Preauthorization Toolkit

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Utilization Guidance Services

Introduction

While many institutions share the goal of establishing a standard method of obtaining preauthorizations for genetic testing, this can be a daunting task. The resources and personnel available for this effort will likely vary between institutions.

Recognizing that each institution will have their own unique set of resources and structure of outpatient clinics, this toolkit is intended to serve as a guide for establishing a centralized preauthorization process while allowing for flexibility in the approach.

The resources within this Preauthorization Toolkit are meant to aid in establishing and implementing a preauthorization workflow that is compatible with your institution's policies and resources. The goal of the toolkit is to help providers, laboratory administration staff, and others navigate the preauthorization process at their institutions while adhering to payer policies and utilizing available resources.

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Laboratory Stewardship

Laboratory Stewardship for Genetic Tests

According to the Utilization Review Accreditation Commission (URAC), utilization management is, "the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures and facilities under the provisions of the applicable health benefits plan, sometimes called 'utilization review'." Such reviews can take place prior to the onset of the service (prospective review) or after services have been rendered (retrospective review). For information about prospective review processes, see ***Preauthorization Basics***.

Laboratory stewardship is synonymous with the term utilization management and highlights the collaborative approach to assessing the appropriateness of a requested genetic test. Three guiding principles are generally applied in laboratory stewardship: Right test, right patient, right time. These guiding principles are outlined below and may also be helpful for informing genetic testing practices for ordering providers. Involving a genetic counselor in pre-test counseling and test selection can also be particularly helpful for navigating this decision making process.

Is it the right test?

Often the first step in review for genetic testing is determining if the selected test is the most appropriate test for the patient. There are several aspects that health plans consider when assessing the medical necessity of a test:

- **Analytical validity:** How well does a test predict the presence or absence of a particular genetic change or mutation?
- **Clinical validity:** How well does the genetic change being analyzed predict the presence, absence, or risk of a specific disease?
- **Clinical utility:** How well does the test provide information about the diagnosis, treatment, management, and/or prevention of a disease that will be helpful to the patient?
- **Test methodology:** Does the test utilize the most appropriate technology for this patient and this disorder? For example, if the most common genetic etiology for the suspected condition involves large gene deletions or duplications, sequence analysis may not be the best first-tier test. Also, a broad panel approach is less likely to be reimbursed by a payer if there is a targeted test that is available and more appropriate for that patient (see ***Multi-Gene Panels*** on page 8 for additional information about testing strategy.

Is it the right patient?

Compared to many other medical disciplines, genetics presents the unique challenge of having to evaluate the patient in the context of their family history. Many times, family history must be considered when it comes to utilization review of genetic testing. Healthcare providers, when faced with an unaffected patient, may be surprised to learn

that their patient's affected relative is the most appropriate person to test **first** for a genetic condition. This is because the affected relative is more likely to have a causative, pathogenic mutation identified on genetic testing, allowing the patient and other unaffected relatives to receive known familial mutation analysis (targeted testing for the presence or absence of the specific mutation that was found in the affected relative). This provides the following potential benefits:

- **More complete reassurance with a negative test result.** If an unaffected patient receives full gene analysis and the causative mutation in their family has not been previously identified, a negative test result fails to be a "true negative." While it is possible that the patient simply did not inherit the condition, it is also possible that the familial mutation is not detectable with that test (for example, it is in a different gene, or in a region of the gene that was not effectively evaluated). This means that the patient cannot be completely reassured about the risk to develop symptoms of the condition. Alternatively, if the mutation in the family is known, and the patient is not found to have the mutation, both the patient and their healthcare providers can be more confident in the result and its implications for medical management.
- **Lower risk of uncertain results.** Targeted testing for a known familial variant will typically provide clear results; either the patient has the variant or they do not. When doing broader analysis, such as full gene analysis or a multi-gene panel, there is a greater risk that variants of uncertain significance (VUSs) will be found. These are genetic variations for which there are insufficient data to classify them as definitively pathogenic or benign. A VUS is often a confusing outcome that may increase patient distress and could lead the patient to undergo unnecessary diagnostic and preventative measures that are costly and risky in nature.
- **Decreased costs.** In general, targeted testing for a known familial mutation is more cost-effective than full gene analysis or panel testing. Such cost savings not only benefits the health plan but may also benefit the patient and their medical institution, who may have to absorb the additional cost of broader test methods.

Is it the right time?

