

To Pay or Not to Pay? Is that the Question?

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GENETIC TESTS ARE AN INCREASINGLY important tool for diagnosis and disease management. Correctly diagnosing a disease or determining which medication or dose to prescribe is essential to managing health and disease. Diagnostic data drive more than 70% of healthcare decision making but reimbursement from both public and private payers has emerged as the new crucible with increasing uncertainties for the entire sector.

In recent years, developing the test has become the least difficult aspect, when compared with getting tests covered and reimbursed in the current healthcare environment. For these reasons, institutions, hospitals, and companies are committing dedicated personnel to just getting testing reimbursed. If you are one of those reimbursement personnel, read no further—this will be too elementary for you. However, if you are curious about the realm of reimbursement from the clinical care point of view, this may reveal a bit of the complexities.

Current practice, and seemingly simple steps, toward reimbursement is first to confirm that the insured and/or assignee has coverage for the test. Then the provider's office or the testing laboratory must complete the health insurance company's precertification or authorization processes. This includes completing various forms and multistep data capture, verification, and medical necessity review processes to receive a decision of coverage and/or denial. Then other bureaucratic steps to petition for access or reconsideration can be unique to each and every payer (even different processes can occur within a single payer based on the patient's policy). Sometimes these forms and application procedures are so complicated, and can present such time-bound challenges, that only experienced personnel can successfully navigate the gauntlet. This scenario presents significant impediments to diagnostic innovation, timeliness of clinical management, and overall efficiencies of healthcare delivery. The promise and rate of adoption for precision medicine is running headlong into an arcane, nonresponsive, and systemically dysfunctional coverage/reimbursement environment.

Although the uninitiated might imagine that the test itself would be the most critical element in determining payment, in fact each insurance policy has different requirements for copayments, deductibles, special exemptions, exceptions, exclusionary statements, as well as annual minimums to be met before reaching eligibility for reimbursement or limita-

tions of the same. These are not dependent on the characteristics of the test alone. For instance, the insured might be required to make a copayment for services rendered on the date such services are provided, or their policy may even exclude (implicitly or explicitly) certain medical services, such as genetic testing. This is largely true, for the military, because the insurer for U.S. military personnel does not pay for most genetic tests regardless of established standard of care practices.

A “Denial of Reimbursement” of the submitted claim for payment by the policyholder's insurance company is a common outcome of most genetic test submissions. There have developed a number of perverse incentives and disincentives in the risk-based health insurance market in the United States. In addition, there are also many legitimate questions arising from evidence-based medicine practice guidelines, appropriateness of testing considerations, health economic value, demonstrated medical actionability, and questionable clinical utility evidence of such services. In essence, private health insurers are acting as a judiciary agent on behalf of the policy holder and helping to manage limited resources to provide access to proven high-quality healthcare services for an annual fixed premium payment. This can be considered an important safety valve on better medicine for all, or it can impede necessary innovation in advancing better diagnostics. The truth is likely somewhere in the middle.

Insurance companies can deny a claim for many reasons. The first step is to find out why the claim was denied. This process is called Claim Denial and Appeal Management and involves direct interaction with the insurance company to find out why the initial claim was denied. Common reasons for claim denial are as follows:

- incomplete and/or inaccurate insurance information,
- lack of precertification and/or prior authorization,
- noncapture of tests and/or procedures (descriptors),
- diagnosis and/or procedure coding errors and/or omissions,
- past timely filing limits,
- insufficient medical necessity, or
- copay, deductible, patient portion policy requirements.

If the claim is denied, then the claims appeal process is the next step, and perhaps the next step, and maybe even the next step, which leads to a lengthy and costly process. This takes a great deal of fortitude, perseverance, and rigorous advocacy

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on behalf of patients, families, and communities. Enlisting the support of providers, advocates, and additional evidence is often required, for example, medical care teams, hospitals, professional associations, medical specialty societies, health technology assessment groups, patient support organizations, consumer groups, published peer-reviewed medical literature, compiled clinical evidence dossiers, medical necessity support letters, and even demands for accountability to the insurance company's own established policies can be used to reverse the claim denial.

These appeal tactics for genetic testing services usually involve a lengthy claim-by-claim management approach (i.e., one-off claim appeals processes) until the insurer is driven to overturn the denial in response to (1) a larger percentage of overturned similar or the same denials, (2) the expense of adjudicating said denials, (3) physician ordering pressure, and/or (4) direct payer engagement to consider a formal coverage and payment policy for the testing service or for the provider under a negotiated contract.

Insurance companies spend a great deal of time and infrastructure adjudicating claims of all sorts. Eventually, they should pay the claim if and when the conditions are met for a clean claim submission and the requirements of medical necessity are demonstrated. Most insurers use automated auditing and claims management software, often called "claim review programs" to sift through millions of submitted claims. Some in the business have crassly called these *denial engines* because their intent is to reduce the amount of money paid to physicians, hospitals, and other providers. These auditing programs work to find technical errors in billing codes, units of service, dates of service, and special editorial comments

unique to the payer, which doctors, hospitals and clinics, among others, submit for payment. The program's algorithms vary by insurer, therefore, the odds of predicting denials or approvals are a black box, not an exact science.

The complexity of reimbursement for all healthcare procedures and services is something that places a great burden on the healthcare delivery system. It would seem that reform in this regard should be a priority, but various forces dictate otherwise. One would hope that consumer demand for transparency and sunshine on these mechanisms might increase; however, the system is so complex, and the consumer so far removed, a consumer movement for reform does not seem to be on the horizon anytime soon. Genetic testing may suffer an even greater plight because of the inherent complexity involved, even as we enter the age of advanced diagnostic measurement science, molecular quantification of disease, and the realization of precision medicine. The question remains: to pay or not to pay within routine clinical care practice? Or will health insurance reimbursement challenges force this technology into the realm of patient and consumer direct pay? If the latter is established, then sadly precision medicine will become an innovation that increases disparities rather than reduces them.

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