January 24, 2019

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

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013


Dear Secretary Azar and Administrator Verma:

On behalf of the Cancer Support Community (CSC), an international nonprofit that provides support, education, and hope to people impacted by cancer, we appreciate the opportunity to submit the following comments in response to the Centers for Medicare and Medicaid Services’ (CMS) Proposed Rule titled “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses.”

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year CSC services more than one million people affected by cancer through our network of 170 affiliate locations and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $50 million in free, personalized services each year to individuals and families affected by cancer across the globe.

We appreciate the opportunity to comment on this proposed changes. We are seriously concerned about the potential harm that the proposed changes could have on millions of cancer patients nationwide.

Protected Classes
Medicare Part D sponsor formularies must include all or substantially all drugs in the six
protected classes which include: 1) immunosuppressant; 2) antidepressant; 3) antipsychotic; 4) anticonvulsant; 5) antiretroviral; and 6) antineoplastic. The six protected classes policy was instituted so that “Medicare beneficiaries reliant upon the drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations. Further, Part D sponsors have not been allowed to implement prior authorization or step therapy requirements intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug (Centers for Medicare and Medicaid Services, 2016)”

CMS proposes three changes to the current protected classes policy including: 1) implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; 2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and 3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period. These changes appear to focus entirely on systemic cost reductions rather than what is in the best interests of patients. As we noted in our comments on the International Pricing Index, if mere cost cutting to the system is the sole or ultimate goal of policy changes, patients will suffer the consequences. The Medicare statute specifies that any changes to the Protected Classes policy must “ensure that any exception to such requirement is based upon scientific evidence and medical standards of practice.” This does not appear to be the catalyst behind the Administration’s proposed changes.

We are particularly concerned about these proposed changes due to the sensitive nature of their treatment regimens. Through a careful shared decision making process with their care team, cancer patients select therapies that are most appropriate for them based on a range of factors. We are concerned that coverage of at least two drugs per class is not sufficient for the patients the protected classes policy was created to protect. Therapies are often designed to target very specific conditions and may have no therapeutic equivalent. The exclusion of unique cancer therapies could force many cancer patients to lose access to the most appropriate therapy. This applies not only to antineoplastic therapies but also antidepressants. Clinical depression impacts 25 to 50 percent of cancer patients (National Cancer Institute, n.d.). Not only can a diagnosis of depression be devastating to cancer patients and their families, but it also increases costs to the health care system. Mausbach et al. (2018) found that cancer patients with depression had total annual health care charges that were 113 percent higher than non-depressed patients. For patients with comorbidities such as cancer and depression, it becomes even more important that all therapies are clinically appropriate and not adjusted for non-medical purposes.

If patients are not provided with the opportunity to select the most clinically appropriate therapies, they may experience delays in appropriate care, poorer physical and psychosocial health outcomes, and increased out-of-pocketing spending.
Utilization Management

The Administration has proposed the use of prior authorization and step therapy for both new starts or existing therapies. This is not in the best interest of patients and we strongly discourage the Administration from implementing this proposed change.

Prior authorization and step therapy are mechanisms designed to force patients to seek pre-approval or try less costly medications or tests only once they have “failed” (or see no disease improvement) before they can obtain the original treatment prescribed by their provider. Given that patients have unique genetic profiles, comorbid conditions, and other personalized considerations, these policies are short sighted and can cause both medical and psychosocial repercussions for patients.

Our 2016 Access to Care study showed that almost half (45%) of patients reported that the treatment prescribed for them was subject to prior authorization. At best, prior authorization result in delays and at worst, rejection of recommended treatment.

For cancer patients, step therapy policies have the potential to cause significant harm as they may delay access to therapies that are the most appropriate and most effective. Patients have differing responses to treatments and personalized medicine in offering more targeted options. It is critical that providers have the autonomy to exercise discretion in treatment recommendations, incorporating both clinical evidence as well as patient input through shared decision making. Our research shows that step therapy can cause patients to delay care, pay higher out-of-pocket costs, and at times, forgo treatment altogether. Among respondents to our 2016 Access to Care survey who had experienced a step therapy mandate:

- 52.9% experienced unexpected out-of-pocket cost due to the insurance company mandated treatment for prescription drugs
- 52.6% of those who were prescribed treatment by their doctor had to wait 7-30 days to receive the originally prescribed medication
- 52.4% felt that step therapy had delayed their treatment
- 49.1% worked with their doctor’s office to request an exemption from the insurance company and half of those individuals reported not receiving the treatment originally prescribed by their doctor
- 32.1% reporting starting the medication required by their insurance company instead of taking the medication that was originally prescribed for them
- 18.9% started the medication required by the insurance company while simultaneously requesting an exception
- 16% delayed treatment by deciding not to take the medication and waiting until an exception was granted
- 8.5% decided not to start any medication

We have heard directly from patients that prior authorization and step therapy can cause delays in treatment, increased distress, and unexpected costs. Step therapy policies also have the
potential to pose administrative burdens for health care providers who according to Caslino et al. (2009) already spend a considerable amount of time on insurance requirements each year.

As such, we encourage the Administration to retain the existing protections designed to ensure specific Medicare patients can access the therapies that work best for them. We do not support utilization management tactics in Medicare Part B or Part D or in Medicare Advantage plans.

In conclusion, we do not support the proposed changes to Medicare Part D and urge the Administration to not finalize them. Please work with patients and patient advocates to ensure future changes are in the best interest of patients. If we can serve as a resource, please don’t hesitate to contact me at efranklin@cancersupportcommunity.org or 202.650.5369.

Sincerely,

Elizabeth Franklin
Executive Director, Cancer Policy Institute
Cancer Support Community Headquarters

References