Ensuring that a genetic test is ordered at the appropriate time in a patient's diagnostic journey is also an important part of utilization review. Consider whether there are other preliminary studies that should be completed prior to genetic testing. For example, biochemical screening tests (plasma amino acids, acylcarnitine profile, and/or urine organic acids, etc.) may be valuable first-tier tests for many metabolic disorders. The results could help narrow the focus of the test to a single gene or subset of genes that are more likely to be related to the patient's condition, and in some cases may allow more costly genetic testing to be bypassed altogether.

The age of the patient is another important factor to consider for the timing of genetic testing. It is important to exercise caution when it comes to testing asymptomatic minors for adult-onset genetic conditions. While parents may be eager to learn the genetic status of their at-risk child, testing an asymptomatic minor for adult-onset conditions (such as hereditary breast and ovarian cancer syndrome) or for their carrier status raises several concerns, and may not be approved by the patient's health plan.

One concern is the ethical ramifications of testing a child before the age of consent, and not allowing them to decide if or when they wish to obtain information about their genetic status. Also, it may be difficult to establish the medical necessity of such testing if it is requested many years before it would be used to inform medical management or reproductive decision making.

Current Procedural Terminology (CPT) Codes

Current Procedural Terminology (CPT) codes, developed by the American Medical Association (AMA) are five-digit codes that represent a medical service or procedure. These codes serve several purposes:

- They allow health care professionals to accurately and efficiently communicate with colleagues, patients, hospitals, and insurers about procedures they have done or are planning to do.
- They are used for administrative purposes, such as claims processing and development of guidelines for medical care review.

In addition to evaluating the medical necessity of the requested genetic test, ordering providers should be prepared for the possibility that the patient's health plan may take into account the CPT codes requested for the test. This may include whether the billed CPT codes accurately reflect the test being done, and whether AMA guidelines are being followed for the use of the billed CPT codes. Ordering providers may wish to obtain a copy of applicable policies from the patient's health plan to determine whether any CPT code restrictions apply to the test being requested. Having a basic understanding of CPT codes and their use in the billing of molecular genetic testing will help you to understand and address some of the challenges you may encounter when requesting preauthorization of a genetic test.

CPT Code Development

Development and maintenance of these codes continues to be governed by the AMA. The CPT Editorial Panel is authorized by the AMA to revise, update, or modify CPT codes, descriptors, rules and guidelines. They convene several times per year to solicit input from practicing professionals, medical device manufacturers and test developers.

Most CPT codes are updated annually, while some may be added throughout the calendar year. Applicants who desire new CPT codes or revisions to the criteria for existing CPT codes can submit a request to CPT staff, Advisory Committee and Editorial Panel for consideration.

Common CPT Codes for genetic testing

While the AMA has developed thousands of CPT codes that address a wide variety of medical services, this section will focus on the types of codes that are most often used to bill molecular genetic tests. Here's a brief overview of these categories:

- **Tier 1 Molecular Pathology (MOPATH) Codes:** At the time this toolkit was published, this category encompassed CPT code range 81105 to 81383. These are very specific codes that usually address high volume genetic tests. Each code is associated with only one molecular genetic test (for example, CPT code 81223 is only used for CFTR full gene sequence analysis).
- **Tier 2 Molecular Pathology (MOPATH) Codes:** At the time this toolkit was published, this category encompassed CPT code range 81400 to 81408. These are non-specific codes that address tests that are usually ordered at a lower volume than those billed with tier 1 codes. Each tier 2 code could be used to represent different molecular genetic tests, and the codes are organized based on test complexity. AMA guidelines include restrictions on exactly which genetic tests can be billed with each of these codes.
- **Genomic Sequencing Procedure (GSP) Codes:** At the time this toolkit was published, this category encompassed CPT code range 81410 to 81471. These codes represent molecular test methods that simultaneously assay multiple genes or genetic regions (i.e. panel tests). AMA guidelines stipulate the number and type of genes that must be included on the panel for a GSP code to be used.
- **Unlisted Molecular Pathology (MOPATH) Codes:** For the purposes of molecular genetic testing, this category primarily includes CPT code 81479. This code is used to represent any molecular genetic test (sequencing, deletion/duplication analysis, targeted mutation analysis, and/or multi-gene panel) that is not described by a code from one of the above categories. As such, this code is very non-specific, and could represent different genetic tests.

