March 5, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave, S.W.
Washington, DC 20201


Dear Administrator Verma:

The American Society of Clinical Oncology (ASCO) is pleased to provide comment on the 2019 Draft Call Letter. ASCO is the national organization representing nearly 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

We applaud the Agency’s commitment to ensuring access to necessary treatment for cancer patients. Our comments focus on updating and streamlining prior authorization requirements and policies to prevent and mitigate the opioid epidemic’s consequences throughout the country.

Traditionally, cancer therapies were provided intravenously and reimbursed by Medicare through the Part B benefit. Many anticancer drugs are still administered via infusion, but recent scientific developments and advances have increased the proportion of orally administered anticancer drugs covered by Managed Care Organizations (MAOs) and Part D Plan Sponsors (Plan Sponsors) through the Medicare Part D benefit.
CMS should go beyond the transparency, adherence to timelines and other requirements laid out in the Draft Call Letter and examine the impact of MAO’s and Plan Sponsors’ business practices on patient care and outcomes.

The rise in orally administered cancer therapies has created new challenges in securing patient access to the most appropriate treatment at the most appropriate time for their diagnosis and unique clinical condition. We wish to reaffirm our support for the strong “protected class” standard that requires each unique antineoplastic molecular entity to be covered by each Part D plan’s formulary.

As providers are increasingly held to account for quality outcomes, it is important to understand the impact of actions taken by MAO and Plan Sponsors that affect patients in ways beyond providers’ control. There is increasing interference by MAOs and Plan Sponsors through non-medical switching, delays in prior approval requests and deliveries of incorrect prescriptions. MAO and Plan Sponsors also make medical decisions that impact patient care without the approval of physicians, including adjustment of dosage amounts. Such decisions are medical practice and should never be made independently by an administrative intermediary. Cancer care decisions should be guided by the medical team and the patient. Additionally, ASCO members have significant concerns about the unnecessary administrative burdens imposed by Part D MAO and Plan Sponsor policies.

The *American Society of Clinical Oncology Policy Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies* outlines adverse impacts on access to high-quality, high-value cancer care resulting from these policies, and lays out recommendations for streamlining and simplifying utilization management and prior authorization processes. Additionally, similar work by numerous provider organizations has led to the adoption of certain principles for the design and implementation of prior authorization programs. The *Consensus Statement on Improving the Prior Authorization Process* was recently adopted by the Association of Health Insurance Plans (AHIP) and Blue Cross/Blue Shield Association (BC/BS), signaling the recognition of the need to address delays in patient care and administrative burdens resulting from prior authorization policies. We urge the Agency to consider ASCO’s Utilization Management statement, as well as the consensus principles to protect patient access to the most appropriate treatment.

Several other business practices also impede timely access to necessary cancer therapies. We urge you to consider the following recommendations from ASCO’s comments (attached) to

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CMS-4182-P, the proposed rulemaking revisions to the Medicare Prescription Drug Benefit Program (Part D) for 2019:

- As CMS weighs new policies it is imperative to also find ways to guard against instances where financial toxicity will impede access of cancer patients to life-saving and life-extending drugs.
- CMS should clarify “any willing pharmacy requirements” to explicitly recognize in-office physician dispensing as capable of meeting the standard terms and conditions for network participation.
- ASCO supports the Agency’s efforts to eliminate arbitrary barriers erected by MAOs and Plan Sponsors intended to limit the number and types of pharmacies that can dispense drugs for certain conditions, including oral cancer therapies.
- CMS should exempt cancer drug therapies from specialty tiers because specialty tier placement imposes high cost-sharing burdens that target cancer patients. Given the limited treatment options available to many cancer patients it is fundamentally unfair and counterproductive to include cancer drug therapies on a specialty tier.

One promising approach Medicare could take to promote the appropriate selection of anti-cancer therapies is the implementation of high-value clinical pathways. ASCO strongly supports the use of clinical pathways that promote access to the right drug, for the right patient at the right time. We urge CMS to explore mechanisms to promote the use of high-value clinical pathways by MAO and Plan Sponsors and MAO and Plan Sponsors.

**ASCO supports the continued exclusion of beneficiaries with cancer or in hospice from Part D Opioid utilization policies, to ensure access to medically necessary pain medicine.**

Opioid therapies are often an essential component of cancer care and may be necessary during any phase of treatment, including supportive care with no active anti-cancer therapy. There is broad agreement among clinicians that opioid therapy is generally the first-line approach, alone or in combination with other medications, for management of moderate to severe pain associated with active cancer, whether or not the patient is receiving anti-neoplastic therapy.

Many advances have been made in cancer treatment, and many survivors cope for months and years with the delayed side effects of curative as well as life-prolonging cancer therapies. Cancer survivors often suffer from well-recognized post-cancer or post-treatment syndromes, such as inflammation of peripheral nerves from chemotherapy (peripheral neuropathy), painful swollen limbs (lymphedema), post-surgical pain syndromes such as phantom limb pain, pain from rejection of normal tissues (graft versus host disease after transplant), or post-radiation therapy nerve syndromes.

Many of the new laws, guidelines, and regulations restricting access or limiting doses of prescription opioids specifically exempt patients with cancer-related pain. This recognizes the unique nature of their disease, and potentially life-long adverse health effects from having had cancer.
The “hard edit” of 90 MME (morphine milligram equivalents; approximately equal to 60 mg of oxycodone) per day to be implemented by Medicare Part D plans would mean that patients requiring over 90 MME per day would need to be approved for such treatment through a special exceptions process. We applaud the Agency for specifically exempting patients with cancer and patients in hospice from these requirements in recognition of the special needs of these populations.

Finally, ASCO is a strong supporter of the policies within the Comprehensive Addiction and Recovery Act (CARA) intended to address the opioid addiction epidemic. We applaud the Agency’s dedication to implementing policies to prevent and mitigate the opioid epidemic’s consequences throughout the country. As CMS continues implementing CARA’s directives, the Agency must consider the unique needs of specific populations to prevent any unintended gaps in patient access to medically necessary pain medication, including the cancer patient population.

ASCO is also on record in support of the Agency’s proposal that exempts cancer patients from CARA’s new drug management program for at-risk beneficiaries. The proposed policy acknowledges that oncologists are specially trained to help patients cope with pain that cancer patients may encounter throughout their cancer treatments. Prescription medications with addictive potential are widely used in palliative care and to treat pain associated with both chemotherapy and radiation therapy treatments. The Agency’s decision to exempt cancer patients from the program recognizes their unique needs and will help insure their immediate and timely access to medically necessary pain relief during all stages of treatment.

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Thank you for the opportunity to provide comment on the 2019 Draft Call Letter. Please contact Sybil Green at Sybil.Green@asco.org with questions.

Sincerely,

Bruce Johnson, MD, FASCO

President, American Society of Clinical Oncology