Prior Authorization

Prior authorization (PA) requirements have become a top concern of cancer care providers and their patients. These utilization management mechanisms aim to curb the provision of care that is not medically necessary or appropriate. Yet in practice they may hinder patients' access to necessary services and treatments, potentially leading to delays in care and harm to patients. They also often pose administrative burdens on multi-disciplinary provider teams, patients, and families.

PA is a tool used by many payers, including certain Medicare and Medicaid plans and private commercial plans sponsored by insurers and self-funded employers. It generally requires patients or their providers to secure pre-approval as a condition of coverage or payment for a specific medication or service. Yet in addition to delays, some payer approval processes are not sufficiently transparent, and may include determinations made by personnel with limited knowledge of oncology. In light of these concerns, ACCC members and other stakeholders have sought policy changes to address certain problematic PA practices, and policymakers have begun to respond.

Federal Regulatory Action

In January 2024, HHS/CMS published a rule on prior authorization, applicable to many of the plans regulated by the federal government via HHS. It includes electronic interoperability requirements and imposes timeframes and processes for plan decisions. Plans must also provide a reason for denials and publicly report certain metrics. The rule doesn't apply to PA decisions for prescription drugs.

The regulation specifies that plans must send decisions within 72 hours for urgent requests and 7 days for non-urgent requests. It applies to Medicare Advantage (MA) plans, Medicaid and CHIP fee-for-service and managed care plans, and certain private plans ("Qualified health plans") sold on the Obamacare exchanges, but it does not apply to employer-sponsored health plans, many of which are regulated by the Dept. of Labor. Most of these policies are effective on 1/1/2026, with metrics being required to be reported by March 2026.[1]

Additionally, the final Medicare Advantage and Medicare Part D rule, published in 2023 and effective as of January 1, 2024, clarifies clinical coverage criteria to ensure that those

[1] CMS Interoperability and Prior Authorization Final Rule CMS-0057-F | CMS; CMS finalizes rule tightening prior authorization turnaround for insurers | Healthcare Dive

covered by MA plans have access to the same medically necessary care they would receive under Traditional Medicare.[2]

Federal Legislation

ACCC had previously endorsed the "Improving Seniors' Timely Access to Care Act," which was approved by the House Ways and Means Committee in 2023. An updated version of this legislation was reintroduced in June 2024 and incorporates key elements detailed below:

- Requirements for an electronic PA program;
- Transparency and reporting requirements; and
- Enrollee protections, which include allowing for the waiver or modification of PA requirements for contracted providers and suppliers, based on their performance and demonstration of compliance with requirements, such as adherence to evidence-based medical guidelines and other criteria.

The legislation also clarifies that the HHS Secretary may establish timeframes for Medicare Advantage (MA) plans to respond to different types of prior authorization requests, such as requests for expedited determinations, real-time decisions for routinely approved items and services, and any other type of prior authorization request. The provision cites "24 hours" as an example of a timeframe the HHS Secretary could establish.

Limitations of the Legislation

While it is helpful to codify certain protections, this legislation has a much more limited reach than the recent CMS regulation. For example:

- It only applies to MA plans;
- It has no mandated timelines for expedited or standard decisions; and
- Like the regulation, it does not apply to decisions relating to prescription drugs.

Recommended Actions for policymakers

ACCC recommends that this or any other federal legislation or policy relating to PA include the following provisions, in addition to the protections in the legislation described above:

- Broad applicability to all plans, including ERISA-governed plans;

[2] HHS Finalizes Rule to Strengthen Medicare, Improve Access to Affordable Prescription Drug Coverage, and Hold Private Insurance Companies Accountable to Delivering Quality Health Care for America's Seniors and People with Disabilities | HHS.gov

- Timelines for expedited and standard decisions that are, at a minimum, no longer than those in the CMS regulation;
- Mandate that suppliers and providers may seek a waiver from PA requirements, based on their compliance with specified requirements, such as evidence-based medical guidelines; and
- Clear enforcement mechanisms, including enrollee and provider education on the availability of appeals processes.

ACCC welcomes input and the exchange of ideas on this important policy issue with a range of interested stakeholders.