

## **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<sup>1</sup>. 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.

### **Congress and CMS Should Address Laboratory-specific Challenges with Prior Authorization to Support Patient Access**

In January 2024, the Centers for Medicare and Medicaid Services (CMS) released the CMS Interoperability and Prior Authorization Final Rule, which, if fully implemented, will require payors to follow

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<sup>1</sup> <https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html>

certain guidelines when using prior authorization to provide greater transparency for prior authorization policies, facilitate information exchange necessary for prior authorizations, and tighten some timeframes for decision-making<sup>2</sup>. However, the rule as written would not mitigate the most significant challenges faced by clinical laboratories due to prior authorization policies, especially those stemming from a misalignment between laboratory workflow and order processes and prior authorization processes.

The rule calls for impacted payors 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, but 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.

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. 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**

### **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 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 date a timely claim for reimbursement is submitted to the plan, precluding administrative payment denials based on clinical laboratory test "date of service."
- Direct CMS to update the laboratory "date of service" definition to clarify that the "date of service" cannot be used as rationale to deny appropriate coverage or restrict beneficiary access to services.
- 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 prior authorization processing.
- Direct CMS to further shorten the timeframe for impacted payors to provide a prior authorization decision to 24 hours for expedited requests or 72 hours for standard requests.
- Direct CMS, consistent with Medicare fee-for-service, to require Medicare Advantage plans to accept

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<sup>2</sup> CMS Interoperability and Prior Authorization final rule (CMS-0057-F), 89 FR 8758

appeals filed within 120 days to alleviate the burden of appealing complicated, inappropriate prior authorization denials.

## Enhance Transparency of Payer Prior Authorization Policies and Processes

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

## 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 a prior authorization approval 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.

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