Step Therapy in Medicare Advantage (MA) Plans for Part B Drugs

Biotechnology Innovation Organization meeting with the Office of Management and Budget
October 5, 2018

Biotechnology Innovation Organization

Background: CMS Memo on Step Therapy for Part B Drugs in MA

- On August 7th, 2018 the Centers for Medicare & Medicaid Services (CMS) rescinded a 2012 memo to Medicare Advantage (MA) plans that prohibited use of step therapy for Part B drugs.
- The memo allows MA plans to implement step therapy for Part B drugs beginning on January 1st, 2019.
  - Plans can require management among Part B drugs, and across Part D and Part B drugs.
  - The memo and subsequent Q&A document released on August 29, 2018 leave important questions unanswered around process and beneficiary protections.
- BIO has highlighted our serious concerns with the policy, and lack of additional detail and patient protections in a letter to the Secretary (September 10th, 2018).
  - Called for withdrawal or at minimum, a delay to 2020 to allow for appropriate implementation of patient protections and transparency requirements.

MA Part B Step Therapy Policy: Major Concerns

CMS Oversight of Step Therapy	MA plans are not required to submit information about their step therapy policies to CMS for review.
Beneficiary Transparency Around Use of Step Therapy	MA plans are not required to disclose the specific drugs subject to step therapy, or provide clinical justification for step therapy requirements.
Appeals Process Timeline	The appeals processes CMS recommends is insufficient – 14 days, 72 hours expedited (Part C benefit).
Protections for Beneficiaries on Existing Therapy	The 108 day lookback CMS suggests to establish a "new" prescription for purposes of step therapy is problematic for these medicines.
Cost-Sharing Implications	Potential to create higher cost-sharing obligations for beneficiaries, and reduce the protections provided by the maximum out-of-pocket cost limits in MA.
Notice and Comment Process	Reversal of longstanding policy grounded in statute without notice and opportunity for stakeholder feedback.

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MA Part B Step Therapy Policy: Major Concerns cont'd

- It is critical that CMS treat Part B medicines subject to this policy as a drug benefit rather than a medical benefit for purposes of beneficiary protections, transparency, and oversight.

- For instance, the safeguards that exist under Medicare Part D, that are related to the nondiscrimination requirements, should be extended to this new policy.

	Medicare Part D	MA Part B Step Therapy
During open enrollment, will the beneficiary be able to go to Plan Finder at Medicare.gov and find out if their drug is covered and if step therapy applies?	✓	✗
Are plans required to submit their step therapy and prior authorization requirements to CMS?	✓	✗
Are plan step therapy requirements reviewed for clinical appropriateness?	✓	✗
Are MA plans required to ensure beneficiaries are able to stay on their therapy for the first 60 days they are on their plan (e.g., policy to prevent bait and switch)?	✓	✗
Do plans have to adhere to specific requirements for appeals and exceptions, including 24 hour review of an emergency appeal for a drug?	✓	✗

OIG Report: MA Service and Payment Denials

- In September, OIG released a report: "Medicare Advantage Outcomes and Audit Findings Raise Concerns About Service and Payment Denials
  - OIG conducted this review noting that "a central concern about the capitated payment model used in MA is the potential incentive for MAOs to inappropriately deny access to services and payments in an attempt to increase their profits."

Key Takeaway: High numbers of overturned denials upon appeal, and postponed performance problems identified by CMS audits, raise concerns that some beneficiaries and providers may not be getting services and payments that MAOs are required to provide.

MA Step Therapy Policy: BIO Asks

- BIO has serious concerns with the policy and has called for reversal, or a delay until 2020 to provide for a notice and comment process to address these issues.
- BIO urges OMB to consider addressing the following through potential preamble language in the pending rulemaking (RIN:0938-AT59):

CY 2019

- Provide opportunity for CMS inquiry into an MA plan's use of step therapy.