For a complete listing of CPT codes, descriptions, and guidelines, refer to the latest version of the AMA CPT Professional Edition codebook, available for purchase on the AMA's website.

CPT Code Challenges and Limitations

The current structure and availability of CPT codes have some limitations for their use in the billing of molecular genetic tests. This presents several challenges to ordering providers, laboratories, and payers.

Most molecular genetic tests are represented by non-specific CPT codes (tier 2 and unlisted codes). This introduces a level of ambiguity and inconsistency in billing practices that makes it challenging for insurers to conduct medical necessity reviews for these tests. It can also make it difficult for labs to adequately represent the different methods that are used to do these tests.

Coding Genetic Tests: Multi-Gene Panels, Exome Sequencing, and PLA Codes

Multi-Gene Panels: The Payer's Perspective

Next-generation sequencing (NGS) allows the simultaneous analysis of multiple genes. With the availability of this technology, broad multi-gene panels that use NGS have

increasingly replaced the use of single-gene tests. However, while some patients may benefit from a broader panel approach, it is important to note that when it comes to genetic testing, *more* is not always *better*. It is important to balance the potential benefits of a panel with the potential risks and limitations and ensure that it is the best approach for a particular patient's situation.

Potential Benefits of Multi-Gene Panels

- May allow for the detection of rare genetic causes or atypical presentations of a disorder. Therefore, in some situations, the diagnostic yield may be greater than more targeted testing.
- May allow a diagnosis to be obtained more quickly than sequential single-gene testing and negate the need for the patient to return to clinic for multiple blood draws.
- May be more cost effective than traditional Sanger sequencing test methods. Whether this translates to cost savings for the patient, health plan, or billing institution is dependent on how the panel is billed (see below for more details).

Potential Risks and Limitations of Multi-Gene Panels

- May increase the risk of finding a variant of uncertain significance (VUS). This type of finding may be distressing to the patient and could lead them to undergo unnecessary diagnostic or preventive measures that are potentially costly or invasive.
- May include genes of uncertain clinical significance (genes that are included in a panel due to their molecular make-up but have not yet been linked to a particular syndrome or group of symptoms). Finding a mutation in such a gene would have limited or unclear value for informing the patient's medical management.
- May be billed in a manner that does not result in cost savings, but instead generates costs that are significantly greater than single-gene analysis (see below for more details).

Multi-Gene Panel Billing Challenges

While new GSP codes continue to be released by the AMA each year for multi-gene panel testing, the number of new panels coming to market continues to vastly outpace the availability of CPT codes to address them. This can lead to a great deal of inconsistency in how panels are billed across labs, providing additional challenges for insurance approval and reimbursement.

While a perceived benefit of multi-gene panel testing is the decreased diagnostic cost due to efficiency gains, this cost savings is not often reflected in current billing practices. Instead of using a single panel code, such as a GSP code, many panels are billed with "stacked" CPT codes. These codes may be associated with all, or a subset, of the individual genes included on the panel. Such billing practices do not accurately reflect the methodology of the test and may result in the billed price of the panel being significantly greater than the list price, with the extra cost being passed on to the member or billing institution.

Exome Sequencing

As with broad multi-gene panels, Next Generation Sequencing (NGS) has made exome sequencing a more common approach to genetic testing. Exome sequencing assesses the coding regions of genes associated with human disease. The patient's symptoms, personal medical history, and family history are important factors for the effectiveness of this type of test. It is important to balance the potential benefits of broad testing strategies with the potential risks and limitations and ensure that it is the best approach for a patient's situation.

Potential Benefits of Exome Sequencing

- May allow for the detection of rare genetic causes and/or atypical presentations of a disorder. Therefore, in some situations, the diagnostic yield may be greater than more targeted testing.
- Like multi-gene panels may allow a diagnosis to be obtained more quickly than sequential genetic tests and negate the need for the patient to return to clinic for multiple blood draws and may be more cost effective than traditional Sanger sequencing test methods. Whether this translates to cost savings for the patient, health plan, or billing institution is dependent on how all steps of the genetic testing process are billed.

Potential Risks and Limitations of Exome Sequencing

- Increases the risk of finding a variant of uncertain significance (VUS). This type of finding may be distressing to the patient and could lead them to undergo unnecessary diagnostic or preventive measures that are potentially costly or invasive.
- Increases the risk of finding an unrelated health concern, such as a genetic change that causes health conditions that were not previously known in the patient or family member.
- May include genes of uncertain clinical significance (genes that are included in a panel due to their molecular make-up but have not yet been linked to a particular syndrome or group of symptoms). Finding a mutation in such a gene would have limited or unclear value for informing the patient's medical management.
- May be billed in a manner that does not result in cost savings but instead generates costs that are significantly greater than single-gene analysis (see below for more details).
- May not be the "end all" genetic test if the patient's symptoms or family history change.

