Prior Authorization Reform is Needed for Timely Patient Access to Critical Laboratory Tests

Clinical laboratory test services range from routine testing to ascertain basic health, to the most advanced and innovative genetic testing, foundational to personalized medicine. Timely access to laboratory testing for patients and the providers who care for them is critical because these tests inform approximately 70% of health care decisions, help guide treatment and impact patient outcomes[1]. For patients, some payor policies result in denials and delays in testing, which can have life-threatening consequences.

Aggressive Prior Authorization Policies Harm Patients and the Laboratories that Serve Them

Prior authorization policies enacted by many payors are increasingly moving beyond limited efforts to ensure appropriate utilization of testing and being applied more broadly, often blocking or delaying access to necessary care. These policies harm patients by restricting access to a wide array of necessary tests, including liver and metabolic panels, genetic testing for mutations that increase the risk of developing cancer, prenatal screening tests, infectious disease testing, and biomarker testing used to determine the most effective cancer treatment.

For clinical laboratories, aggressive prior authorization practices often result in reimbursement denials for medically necessary testing services already performed. These practices also increase inefficiency in the healthcare system by forcing laboratories, ordering providers, and even payors to devote precious time and resources to obtaining and submitting medical documentation retroactively for test results that have already been delivered.

Aggressive prior authorization practices put patients and laboratories in an untenable position and negatively impact patient care. If a laboratory waits to run a test, often for days until prior authorization requests are approved, crucial results would be delayed, preventing clinical decision-making for patients and potentially causing real harm. If a laboratory proceeds with testing samples without authorization, it risks not getting reimbursed for even the most routine tests.

CMS Regulations are a Step in the Right Direction, but More Changes are Needed

In January 2024, CMS finalized a much-anticipated rule requiring some payors to follow certain guidelines

when using prior authorization[2]. The rule aims to provide greater transparency for prior authorization policies, facilitate the exchange of information necessary for prior authorizations, and tighten some timeframes for prior authorization decision-making. Impacted payors will be required to implement and maintain a Prior Authorization Application Programming Interface (API), an electronic system with multiple components that patients, providers, and payors can utilize to monitor the progress of prior authorization requests.

The API concept holds great promise. Successful implementation will require electronic health record (EHR) vendors to prioritize integration with APIs and other systems used by ordering providers, payors and laboratory benefit managers (LBMs), which often facilitate prior authorization processes for and regulate access to laboratory testing services. Some LBMs have their own electronic portals, which users report do not always work as they should, and many LBMs necessitate labor-intensive appeals for prior authorization on behalf of the payors.

Importantly, the rule application is limited to Medicare Advantage plans, state Medicaid fee-for-service (FFS) programs, Medicaid managed care plans, state Children's Health Insurance Program (CHIP) FFS programs, CHIP managed care entities, and qualified health plan issuers on a federally facilitated exchange. While the rule takes steps in the right direction, further safeguards and proper implementation are needed to ensure clinical laboratory testing is neither delayed, nor payment denied, for covered services by prior authorization processes.

ACLA Recommendations to Congress on Prior Authorization Reform

Enhance Transparency of Payer Prior Authorization Policies and Processes

Building upon the CMS rule, Congress should:

- Require all payors to make publicly available—in an easily accessible electronic format—coverage policies and documentation requirements for items and services requiring prior authorization. If coverage policies and/or criteria are developed or overseen by a third-party LBM under contract with the payor, this information should be clearly marked to provide full transparency and accountability when patients and medical providers have questions about a given coverage policy.
- Require all payors to publish annual prior authorization use and performance statistics to include: the number of prior authorization requests received, the number of prior authorizations granted and denied with decision timeframes, the number of incomplete prior authorizations, denial reasons, and the number of denied prior authorization requests appealed and the results. To ensure the data is meaningful, these metrics should be broken down by ordering provider specialty.
- Require payors to make public a summary by test description and HCPCS code of the number of prior authorization requests received and granted, not completed, or denied.
- Require CMS to establish a "hotline" through which providers can identify instances when payors have failed to comply with CMS rules on prior authorization and to develop a clear resolution

[2] CMS Interoperability and Prior Authorization final rule (CMS-0057-F), 89 FR 8758

process outside of the appeal process when prior authorization problems are reported.

Align Prior Authorization Processes with Laboratory Order Processes

To alleviate fundamental misalignment between laboratory order processes and prior authorization processes, Congress should:

- Require payors to accept prior authorization requests from laboratories as suppliers of services and allow labs to check on the status of prior authorization requests, regardless of the contract status with the payor.
- Require payors to accept submission of prior authorization requests for laboratory services either before specimen collection (the date of service) or at any time between specimen collection and the data a timely claim for reimbursement is submitted to the plan, precluding administrative payment denials based on clinical laboratory test "date of service."
- Require payors to accept patient information included on a test requisition form (TRF) submitted by the ordering clinician, along with physician attestations, as valid medical documentation for the purpose of prior authorization processing.
- Direct CMS, consistent with Medicare fee-for-service, to require Medicare Advantage plans to accept appeals filed within 120 days and should work with CMS to require impacted payors to provide a prior authorization decision within 24 hours for expedited requests or within 72 hours for standard requests.

Ensure Functionality of Payer Prior Authorization Portal Technology

To ensure payor technology is functioning properly, Congress should:

- Direct CMS to require payors leveraging electronic prior authorization portals to allow providers to report portal faults to payors and CMS. Such faults must be successfully resolved within 72 hours, with providers informed of the resolution. Payors should establish an alternative claims adjudication process when electronic systems are down.

Prevent Additional Coverage Barriers Following Prior Authorization Approvals

Congress and CMS should develop policies to ensure that payors are required to honor their decision-making, including:

- When a payor gives prior authorization for a laboratory test based on documentation that supports the medical necessity of the test, the payor should not be allowed to later deny payment for the test on the basis that it was not medically necessary for the patient.

For more information, contact Mary Lee Watts,
ACLA Vice President of Government Affairs and Policy at mlwatts@acla.com.