- And address the following with appropriate notice and comment processes for future years:

CY 2020

- Advanced review of step therapy policies by CMS
- Use of the Part D appeals process timelines
- Beneficiary notification processes
- Defining a "new" prescription
- Requirements to prevent bait and switch
- Clarity on how providers can register concerns with the policy

It is critical that CMS first collect information on MA step therapy polices and allow both Agency review and beneficiary review via Medicare Plan Finder

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James C. Greenwood
President & CEO

September 10, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, D.C. 20201

RE: Step Therapy for Part B Drugs in Medicare Advantage

Dear Secretary Azar:

The Biotechnology Innovation Organization (BIO) is writing to express our strong concern with the recent decision by the Centers for Medicare and Medicaid Services (CMS) to reverse long-standing policy and now allow Medicare Advantage (MA) plans to utilize step therapy requirements for Medicare Part B drugs. Because of the serious harm that such a policy could cause to some of the sickest and most vulnerable Medicare populations, I respectfully request that the Administration reverse, or at least suspend, this new policy, pending further discussions with stakeholders on whether such a policy should be implemented and if so, how to do so in a manner that is fully transparent to and protective of Medicare beneficiaries.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced other healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. To that end, we closely monitor changes to Medicare's reimbursement and coverage policies for the potential impact on patient access to drugs and biologicals. We therefore have significant concerns with CMS' recent changes to its utilization management policies for Part B drugs.

CMS' August 7, 2018 memo to MA plans rescinded a 2012 memo that explicitly prohibited plans from imposing additional requirements for accessing Part B drugs such as step therapy. The 2012 memo specifically noted plans' statutory requirement to provide "equal access to items and services covered by Original Medicare in their service area."[1] Despite this clear statutory requirement, CMS has abruptly reversed course. According to the newly issued guidance, MA plans are now permitted to implement step therapy for Part B drugs, beginning January 1, 2019.

[1] CMS Memo to Medicare Advantage Organizations. 17 September 2012.

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Additionally, MA prescription drug plans are permitted to require use of a Part D therapy prior to providing coverage for a Part B therapy.

This sudden reversal of long-standing Medicare policy, without any statutory change or opportunity for public comment, raises significant concerns. As an initial matter, CMS has not identified how this new policy change can be squared with the mandate for parity in covered benefits between Medicare Advantage and original Medicare that was clearly articulated and defended in the now-rescinded 2012 memo.

But more fundamentally, allowing MA plans to utilize step therapy for Part B drugs effectively puts insurers between providers and their patients – restricting patient access to the drugs their providers believe they need and potentially increasing patient costs and overall healthcare spending as well. Imposing these stringent requirements can be unduly burdensome on patients, subjecting them to potentially harmful side effects and diminished health outcomes. These potential consequences are especially concerning when considering that this new policy is intended to impact those Medicare beneficiaries seeking treatment for the most serious, often life-threatening conditions, such as cancer, autoimmune disorders, ESRD, and hemophilia – conditions that already are complex for providers and patients to manage appropriately and that often can require immediate access to the most effective therapy available in order to avoid life-threatening or irreversible negative complications. Policies such as step therapy that delay access to the most appropriate therapy in an effort to reduce upfront expenditures are not only a bad prescription for patients, but they are short-sighted, as there is substantial potential for increased overall healthcare costs and adverse patient outcomes due to avoidable hospitalizations, doctors' visits, and procedures.

Of additional concern is the complete lack of CMS oversight and beneficiary protections within CMS' new policy. In fact, CMS explicitly states that health plans ***are not required*** to submit their step therapy policies to CMS for review. In addition, health plans are required to include only a general disclosure in plan documents that Part B drugs ***may*** be subject to step therapy, but plans do not have to specify whether step therapy will indeed be required or for which drugs. Essentially, CMS will not know which plans are implementing step therapy and in what manner. More troubling, nor will beneficiaries. This lack of oversight and transparency is simply unacceptable.

We strongly urge the Agency to reverse course on this new policy, given its potential for serious negative impacts for Medicare beneficiary access to timely and appropriate treatment. However, if CMS insists on proceeding with this new policy, we recommend that the Agency pause implementation of the guidance until 2020, and work with affected stakeholders to address critical implementation issues, including ensuring: sufficient oversight by CMS; clear clinical criteria for step therapy policies; transparency of step therapy policies to beneficiaries and robust beneficiary protections; timely exceptions and appeals processes; sufficient protections for those on existing therapies; and protection for beneficiaries from higher cost-sharing. Our more detailed comments follow.

Lack of CMS Oversight. CMS places virtually no requirements on plans that want to establish step therapy requirements in Part B. CMS merely "encourages" MA-PD plans to use Part D pharmacy and therapeutics (P&T) committees "to determine when it is medically appropriate to use step therapy."[2] Further, even if a P&T process is used, such recommendations are not binding on the plan sponsor. And, CMS will not know what process the plan has gone through – if any – to institute step therapy requirements. CMS states that plans **are not** required to submit their step therapy requirements to CMS for review.[3] This is inconsistent with requirements in Part D, where plans must submit step therapy protocols to CMS for review of their clinical appropriateness. Further, without submission of any information to CMS, the Agency will not even know which plans are requiring Part B step therapy and for which drugs.