PLA Codes

Proprietary Laboratory Analyses (PLA) codes are an addition to the CPT code set approved by the AMA. They are codes that correspond with a descriptor for labs that

want to further identify their test. These codes are requested by the lab that is offering the test for which the code will apply.

PLA codes can create an added level of review for payers to ensure tests are being described and coded as specifically and accurately as possible. Some layers that PLA codes add are:

- If a test has a PLA code, that code takes precedence over any tier 1 (or other type) of CPT code.
- New PLA codes are posted on a quarterly basis, which is more frequent than other CPT codes.

Preauthorization

The Basics

Preauthorization vs. Predetermination

Preauthorization is a mandatory process that allows an ordering provider to determine coverage and secure an approval from a payer for a proposed treatment or procedure, such as genetic testing. The exact process depends on the requirements set forth by the patient's health plan, but usually involves providing clinical information and the rationale for the procedure so that medical necessity can be established.

Predetermination is like preauthorization in that it involves a review of a proposed treatment or procedure for medical necessity. However, this process takes place *before* services are rendered. This allows any limitations under the patient's health plan to be addressed before services are provided. While preauthorization is required, predetermination is offered as a courtesy.

Covered vs. Approved

You call and speak with a representative of your patient's health plan to ask if a genetic test is covered. They tell you it is a covered benefit under the plan. Then your patient comes to you weeks later after receiving a letter from their plan stating that the test was not approved because it is not considered medically necessary. What went wrong?

It is important to be aware that just because a procedure is considered a covered benefit, does not mean it is automatically approved or reimbursed. When a test is listed as a covered benefit under a health plan, this simply means that it is eligible for reimbursement *if the request is found to meet medical necessity requirements* following preauthorization or predetermination review. Therefore, "covered" and "approved" are not one and the same.

When speaking with a representative of a patient's health plan prior to requesting genetic testing, it is important to ask not only whether the test is a *covered* benefit, but also whether *preauthorization* is required.

The Appeals Process

If a preauthorization or predetermination for genetic testing is not approved by a patient's health plan, many plans will offer the opportunity for the ordering provider or patient to file an appeal. This allows the case to be re-reviewed, typically by a different medical director than the one that originally denied coverage of the test, to determine if the decision can be overturned. The denial letter provided by the health plan will typically include information about appeal availability and submission instructions.

A peer-to-peer discussion typically takes place between the ordering provider and a reviewer (usually a medical director) from the health plan. This allows the ordering provider to obtain clarification about the rationale for the denial and present additional evidence, if available, about the medical necessity of the denied test. In some cases, depending on health plan restrictions, this discussion can be used as a verbal appeal, and may provide an opportunity for overturning the denial.

Tips for Peer-to-Peer Discussions and Appeals

- ✓ **Keep the conversation civil.** Recognize that reviewers are obligated to enforce health plan policies, while also balancing the needs of the patient. Treating them in a hostile manner during a peer-to-peer discussion is not likely to improve the odds of a denial being overturned.
- ✓ **Read the denial letter carefully prior to initiating an appeal or peer-to-peer indication, to fully understand why the test was not approved.** Ask the health plan for further explanation of the denial reason, if needed. You may also wish to obtain and review a copy of the policy that was referenced for the denial.
- ✓ **Provide additional clinical details as needed to support medical necessity of the test.** If a letter of medical necessity was not included in the original preauthorization submission, consider adding one to the appeal documentation. If participating in a peer-to-peer discussion, have the patient's chart handy so that you are prepared to address additional questions about their medical history.
- ✓ **Provide evidence to back up your arguments.** Reference any relevant professional society guidelines or peer-reviewed research articles that evaluate the analytical validity, clinical validity, and clinical utility of the genetic test.
- ✓ **Focus on your patient's specific situation.** Explain why the test is medically necessary for this patient, and how the results can be used to better guide and improve their care. If the clinical history does not meet criteria according to the health plan's policies, clarify why you believe an exception should be made. If submitting a letter of medical necessity, ensure that it is tailored to your patient, and not simply a generic template letter.

