Step Therapy Explained

This document identifies certain outstanding questions and concerns related to the Centers for Medicare & Medicaid Services (CMS) August 7, 2018 memorandum to Medicare Advantage (MA) organizations regarding “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage,” as well as follow-up “CY 2019 Step Therapy Q&A” issued by CMS on August 29, 2018.

Introduction:

In August 2018, the Centers for Medicare & Medicaid Services (CMS) issued a guidance allowing step therapy under Part B in Medicare Advantage Plans. Step therapy, appropriately labeled “Fail First,” is an approach that too many health-care providers and companies impose on patients to save money on costs. However, it can also be harmful to patients, potentially leading to extended periods of illness, significant unnecessary follow-up visits and time waiting for this and all too often more complicated downstream medical issues.

Step Therapy and Medicare:

Medicare Part B (Medical Insurance) generally doesn’t cover most prescription drugs used at home. But, it does cover a limited number of outpatient prescription drugs under limited conditions. Generally, drugs covered under Part B are drugs you wouldn’t usually give to yourself. These include drugs you get at a doctor’s office or hospital outpatient setting. Drugs that aren’t covered under Part B may be covered under Medicare prescription drug coverage (Part D).

In most cases with Step Therapy you must first try a less expensive drug on the Medicare Prescription Drug Plan’s formulary (also called a drug list) that has been proven effective for most people with your condition before you can move up a “step” to a more expensive drug. This might mean trying a similar, more affordable generic drug instead of a more expensive, brand-name medication. The more affordable drugs in the first phase are known as “Step 1” prescription drugs. Please note that the formulary may change at any time. You will receive notice when necessary.

However, if you have already tried the more affordable drug and it did not work or if your prescriber believes that it is medically necessary for you to be on a more expensive drug, he or she can contact the plan to request an exception. If your prescriber’s request is approved, the plan will cover the more expensive drug. The more expensive drugs are known as “Step 2” prescription drugs, and Medicare will not cover them until Step 1 drugs are first tried unless an exception is obtained.

Recent trends in prescription drug prices in the United States has led to an increased pressure on health care providers to keep down the cost of prescription medication while maintaining high levels of availability to the patient. The use of generic drugs when possible allows health care plans to pursue both goals effectively. Physicians and managed care providers may disagree on the proper step therapy and patients are encouraged to become knowledgeable in managing their own care.

Also called Step Protocol or a Fail First Requirement, Step Therapy is a type of prior authorization requirement, the process used by some health insurance companies in the U.S. to determine if they will cover a prescribed procedure, service, or medication. The process is intended to act as a safety and cost-saving measure, although it has received criticism from physicians for being costly and time-consuming.
Some facts:

Step therapy is a tool used by health plan to control spending on patients' medications. In 2010, nearly 60 percent of commercial insurers were using step therapy. As of 2014, 75 percent of large employers reported offering employees plans that use step therapy. This type of therapy has shown to have a negative impact on patients, including delayed access to the most effective treatment, disease progression, and significant burdens on health care providers and their patients, as well as increases in health care costs.

Step therapy legislation:

As of 2018, the following 18 states have step therapy laws enacted: Arkansas, California, Colorado, Connecticut, Iowa, Illinois, Indiana, Kentucky, Louisiana, Maryland, Minnesota, Missouri, Mississippi, New Mexico, New York, Texas, Washington, and West Virginia. In the meantime, ten more states have pending approval of such legislation.

Shortcomings:

Opponents of Step Therapy have detailed the pitfalls of this practice. Fail First is used by health insurers to control costs. It is time-consuming from a physician and patient standpoint, is more expensive from a direct and indirect out-of-pocket cost perspective and denies patients the drugs they need when they need them. Some of the most relevant shortcomings are:

- Creates additional barriers leading people to forgo needed medications
- Can cause patients’ medical conditions to deteriorate, increasing the need for medical intervention in the future. As a result, patients require increasingly costly medical care
- Increases frustration and incidents of depression
- Increases the risk of non-compliance and self-medication

Many physicians have seen firsthand the potential problems step therapy has on patients, the lost productivity it leads to, and how it not so subtly undermines the health-care provider-patient relationship and puts an organization, in this case, federal bureaucrats, at the center of decision making.

