repatha lowered the overall risk of CV event, stroke, unstable angina, cardiac revascularization, or death by CV event by 15 percent, among patients with ASCVD in addition to other risk factors, with no new safety concerns.

CVS Health’s utilization management (UM) criteria are based on the most current published evidence and clinical guidelines. Given the FOURIER results and recently published clinical guidelines by the American College of Cardiology and American Health Association, we have updated our standard Specialty Guideline Management (SGM) criteria to provide coverage for populations shown to benefit from PCSK9 inhibitor therapy to reflect current standards of care. The changes will not substantially expand the treatment population but help ensure plan members and providers participate in efficient and clinically based utilization management programs.

A Little History

Treatment for high cholesterol is among the top drug spend drivers for commercial payors.* However, effectively controlling LDL cholesterol through appropriate medication therapy, in addition to diet and lifestyle changes, can help avoid downstream costs from cardiovascular adverse events such as heart attack or stroke. Statins — cholesterol reducing drugs that can be delivered at varying intensities, or doses, depending on the severity of the condition — are the standard first-line treatment.

More recently, PCSK9 inhibitors, a new class of biologic medications, have emerged as an effective adjunct treatment to help lower bad cholesterol. These drugs are indicated for patients with ASCVD, or those with homo- or heterozygous familial hypercholesterolemia — a genetic disorder that results in high levels of LDL — who have failed maximally tolerated statin therapy.

Appropriate Utilization Through UM

PCSK9 inhibitors are appropriate for use among patients with the right condition profile and risk factors as indicated by U.S. Food and Drug Administration approved drug labels, as well as clinical guidelines. The average wholesale price of PCSK9 inhibitors is $16,000 per year compared to approximately $300 a year for commonly used statins.*

Given the high cost of PCSK9 inhibitors compared to other statin therapy, it is critical to ensure that the right patients have access to the medication and payors have appropriate trend management tools in place to manage the impact on trend. Strategies such as including step therapy and prior authorization (PA) can help payors manage cost. So far, effective management has have helped keep spending on PCSK9 inhibitors far below the original estimates.
To help ensure a balance between patient access and payor costs, and to make it more efficient for providers to prescribe these medications to the appropriate patients, we have taken several steps to align our SGM criteria with the latest clinical evidence. With this change, we expect more patients to be evaluated to determine if treatment with PCSK9 inhibitors is warranted and utilization to increase slightly. Updates include:

1. Accept physician reporting of patient LDLC level without documentation
2. Removed requirements for monotherapy treatment with ezetimibe (Zetia) for eligible patients with statin intolerance
3. Coverage for patients with ASCVD on moderate-intensity statins, who are not meeting their LDL goal and are unable to take a high-intensity statin
4. No longer requiring patient triglyceride level to be below 400 mg/dl
5. Eliminated certain age restrictions in children

The updated standard SGM criteria will continue to help ensure appropriate utilization of these high-cost drugs in patients for whom PCSK9 inhibitors are clinically indicated. CVS Health clinical guidelines are continuously reviewed and updated as new safety or medical evidence becomes available to ensure that our UM criteria help control costs for payors while improving health outcomes for their members.

Want to learn more about our updated PCSK9 inhibitors criteria? Ask Us