External Review

An external review is when a claim is looked at by an outside agency, other than the health plan. In most cases, if an appeal is lost, the health plan has an option that allows the appeal to be brought to an outside agency, which is often called an independent review organization (IRO). In many cases where medically appropriate lab tests are denied, a patient is more likely to win an appeal at an IRO.

The success rate with an IRO is often much higher than that with the grievance process within a health plan. In many states, the success rate exceeds 50%. Thus, it is worthwhile for a patient to submit an appeal to an IRO even if they have lost the appeal within the health plan. (For additional information see the *Complex Lab Tests* resource.)

Implementing a Preauthorization Process

Introductory Assessment Questionnaire

The following questions are intended to help you assess the current state of genetic test authorization at your institution. This includes who requests, what and when they request, how they request, who supports the requests, and who communicates the status to the patient.

What are the demographics of types of providers ordering genetic tests that may require preauthorization?

The type of provider (GCs, MDs, NPs, PAs, etc.) may influence which steps of preauthorization they can complete. The types of clinics (genetics only or other specialties) may impact documentation or level of variability in workflows. Testing may need to be handled differently if it is done at your institution or sent out to another laboratory. Considering the big picture of how genetic testing is ordered can help when assessing workflow.

What volume of preauthorization or predetermination requests do you anticipate?

The estimated volume of requests will help guide decisions related to who makes preauthorization requests and how they are managed. For example, if the request volume is relatively small, it may be easier to incorporate the work into existing preauthorization workflows for other services (such as inpatient admissions or radiology procedures).

What is the current process for each clinic or specialty when ordering genetic testing?

Identify who is responsible for selecting the test and reference lab, who obtains the preauthorization, who communicates the result of the preauthorization to patients or families, and who places the actual test orders and completes the requisitions.

Do you have institutional resources available to support a centralized preauthorization process (e.g., revenue cycle team, clinic staff)?

Some institutions integrate genetic test authorizations into existing workflows within revenue cycle teams. However, if a centralized resource such as a revenue cycle team is not an option, consider having a standard procedure or workflow for clinic staff to follow so that the process is clear and equitable.

IS the EMR able to facilitate handoffs in different steps of the preauthorization process (alerts, secure messaging, etc.)? If not, how will each handoff in the process be communicated?

Consider how each step of the process will be tracked to ensure transparency and facilitate clear communication about the status of a preauthorization request.

How will the responsible party be notified that a test has been ordered that requires preauthorization?

Some institutions have linked the test order with a preauthorization that is automatically generated. For example, when a provider orders a test that requires preauthorization a referral is generated that populates a request on the preauthorization team's work queue.

For institutions without an automated process, consider whether a group is already involved in the workflow to assist with notification. Is someone at your institution reviewing testing for appropriateness and could they also review preauthorization requirements? Is the lab able to flag certain tests to be preauthorized?

How will information be passed from one group to the next?

Consider how providers in the clinic will submit an initial request to the revenue cycle team, as well as how denials and appeals will be managed.

Who will be responsible for calling insurance to determine if a preauthorization is required? And, who will be responsible for submitting the authorization? If a preauthorization is not required, who will be responsible for submitting a predetermination?

At some institutions, the revenue group is responsible for determining if a preauthorization is needed, submitting the preauthorization, and completing a predetermination. Other institutions rely on the clinical team to support insurance communications.

Who is responsible for communicating about the expected out-of-pocket estimate with the patient?

Authorization doesn't automatically mean the cost of the test will be covered. The patient may still have a co-pay or deductible, so it is important to consider who will inform and how to inform a patient of potential out-of-pocket costs prior to proceeding with testing.

Who can providers contact if they have questions about preauthorization or the status of a pending preauthorization?

