CMS Reversal on Step Therapy for Part B Drugs
Threatens the Health of Medicare Advantage Beneficiaries

Overview

On August 7, 2018, the Centers for Medicare & Medicaid Services (CMS) reversed long-standing policy prohibiting Medicare Advantage (MA) plans from using step therapy for Part B covered drugs, unless also required in Medicare fee-for-service (FFS). Beginning January 1, 2019, CMS will now allow MA plans to use step therapy for Part B covered drugs – often called "fail first" because it requires patients to fail on one treatment before receiving the treatment recommended as the first choice by their provider. This undercuts statutory protections, threatening timely access to life-saving medicines for patients with cancer and other serious conditions.

Background

- MA plans are required to cover benefits under Medicare Parts A and B, including physician services and certain prescription drugs.
- Some MA plans, termed "MA-PD plans," also provide Medicare Part D prescription drug coverage.
- In a 2012 guidance, CMS stated that MA plans must ensure beneficiaries have "at minimum, equal access to items and services" covered in Medicare FFS. CMS added that coverage policies may not be more restrictive than FFS Medicare or impose extra barriers to Part B drug coverage, such as step therapy, that are not required in FFS Medicare.
- The 2012 guidance tracks the statute, which requires MA plans to provide enrollees "benefits under the original Medicare fee-for-service program option," including items and services for which benefits are available under Medicare Part B. Prior authorization is only allowed in Original FFS for certain specified services.
- On August 7, 2018, CMS announced that MA plans can use step therapy for Part B covered drugs even when Medicare FFS does not use step therapy.
- CMS describes step therapy as a "type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary."
- The agency also will permit MA-PD plans to "require a Part D drug therapy prior to allowing a Part B drug therapy," and vice versa.
- CMS states its "expectation" that use of step therapy for Part B drugs "should not result in increased costs to enrollees," but stops short of prohibiting increased beneficiary costs. Also, CMS acknowledges there may be occasions when patient cost sharing increases when a Part D drug must be tried before a Part B drug.

Concerns

- Plans have 14 days to make determinations when beneficiaries seek an exception to the policy (72 hours for expedited requests).

- The CMS guidance does not discuss protected classes, off-label use, or the criteria plans must follow to set step therapy requirements or to determine when it would be "necessary" for a patient to progress to another therapy."
- CMS guidance merely "encourages" MA-PD plans to use Part D pharmacy and therapeutics (P&T) committees to determine the appropriate use of step therapy and does not have any strict requirement to ensure proper clinical review
- For MA plans without a Part D component, there do not appear to be any review processes of step edits these plans may implement for Part B products.

Medicare Beneficiaries Need Timely Access to Medicare Part B Covered Drugs to Treat Serious, Life-Threatening Conditions

- Beneficiaries receiving Part B covered drugs include some of the most vulnerable in the program – those with cancer, rheumatoid arthritis, compromised immune systems, transplants, hemophilia and ESRD.
- Forcing these beneficiaries to fail on a drug regimen before accessing the treatment recommended as the first choice by their provider could have devastating, potentially irreversible consequences:
    - Patients with cancer may have their cancer spread, risking complications or death.
    - Patients with vision disorders could be at risk of blindness.
    - Patients with multiple sclerosis could miss the window of opportunity to stop the progression of their illness before it becomes disabling.
- For many patients suffering from complex, life-threatening disease, step therapy can lead to a delay in getting the medicines they need, potentially resulting in complications or hospitalizations, as well as increased costs for Medicare and its beneficiaries.
- Step therapy would be particularly challenging for very ill patients when they are least equipped to manage additional bureaucratic hurdles.

Step Therapy Interferes with the Physician-Patient Relationship

- Physicians have raised concerns for years over the paperwork and administrative challenges associated utilization management – including compliance with step therapy requirements.
- The CMS memo provides no guidance for providers and fails to establish a standardized process, likely forcing physicians to adhere to dozens of different, potentially conflicting procedures to care for their patients.

Step Therapy Represents Middlemen-Centered Health Care

- The guidance will mostly benefit PBMs and other middlemen – and closely follows recommendations from the PBM industry in their 2018 comments on the Administration's Drug Pricing Blueprint.
- Patient and provider organizations have sought relief from step therapy requirements, particularly in commercial insurance – the Administration ignored the pleas of the provider and patient community and rolled out a policy that is the opposite of patient-centered care.

- CMS appears to rely on the hope that step therapy will achieve lower drug prices; yet, the agency has not even put this through notice and comment or cited any evidence regarding overall cost savings or beneficiary impacts.
- The agency sought to quell expected criticism from patients by requiring plans to offer "beneficiary incentives" such as gift cards, and poorly defined "care coordination" programs.
- Instead of a gift card to an online retailer or big box store, Medicare beneficiaries with cancer, multiple sclerosis and immune disorders deserve access to the medical care prescribed by their doctor.