Lack of Transparency to Beneficiaries. CMS states that the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents can list each Part B drug subjected to step therapy ***or it can be more general***.[4] This more general option is troubling as beneficiaries will not know if a Part B drug is subject to step therapy, as the plan is only required to say such drugs "may" be subject to step therapy. In addition, if step therapy is used, plans are not required to list the specific drugs for which this requirement applies. Further, CMS notes that plans can add or change step therapy mid-year but does not outline detailed parameters plans must follow to implement such changes or to notify beneficiaries of the changes. At a minimum, plans implementing step edits should be highlighted on the Medicare plan finder during open enrollment. Further, more specificity should be included in the ANOC and EOC documents than is currently required, and CMS should outline additional avenues for ensuring that critical information is communicated to beneficiaries, such as posting requirements on a health plan's website in a clear, accessible manner.

Insufficient Appeals Process. CMS states that a request for a Part B drug is an "organization determination request under Part C" and therefore is subject to a timeframe of 14 calendar days for standard requests and 72 hours for expedited requests (Q/A #11). CMS also states that it "strongly encourages" plans to expedite requests consistent with timelines under Part D (where standard requests are reviewed within 72 hours and expedited requests 24 hours). Given the vulnerability of the beneficiary population receiving coverage of drugs under Medicare Part B, CMS should ***require*** plans to follow the same timelines under Part D to ensure beneficiary access to needed medications without delay. CMS also should outline how it will ensure plan compliance with these standards.

Lack of Protections for Those on Existing Therapy. CMS states that step therapy may only be applied to "new prescriptions or new administrations of Part B drugs" and requires a look-back period of at least 108 days to determine whether the enrollee is eligible for a new start prescription. It is insufficient to apply the 108-day look-back required for Part D step edits to Part B patients. For many conditions commonly treated by Part B drugs, patients may experience a treatment free interval, following which they may return to treatment. For these drugs, the length of time that is treatment-free often can exceed the 108-day look-back period. It is essential that these patients can return to the treatment initially prescribed without being required to go through

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2 CMS Memo to Medicare Advantage Organizations. 7 August 2018.

3 CY 2019 Step Therapy Qs & As. 29 August 2018. See Question #6.

4 CY 2019 Step Therapy Qs & As. 29 August 2018. See Question #5.

a step edit process. This look-back period should be extended (e.g., at least 12 months). In addition, if a plan is not able to determine whether a requested drug is, in fact, part of an ongoing course of therapy, the plan should be required to provide the enrollee with the drug without subjecting the drug to any step therapy. And, in the interest of beneficiary safety, MA plans should not be permitted to force patients first to take a repackaged drug or a medicine that is used off-label, which undermines the role of the Food & Drug Administration in determining safety and efficacy of products for specific indications.

Cost Sharing Implications. CMS also must address the higher out-of-pocket cost exposure that can occur for those patients forced to try a Part D drug before a Part B therapy. Cost-sharing for Part B medicines is set at 20 percent of the Medicare reimbursement rate. A majority of beneficiaries (more than 80 percent) carry supplemental coverage that helps defray their out-of-pocket costs for Part B medicines.[5] A recent Avalere analysis found that, as a result of supplemental coverage, beneficiaries typically have lower out-of-pocket costs for oncology medicines in Part B than in Part D plans.[6] Cost-sharing differences between the Part B and Part D programs have real-world implications for treatment decisions. CMS should clarify that a patient's out-of-pocket cost burden cannot increase due to a step edit requirement.

BIO supports policies that increase patient access, decrease patient cost-sharing, and reduce overall healthcare spending. Unfortunately, the new CMS policy will have the opposite effects. Accordingly, I strongly urge the Agency to halt implementation of this policy until critical issues such as those highlighted in this letter are addressed. I also request the opportunity to meet with you or Deputy Secretary Hargan to further discuss these issues at your earliest convenience.

Sincerely,

Jim Greenwood

James C. Greenwood
President & CEO

cc: Eric Hargan, Deputy Secretary, U.S. Department of Health and Human Services
Seema Verma, Administrator, Center for Medicare & Medicaid Services

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[5] Analysis of the 2013 Medicare Current Beneficiary Survey conducted by The Moran Company for PhRMA. June 2017.

[6] Avalere Health. Moving Certain Part B Drugs to Part D, A Proposal Being Evaluated by The Trump Administration, Would Have Disparate Financial Impacts on Patients. May 2018.