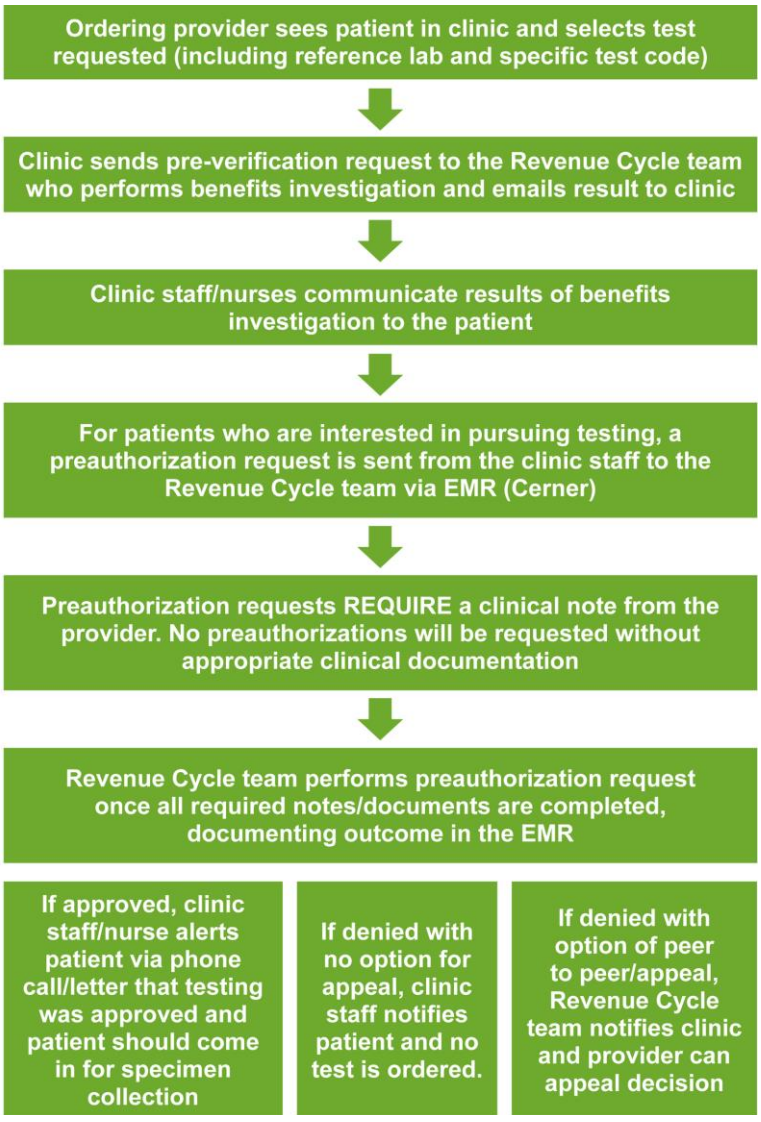
Consider whether this would be best handled by a lab genetic counselor, revenue cycle manager, or other individual depending on your institutional process. Let providers know who they should contact and give them contact information. It may be helpful to create a handout or intranet content with contact details.

Does your institution offer financial assistance?

Some institutions have charity care or financial aid programs, which are beneficial if insurance denies coverage or the patient still has a significant out-of-pocket responsibility even after insurance authorization. It is important to consider whether financial assistance is available and if so, who should be responsible for providing patient education about this resource.

Workflow Considerations

Once these questions have been considered, it is helpful to think about the types of workflows, or pieces of a workflow, that could be incorporated at your institution. An example workflow is included here:



Payer Policies, Medical Necessity, and Documentation

Navigating Payer-Specific Policies

Different insurance companies ("payers") have non-uniform coverage policies for genetic testing. Even when testing for the same gene or genetic condition, medical insurance companies will often have different criteria to establish medical necessity. It is also worth noting that even within the same insurance company, there can be different plans where coverage for genetic testing can vary. Therefore, it is very important to check with the insurance company about the specific policy for the member's plan.

Take Home Message:

Find the Payer,
Find the Plan,
Find the Medical Policy.

Insurance companies may have specific coverage policies for individual genetic tests or have a general genetic testing medical policy. The recommended strategy is to find the payer's website and locate their medical policies, then search by test name (gene name or genetic condition) or CPT code on the payer website. If the payer does not have any genetic testing policies available, the patient or staff from the provider's office or preauthorization department will need to call the payer to determine coverage policies.

If there is a specific medical policy for the gene or condition, it is helpful to review this information:

- Is the test covered if medically necessary, or is it always excluded (possibly for being "investigational" or "experimental")?
- If it is covered, what is the criteria for medical necessity? Are any ICD-10 diagnosis codes required?
- Is there a list of information that is required to obtain a preauthorization (also called "prior authorization")?
- Are any CPT codes specifically included or excluded?

If there is not a specific medical policy, but the payer does have a general genetic testing policy, it is helpful to review this information:

- Is there a list of genes or CPT codes that are specifically covered or excluded? Is the test being ordered covered by this list?
- What are the general criteria for medical necessity?
- Is there a list of information that is required to obtain a preauthorization?

