March 10, 2023

Submitted electronically to: http://www.regulations.gov

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program (CMS-0057-P)

Administrator Brooks-LaSure:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), we are submitting this comment letter regarding a proposed rule by the Centers for Medicare & Medicaid Services (“CMS”) on streamlining the prior authorization process. In this document, we refer to this prior authorization proposed rule (CMS-0057-P) as the “Proposed Rule.”

As background, COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the independent community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding 20 years ago, COA’s mission has been to ensure that patients with cancer receive the highest quality, most affordable, and most accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status.

Simply put, prior authorizations by insurers in Medicare Advantage and commercial plans are out of control. Rather than being used to ensure proper treatment and control waste, prior authorizations – along with “fail first” step therapy and other “utilization management” tactics – are used to control costs. Prior authorizations are roadblocks to Americans with cancer getting the optimal treatment on a timely basis.

In cancer, we are fortunate to have national guidelines and specific treatment pathways to help ensure optimal therapy is provided. However, oncologists and staff are subjected to what are often inane prior authorization discussions with insurer medical staff that have no background in cancer treatment. Insurers approach prior authorizations as a “roadmap” to
allowing or denying treatment. This is an inhumane approach to dealing with patients who are “fighting” cancer but don’t expect to have to fight with their insurers, as well.

COA appreciates the efforts of CMS to address the prior authorization problem, as evidenced in the Proposed Rule. Patients and providers will benefit from the scrutiny of prior authorization rules. We particularly applaud that reporting provisions would require insurers to quantify the number of denials and, as importantly, the reasons for the denials. Insurers being measured and held accountable for their actions will likely in and of itself begin to limit the more trivial prior authorization requirements. However, it is essential that CMS ensure that information is publicly posted in a manner that is easy for patients and other stakeholders to interpret. While transparency is an important first step, CMS should use information shared in these reports to inform future action to limit inappropriate uses of prior authorization.

COA furthermore agrees with CMS’ goal of reducing the burden that prior authorization processes currently place on providers. Strong oversight from CMS will be crucial for ensuring that, if implemented, these proposed changes accomplish that goal. CMS must seek ongoing feedback from providers on how to streamline these processes and limit instances of prior authorization.

Prior authorization as a tool of cost control has a different face with every set of conditions and diseases. In cancer treatment, prior authorization is often required for advanced imaging studies, specialized laboratory testing, molecular and genetic testing, specialized radiation therapy treatments, and related treatments and diagnostic procedures. However, one of the most important areas is that of the actual treatment of cancer with complex drug chemotherapies and immunotherapies.

COA finds it very troubling that the Proposed Rule excludes drugs. CMS must not ignore the increasing problem of drug prior authorizations in cancer treatment, especially as used by Medicare Advantage insurers; this is puzzling that drug treatment is not included in this Proposed Rule and is a serious omission by CMS. Physician-administered drugs under Part B and the increasing availability of oral cancer drugs under Part D are mainstay cancer therapies. As CMS fails to address this critical aspect of cancer treatment, cancer patients are delayed and denied critical life-saving therapies by excessive and misguided prior authorizations, at times even resulting in death. Addressing the drug treatment for a person’s cancer should clearly be part of any effective, comprehensive regulatory initiative to streamline the current onerous prior authorization processes employed by Medicare Advantage plans.

It is difficult for COA to comment on a rule on prior authorizations that carves out cancer drugs. Without the inclusion of drug treatment, the Proposed Rule is an incomplete regulation from CMS. This is why COA is looking to Congress to act in a bipartisan effort to stop insurer misuse of prior authorization.

We will leave you with one of the many, every day stories of oncologists trying to hurdle the obstacles of prior authorizations in fighting to provide their patients with optimal cancer care.

Just two weeks ago, COA Vice President Dr. Debra Patt testified on the pain inflicted by PBMs on patients at a hearing of the Senate Committee on Commerce, Science and Transportation. Speaking to committee Chair Senator Maria Cantwell (D-WA), Dr. Patt related the story of her patient Tania dealing with metastatic breast cancer. In a prior authorization review, the PBM refused Dr. Patt’s request for a drug that she felt, based on clinical evidence, would help Tania. Because the PBM said a peer review of the case would take some six weeks, Dr. Patt had to resort to another treatment plan – an inferior treatment plan – of chemotherapy. Unfortunately, about two weeks after Dr. Patt’s testimony Tania died. Who knows if the denied drug would have helped Tania, but denials rob patients of hope and cause unnecessary suffering.
This is the story of prior authorizations. Unfortunately, this is not an isolated case – oncologists deal with these types of cases on a daily basis.

A new nationwide survey\(^1\) on prior authorizations conducted by Lake Research Partners and the Tarrance Group for the organization Let My Doctors Decide found that:

- 75 percent of health care consumers are concerned that prior authorization can delay or block patients’ access to treatment.
- 71 percent are worried that prior authorization will increase patient costs.
- 74 percent expressed concern that prior authorization can require patients to substitute less effective or ineffective treatments for what their doctors prescribed.
- 72 percent said they are concerned that such policies can override doctors’ recommendations by allowing insurance companies to control treatment decisions.

When patients express concern about prior authorizations, they are not compartmentalizing their medical treatment into services and drugs. They are looking at their complete medical treatment, which involves both drugs and services. CMS needs to do the same in addressing prior authorizations.

It is imperative that the growing problem of prior authorizations be addressed now, not wait until 2026. Furthermore, any solution must include drugs.

**COA recommends that CMS implement a “gold card” program for prior authorizations, which should include drugs, in Medicare Advantage.** COA implores CMS to implement such a “gold card” program in Medicare Advantage as soon as possible. *This cannot wait until 2026!*

If CMS is interested in exploring what would be a simple solution to the growing prior authorization problem – a “gold card” program – we welcome the opportunity to discuss this in detail. In fact, what CMS, **at the very least**, should do is pilot a “gold card” program in Medicare Advantage using its Innovation Center. Once again, we would welcome the opportunity to discuss this in detail.

Sincerely,

Miriam Atkins, MD, FACP
President

Ted Okon
Executive Director

CC: The Honorable Cathy McMorris Rodgers, Chair, House Energy & Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy & Commerce Committee
The Honorable Jason Smith, Chair, House Ways & Means Committee
The Honorable Richard Neal, Ranking Member, House Ways and Means Committee
The Honorable Ron Wyden, Chair, Senate Finance Committee
The Honorable Mike Crapo, Ranking Member, Senate Finance Committee