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Understanding Appeals

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As labs prepare to commercialize a test for the first time, it is important for them to establish billing policies and processes that will ensure proper claims submission, which, in turn, can result in better reimbursement and faster collection times. A well-considered appeals strategy is critical to that effort, as denial rates for new tests are high before a test has been reviewed for coverage by commercial payers.

An effective appeals strategy should consider the following:

Types of Denials

There are many reasons a payer will deny a claim, and the type of denial informs the type of appeal submitted to a payer. Common types of appeals include:

Out-of-network. As commercial payers move toward more limited lab networks, they will often not pay claims to providers that are not under contract. This is a particular challenge for patients, as labs performing proprietary laboratory-developed tests (LDTs) are, by definition, the only providers of that particular test. LDT developers can consider appealing based on the fact that an in-network lab cannot offer the test ordered by the physician and, therefore, neither patients nor providers should be penalized for not using a contracted lab.

Experimental and investigational. Often referred to as E&I, these appeals reflect the payers' concern that the published data available on the test do not support its use. E&I denials are common for some time after a test is commercialized and before coverage policies are established. In response, labs should be prepared to explain the role of the test inpatient care and cite the published evidence available in the appeal. In addition, appeals may be more successful if they are submitted along with a statement (or letter) of medical necessity from ordering physicians, explaining why they think a particular test is an important part of a patient's treatment plan.

Prior authorization. Commercial payers are increasingly relying on prior authorization (PA) in an effort to control the cost and utilization of lab tests. A PA is a request for approval for use of the test before it is ordered and typically involves providing proof that the patient meets certain clinical criteria for eligibility. PAs must be submitted by the ordering physician. If the physician neglects to do so when one is required, the claim is likely to get denied. The lab may have recourse via appeal if CPT codes with established coverage criteria are used for billing the test. Otherwise, appeals on a denial due to lack of PA are likely to be unsuccessful.

Medicare Advantage. Medicare Advantage (MA) plans are mandated to follow a coverage decision issued by a local Medicare Administrative Contractor (MAC). However, MA plans may continue to deny claims, especially shortly after approval and before they have determined that the test has been approved for coverage. Labs should submit an appeal with the effective date of coverage and a description of the criteria for which the test is covered. The MAC's coverage policy should accompany the appeal.

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Low payment. If a lab submits a claim to a payer prior to negotiating a payment rate, it is common for the payer to pay less than the amount charged on the claim. Labs can try to appeal these types of claims based on the strength of the evidence available, the limited alternatives, and the novelty of the test. If the reimbursement amount falls below a payment rate set by Medicare, labs can also try to appeal based on what Medicare has agreed to pay.

Levels of Appeals

Part of an appeals strategy is to determine how many levels of appeal to pursue, as there is no guarantee that an appeal will be overturned after the first attempt. For commercial payers, the first appeal is submitted to the payer along with any supporting documentation. If the claim is still denied, it can be filed for external review. Health plans are required to offer this either through the state or states in the health plan's service area or the Department of Health and Human Services.

For Medicare, there are five levels of appeal. The first level, called a redetermination, is handled by the MAC that is processing the claim. If that is unsuccessful, a second-level appeal, or reconsideration, can be filed with a qualified independent contractor that was not involved with the first appeal. A Level 3 appeal involves an administrative law judge. Appeals at Level 4, reviewed by a Medicare Appeals Council, and Level 5, a judicial review by a federal district court, are rarely pursued by labs unless there is sufficient evidence and documentation of medical necessity.

For new tests, more than one level of appeal is typically needed. Payers often deny a test because it is not considered medically necessary or because it is considered experimental and investigational. The payer may deem the test inappropriate or unnecessary based on its own internal review. Medical records and a cover letter supporting medical necessity should accompany the first-level appeal. It is common for the initial appeal to be unsuccessful and require higher level appeals, which typically prompt an independent and external review to determine whether the test is an appropriate part of the treatment based on the doctor's rationale.

Appeals Process

The appeals process can be lengthy and time-consuming, and each successive level of appeal is typically more expensive. However, it is often in a lab's interest to try to overturn initial denials in order to (1) receive payment and (2) establish a record of utilization that can be used when approaching payers for coverage. An appeals strategy should balance the likelihood of success on appeal with the resources required to achieve it.

Appeal letters. Appeal letters should be customized to the type and level of appeal. Many labs develop templates for the more common types of appeals, which help expedite turnaround times after a denial is received. Letters should include the name and description of the test, a response to the specific reason for the denial, references to published clinical data (if relevant), and documentation that supports the appeal.

Write-offs. Labs should be prepared for write-offs, classifying them and using them to determine appeals success. Labs should be prepared to write off a considerable amount of these tests before they start to see a return. Even with coverage, labs will likely need to appeal some denials to get reimbursement from commercial payers and Medicaid.

When taking write-offs, it is important labs have a standard way of classifying them. Which are contractual or allowed amounts that are agreed upon with an out-of-network payer? Which are for medical necessity, out-of-network, plan exclusions, or other reasons?

Understanding and documenting the type of write-off by payer helps labs monitor when appeals are successful and when a different approach is needed. It can also be helpful in convincing other payers to pay reasonable rates or to establish a contract if the rates are quantified by what other payers are paying.

Technology

A billing platform is critical in allowing labs to track different requirements for appeals by payer, allowing the different appeal levels to be set programmatically. The technology can automatically integrate the documentation required for appeals into a package that meets the unique requirements of different payers. The same platform should be able to track the status of an appeal in process, how the payer has responded, how much longer before follow-up is needed, and to what degree efforts are successful. Without a good software solution to facilitate this process, the labor required to manage appeals will increase while the ability to collect will likely diminish.

Summary

In summary, an appeals strategy that considers the type and level of appeal and provides supporting documentation tailored to each appeal is likely to result in increased collections. In addition, labs should consider investing in billing technology that will automate and track the appeals process to further optimize revenue.

Becky Foster is an independent consultant to diagnostic labs, biotechnology manufacturers, and digital health companies. She has spent over 20 years working on managed care and reimbursement strategy and policy. She is experienced in creating and implementing strategies for obtaining coverage from payers and developing billing and coding plans.

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