Insurance coverage policies can change over time, so even if a test was denied in the past as being "experimental" or "not medically necessary," it is helpful to review any updates. Payers can be contracted with specific genetic test laboratories, so it may be necessary to determine through the payer website which genetic testing laboratory is in-network.

Some insurance companies will have portals to approve genetic testing (examples: some plans for UnitedHealthcare and Blue Cross Blue Shield); others require standard letters of medical necessity to be faxed or sent in for review. Determining where preauthorization requests should be sent can be challenging, as not every insurance plan will have this information readily available on the member's insurance card or online. Calling an insurance company to obtain this information can be a time-consuming task, so it is helpful to keep a list of the preauthorization department phone and fax numbers for the primary payers in your area. It is recommended to have a dedicated person or department devoted to preauthorization requests to develop expertise in this part of the process. For more information about payer policies, see ***Additional Resources***.

Medical Necessity Documentation and Required Test Rationale

While technology assessments form the basis for medical necessity criteria, there is considerable variability among payers. Providers and institutions need to understand what evidence and other considerations were used in the development of medical necessity criteria to write a successful letter of medical necessity.

Documentation Do's and Don'ts

Submitting a preauthorization or predetermination frequently requires submission of documentation to establish medical necessity of the requested procedure. Providing the right type of information can mean the difference between having the request approved and having it denied. Here are some tips about what to submit as part of a preauthorization or predetermination.

- ✓ **Clearly indicate the exact name of the requested test, the performing laboratory, and associated CPT codes.** This will ensure an accurate review of the request. As explained previously, some codes are non-specific and can be associated with a large number of different genetic tests. If the patient's plan does not know exactly which genetic test is being requested, it may not be possible for medical necessity to be established.
- ✓ **Include medical records that are relevant to the requested procedure.** This may include a copy of the test requisition form, recent clinic notes, medical family history, and the results of previous medical procedures that are relevant to the request (for example, echocardiogram and electrocardiogram reports if a cardiovascular genetic test is being requested). Records should include patient identifiers, such as the patient's name and date of birth. Note that ICD-10 codes alone are typically insufficient clinical information for review of genetic test requests.
- ✓ **Do not submit the patient's entire medical record.** It can be tempting to provide the patient's complete chart to ensure that the health plan has all the documentation needed to review the request. However, sending a large amount of information can bury relevant details and result in processing delays. Instead, it is preferable to limit

the submitted medical records to documents that are directly related to, and support the medical necessity of, the requested test.

- ✓ **Include a letter of medical necessity, when appropriate.** This letter outlines the patient's relevant clinical history and rationale for the requested test. This documentation helps draw the reviewer's attention to key information. Template letters supplied by the performing laboratory may provide a helpful starting point but tailoring the letter to the patient's specific situation usually has a greater impact and often provides more helpful information to the reviewer.

What to Include in a Letter of Medical Necessity for Genetic Testing

- ❑ The requested test name, methodology, CPT codes, and performing lab. Consider including a gene list when requesting a multi-gene panel, especially if this information is not readily available on the laboratory website.
- ❑ Details about the test indication, including relevant medical and family history.
- ❑ Previous test results related to the indication, especially any prior genetic testing.
- ❑ How the test results will be used to direct patient care (e.g., initiating or discontinuing specific treatments, surveillance for comorbid conditions, etc.).
- ❑ Why the requested test is a better option for the patient compared to traditional test methods or less costly alternatives.
- ❑ References to support the appropriateness of the test, including professional society guidelines and research articles that address the clinical validity and utility.

Partnering with Payers to Reduce Administrative Burdens

The preauthorization process exists to ensure tests are used appropriately and to prevent misuse and abuse. Genetic tests often require preauthorization, due to cost, complexity and specific coverage criteria. However, the preauthorization process is perceived as an administrative burden by providers and is expensive for providers and payers alike. "Gold carding" is a way to reduce the burden of insurance preauthorization requirements by applying a "trust and verify" approach instead of requiring a prospective review of each case. Typically, a health care provider must clearly demonstrate that a decision to use a test or procedure is evidence-based and aligns with coverage criteria set by the insurance plan.

One of the key advantages of gold carding is reducing redundancies in circumstances where genetic testing is reviewed by both the institution and payer. The institutional review of genetic testing is typically completed by an individual or team with expertise in genetics. This expert review is often not easily feasible with the payer's resources.

