The recent Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk (FOURIER) study demonstrates the value of Repatha, a PCSK9 inhibitor, compared to LDL cholesterol lowering therapy with ezetimibe to help manage high cholesterol in patients with ASCVD and demonstrate that Repatha can help reduce the risk of a CV event among patients with other cardiovascular diseases (CVDs). 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, 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 is 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 Heart Association, we have updated our standard Specialty Guideline Management (SGM) criteria to provide coverage for population-wide access to benefit from PCSK9 inhibitor therapy to reflect current standards of care. The changes will not substantively increase the trended population but help ensure plan members and providers have sufficient and clinically based utilization management programs.

A Little History
Treatment for high cholesterol is among the top-drug spend drivers for commercial payers. However, effectively controlling LDL cholesterol through appropriate reductase 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 administered as varying intensities, or doses, depending on the severity of the condition – are the standard frontline treatment.

More recently, PCSK9 inhibitors, a new class of biological medications, have emerged as an effective adjunct treatment to help lower LDL. These drugs have shown to be highly effective even in those with heterogeneous 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 $300 per 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 access to the medication and payors have appropriate trend management tools in place to manage the impact on trend.

With the recent Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk (FOURIER) study demonstrating that Repatha, a PCSK9 inhibitor, can help reduce the risk of a CV event among patients with other cardiovascular diseases (CVDs), when added to high- or moderate-intensity statin therapy these drugs help effectively lower levels of low-density lipoprotein (LDL).

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 the change, we expect fewer than one percent of 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 LDL level without documentation.
2. Removed requirements for mammography treatment with paclitaxel (Taxol) for eligible patients with breast masses.
3. Coverage for patients with ASCVD on moderate-intensity statins, who are not meeting their LDL goal and are unable to have a high-intensity statin.
4. No longer requiring patient triglyceride level to be less than 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. With the clinical guidelines continually reviewed and updated as new safety or medical evidence becomes available to ensure that our SGM criteria help control costs for payers while improving health outcomes for our members.

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

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- Adherence

References

4. CVS Health. For health care providers: Repatha: A Little History
5. This document contains internally sourced data as well as references or representations of information or data collected via external sources.

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