Step Therapy Actions

Federal Step Therapy Coalition

Another letter was addressed to Secretary Azar from the Federal Step Therapy Coalition, which circulated as a sign-on letter, regarding CMS’s proposed step therapy policy changes. The letter urged the administration to consider certain patient protections as they implement the new policy changes:

September 26 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Re: Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage

Dear Secretary Azar,

The undersigned organizations, representing millions of Medicare beneficiaries with complex, chronic conditions and the providers who care for them, write today in response to the recent announcement that Medicare will permit the use of step therapy protocols for Part B drugs in Medicare Advantage (MA) plans beginning this coming year. Our organizations and the individuals we represent are intimately familiar with step therapy practices across the country and come to you with a diversity of perspectives on how these policies impact care, health outcomes, and the overall well-being of millions of Americans. We recognize the administration’s efforts to explore methods for controlling healthcare spending. However, we seek to share our significant experience with this topic and put forward some proven solutions to ensure any Part B step therapy protocols allow for appropriate utilization management while recognizing the primacy of the patient-physician relationship for MA beneficiaries.

Each day, our patients and providers face the reality of step therapy and its impact on care, health, and well-being. When these policies interfere with the patient-physician relationship, they can result in delayed treatment, increased disease activity, loss of function, and potentially irreversible disease progression. For providers, step therapy exacerbates administrative burdens as they help patients navigate complicated and often opaque coverage determination processes. Step therapy protocols are not required to follow clinical practice guidelines, creating unnecessary and harmful hurdles to accessing accepted standards of care. Such experiences have made us experts on the impacts of step therapy policies and prompted us to advocate for a more patient- and provider-friendly system. This advocacy work has resulted in a consensus model of step therapy protections that is already in place in numerous state insurance markets across the country. Additionally, this model is currently being considered in Congress for application to health plans governed under the Employee Retirement Income Security Act (ERISA). Due to the nature of the Medicare population, reasonable guardrails are especially important to include as MA plans gain this additional authority to implement step therapy protocols. We think including specific beneficiary protections and guardrails are necessary and that such protections should be instituted on day one.

Specifically, when faced with step therapy, it is critical that patients can receive an exception to one of the required steps when the plan-directed medication is inappropriate. Too often, step therapy protocols create a one-size-fits-all approach to treatment that runs counter to the growing movement for patient-centered care. Additionally, a recent study shows that step therapy protocols are inconsistent across plans, creating additional confusion and frustration for patients and the providers acting on their behalf. Therefore, step therapy policies should be explicit regarding the circumstances that warrant and the processes for requesting an exception. We recognize that balance needs to be struck so the exceptions process is not overly prescriptive. However, we believe beneficiaries should have access to a patient- and provider-friendly exemption process when:

(1) the treatment is contraindicated;

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(2) the treatment is expected to be ineffective based on the physical or mental characteristics of the patient or the nature of the treatment;
(3) the treatment will cause or is likely to cause an adverse reaction to the individual;
(4) the treatment is not in the best medical interest of the patient because the provider is already following applicable clinical practice guidelines or because the treatment is expected to decrease the individual’s ability either to perform daily activities, occupational responsibilities, or adhere to the treatment plan; or
(5) the individual is stable on another drug to treat his or her condition.

We commend CMS for their actions to require MA plans to exclude beneficiaries with existing prescriptions from step therapy requirements. We greatly appreciate CMS’s recognition of the need for stable patients to remain on their course of treatment and request clarity on whether this protection will extend to those enrolling in a Medicare plan for the first time. The undersigned organizations believe this protection should extend to both new and existing Medicare beneficiaries who are stable on their medications.

We also encourage CMS to require plans to meet the Part D appeals process response timeline of 72 hours or 24 hours in life-threatening cases. Delays in treatment can have devastating health implications that are avoidable when patients and providers receive timely responses to their exception requests. These delays can also create unnecessary costs to the system when individuals need to seek additional medical care to properly manage their conditions. We appreciate that CMS is “strongly encouraging” MA plans to follow this timeline but feel patients would be best served if it were an explicit requirement. Lastly, reforms should require plans to make the appeals process transparent and straightforward, so patients and physicians can easily access the information they need to meet the plan’s documentation requirements.

As mentioned, this step therapy reform model is already in place in numerous states across the country, including Indiana, Texas, Iowa, and West Virginia. In 2018 alone, two additional states enacted robust step therapy protection laws. These commonsense guardrails on step therapy recognize the primacy of the patient-provider relationship while maintaining the ability for insurers to use this tool to manage utilization, and we think CMS would be well-served by basing the MA step therapy appeals process on this model.

We welcome the opportunity to further discuss these solutions with you and how they can best be translated to the Medicare population. For additional information, please contact Patrick Stone, Vice President of Government Relations and Advocacy with the National Psoriasis Foundation, at pstone@psoriasis.org.

