ASCRS

Issue Brief

Step Therapy in Medicare Advantage and Part D

In an effort to reduce high prescription drug costs, the Trump administration announced in 2018 a new policy that was effective January 1, 2019, to permit Medicare Advantage (MA) Plans to begin using step therapy for Part B drugs administered in the office or facility. Following the policy announcement, CMS released a final rule, opposed by ASCRS and the medical community, which codifies the use of step therapy in MA plans and expands step therapy and prior authorization in Part D plans effective on January 1, 2020.

Background

Step therapy, also known as "fail first," is a cost-containment strategy that requires physicians to prescribe an insurer's preferred treatment first, and only covers more expensive treatments if the patient does not respond to the initial treatment. Previously, MA plans were prohibited from using step therapy; however, as part of the overall effort to reduce the costs of prescription drugs, CMS announced in August 2018 that plans may begin using step therapy for the 2019 benefit year.

The new guidance strongly encourages insurers to notify beneficiaries if they will incorporate step therapy in MA or Part D plans, and step therapy can only be used for new prescriptions. To encourage beneficiaries to participate in these programs, the guidance allows plans to offer rewards, such as gift cards, in exchange for participation. Rewards may not be made in the form of monetary or cash rebates, and the value must be reasonable or appropriate. CMS will consider a reward or incentive as reasonable or appropriate value if it is equivalent to more than half the amount saved on average per participant as a result of participating in step therapy.

The new guidance is targeted at Part B drugs administered in the office or facility, but also permits MA plans that offer Part D drug coverage to use step therapy to require a Part D drug prior to using a Part B drug, or vice versa. Plans' use of step therapy must continue to comply with national and local coverage determinations.

In additional guidance, CMS stated that plans using step therapy would be able to require the use of off-label drugs, such as Avastin, if they were less expensive than the on-label drug. In addition, CMS is strongly encouraging plans that step therapy can only be used for new prescriptions, and patients who are well controlled with an existing treatment cannot be made to change to a less expensive treatment, even if they change plans.

In May of 2019, CMS released a final rule that implements ASCRS- and ophthalmic community-opposed policies to allow MA Plans to implement step therapy for Part B drugs administered in the physician office, as well as expands step therapy and prior authorization for Part D plans.

Prior to the release of the final rule, ASCRS, along with the American Academy of Ophthalmology, met with Health and Human Services (HHS) Secretary Alex Azar in January 2019 to reiterate our opposition to the use of step therapy. We explained that these policies will prevent or delay beneficiary access to the most appropriate treatment, which could have the unintended consequence of worsening a patient's condition. Following the meeting, we submitted a list of suggested reforms and patient protections that should be implemented if plans use step therapy. In addition, ASCRS joined the Alliance of Specialty

Medicine, the medical community, and a broad coalition of medical and patient advocacy groups in meetings and letters to CMS, and to Congress, opposing the use of step therapy.

Following our advocacy, CMS did make one modification to the step therapy policy in the final rule. Specifically, CMS extended the lookback period—during which an insurer must determine whether the patient has tried and failed a less-expensive treatment before applying step therapy to a more expensive, new drug—from the proposed 108 days to a full year. This change is a result of advocacy by ASCRS and AAO during the meeting with HHS Secretary Alex Azar.

Additionally, CMS finalized its proposal to require Part D plans to develop real-time benefit tools (RTBTs) to integrate with prescribers' EHR systems as a tool to help inform patients about their formulary options and potential out-of-pocket costs. CMS is requiring that each Part D plan adopt one or more RTBTs that are capable of integrating with an e-prescribing system or electronic health record (EHR) no later than January 1, 2021.

Legislation

Bipartisan legislation to address step therapy has been introduced in both the House and Senate. In April 2019, Representatives Raul Ruiz, MD (D-CA) and Brad Wenstrup, DPM (R-OH) introduced the Safe Step Act, a bipartisan bill to improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them. Following its release, Senators Lisa Murkowski (R-AK), Doug Jones (D-AL), and Bill Cassidy, MD (R-LA) introduced a companion bill in the Senate that would limit the use of step therapy by requiring group health plans to provide an exception process for any medication step therapy protocol. Additionally, insurers would be required to implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.

Next Steps

ASCRS will continue to oppose the use of step therapy and will work with the medical community to advocate to ensure Medicare beneficiaries have access to care.