Sincerely,

Signatures on File

National Health Council

The National Health Council (NHC), the American Cancer Society Cancer Action Network (ACS CAN) and several patient-advocacy organizations, including the Alpha-1 Foundation, also sent a letter to Secretary Azar, regarding the proposed Step Therapy policy changes.
The text details critical patient protections to be taken into consideration as the current administration implements new policy changes aimed to reduce prescription drug spending that could potentially affect millions of Americans living with serious chronic conditions, such as Alpha-1 Antitrypsin Deficiency (Alpha-1), and who rely on drug therapies to maintain their quality of life, prevent co-morbidities and prevent recurrence or progression of their condition or disease.

This letter was also open to patient advocacy organizations and provider organizations, and the Alpha-1 Foundation supported this initiative to maintain healthcare standards and protect the interests of the Alpha-1 community. To see the entire text, please continue reading.

Alex M. Azar II  
Secretary  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Azar:

The undersigned groups represent millions of Americans living with serious chronic conditions. We want to take this opportunity to share with you our thoughts on the Administration’s proposals to reduce prescription drug spending. The individuals we represent rely on drug therapies to treat their diseases, to maintain their quality of life, prevent co-morbidities, and often to prevent recurrence or progression of their disease. Making prescription drug therapies more affordable is critical for our patient populations.

As the Administration continues to move forward with the recent policy change that would allow Medicare Advantage (MA) plans to use step therapy, we ask you to be mindful of the potential impact on beneficiaries and to implement further safeguards that will assure patient care is not negatively impacted. For many of the people we represent there are few therapeutically equivalent drugs for treating their conditions. Therefore, asking patients to take a drug that is not designed to treat their specific health circumstances could negatively impact care.

As the Administration proceeds with allowing step therapy for physician-administered drugs in MA plans we strongly urge you to accompany the policy with a set of patient protections including:
• **Adherence to evidence-based treatment guidelines**: CMS should require step therapy protocols follow clinical practice guidelines and best practices that have been vetted through the peer review process.

• **Protection for mid-treatment patients**: We understand that CMS is considering ensuring that patients who are currently using medication that has already been proven to work effectively would not be required to change medications. We support this approach. We appreciate your stated commitment to ensuring that these beneficiaries would not be required to change medications and urge CMS to engage in active monitoring and oversight to ensure plans comply with this requirement and have the correct, real-time information required to do so.

• **Recognized standard of care**: MA plans should be required to start step therapy with the recognized standard of care – even if that recognized standard is not the least expensive drug. We ask that CMS work with stakeholder groups to make sure that plans do not deny coverage to patients for medically necessary services including:
  
  o Requiring step therapy to be aligned with evidence-based clinical practice guidelines and appropriate clinical evidence;
  
  o Ensuring that beneficiaries with chronic conditions who may have prior experience with a given drug (even if that experience was in a prior plan year), are not required to undergo step therapy requirements; and
  
  o Ensuring that none of the policies or procedures implemented by plans are discriminatory.

• **A simple and expeditious exceptions & appeals process**: Treatment for patients who need a drug higher in the step protocol should not be delayed by a lengthy appeals process. While the new policy states beneficiaries can use the Part D exceptions process, CMS should closely monitor the extent to which exceptions are being sought to determine whether additional beneficiary protections (e.g., exemption of specific categories and classes of drugs) may be warranted.

• **Full transparency and oversight**: Medicare beneficiaries should know in advance of enrolling whether an MA plan uses restrictive step therapy and understand what impact it may have on access to needed treatments. While CMS intends to require plans to notify beneficiaries through the Annual Notice of Coverage (ANOC), those newly entering the MA plan may not be provided advance notice of this policy. Therefore, the Medicare.gov plan finder should also convey this information. We also encourage CMS to establish a system that will ensure plans comply with patient and provider protections to prevent discrimination. We request CMS collect and provide
to the public information on how many patients are seeking exceptions and appeals, and details of how many are granted.

Thank you again for the opportunity to share our thoughts with you. We look forward to the opportunity to continue a dialogue about these important issues, and the potential impact on patients. If you have additional questions, or would like to discuss any of the issues addressed please reach out to Keysha Brooks-Coley, Vice President, Federal Advocacy, American Cancer Society Cancer Action Network at keysha.brooks-coley@cancer.org or Eric Gascho, Vice President, Policy and Government Affairs, National Health Council at Egascho@nhcouncil.org.

Sincerely,

Signatures on File

**ASP Coalition:**

The Part B Access for Seniors and Physicians (ASP) Coalition submitted a letter on September 12th, 2018 to Senate and House leaders asking them to urge CMS to reconsider the guidance allowing step therapy in MA plans for Part B drugs. The coalition also held a Capitol Hill briefing on September 20th regarding Part B access and step therapy. A summary of the briefing can be found here.

**Sources:**

The Hill, Medicare, eHealth Medicare, Bio, AAD, National Health Council, American Cancer Society Cancer Action Network, National Psoriasis Foundation, ASP Coalition,