The disadvantages of gold carding include potential risk to the health plan (provider behavior drifts and may result in an increased number of inappropriate requests) and the process can be difficult to implement in a system where there are multiple payers. Additionally, tracking of payer-specific policy adherence for approval may be challenging.

Tips for Success

- ✓ Build trust – open a dialogue with your payer about existing processes for test stewardship at your institution, administrative burden by having duplicate processes (internal case review as part of a stewardship program, then additional preauthorization review at the health plan), and gather and show your data.
- ✓ It is possible that the term "gold-carding" might receive a negative reaction. Consider approaching the topic with terms such as "collaboration" or "partnership" to reduce system inefficiencies and redundancies and improve quality of patient care.
- ✓ Be creative and flexible about workflow.
- ✓ Celebrate small successes – this is plan-specific and often test-specific, so be patient and celebrate the small victories.
- ✓ In circumstances when policies are not favorable or are nonexistent, consider helping to write policies.

Case Examples

Integrated Health System Model of University of Pittsburgh Medical Center's (UPMC), Children's Hospital of Pittsburgh (CHP) and UPMC HealthPlan

Background: UPMC HealthPlan has a few genetic testing policies, including CMA, exome, and general genetic testing. CHP genetic counselors participate in an annual review of all genetic testing policies. These policies do not contain a lot of specificity for genetic tests, so CHP created internal criteria for specific tests, such as connective tissue disorders.

Implementation: Over a year, CHP genetic counselors reviewed 620 tests, approved many, denied some, modified some or asked for additional clinical information. The health plan is most interested in these cases where the team modified the test or asked for additional clinical information, since this involves an administrative burden to gather more information, and as such, helps relieve the burden of medical directors.

An authorization request for UPMC HealthPlan patients seen at CHP goes directly to CHP genetic counselors. If the CHP genetic counselor reviews and agrees that the request meets criteria, it is marked as approved. However, if the genetic counselor

reviews and assesses that the request does not meet criteria, the provider can still submit it to UPMC for review. There are some examples that have followed this second review and have gone on to be approved, often through a peer-to-peer review.

A quarterly audit is done to assess concordance rate between the CHP genetic counselor assessment and the medical policy criteria. A concordance rate of 80% is considered acceptable.

Lessons learned: This process builds trust with the payer, helps the health plan reduce administrative burden, and provides support to the CHP GCs and providers when there may be a disagreement about an authorization, because the request can follow the usual process.

Seattle Children's Hospital Model

Background: Seattle Children's Hospital has laboratory genetic counselors participate in a two-phase case review of all genetic test orders coordinated through the institution. The goal of the review is to identify and correct order errors and improve test requests, focusing on quality and cost. The first step of review occurs at the time of preauthorization; genetic test requests are reviewed again at the time of order.

Approximately 7% of requests are cancelled at the time of preauthorization review and 21% are modified (e.g., improved medical necessity documentation, sequential testing recommended), which helps remove waste in the process (i.e., preauthorization is only submitted for appropriate requests) and improves the chance of efficient authorization. Through an additional review at the time of order, genetic tests that have not been preauthorized can also be identified and redirected to the insurance services department.

Implementation: The genetic stewardship program leadership first connected with the institution's payer relations director to explain the goals of the stewardship program and the data showing the impact of the case review process. The director facilitated meetings with a local payer who might be amenable to a more streamlined authorization process, which had been completed for another service in the institution. The stewardship team gave a brief presentation to the medical director about the program, including details about standard review procedures and the processes for tracking requests and capturing intervention data. As a result, the payer agreed to exempt a subset of genetic tests from the prior authorization requirements, under an agreement that the genetic counselors reviewing requests would align with the payer coverage policies. The requests are subject to periodic audits to ensure concordance with the plan policies.

Lessons learned: This process builds trust with the payer and helps reduce administrative burden for both the health plan and the institution. The process can also help patients access genetic testing more efficiently.

To learn more, see ***Additional Resources*.**

Additional Resources

Links to Major Health Plan Coverage Policies

Aetna
http://www.aetna.com/cpb/medical/data/100_199/0140.html

AIM Specialty Health
https://aimspecialtyhealth.com/resources/clinical-guidelines/genetic-testing/

Cigna
https://www.cigna.com/health-care-providers/coverage-and-claims/policies/

eviCore healthcare
https://www.evicore.com/provider

Humana
http://apps.humana.com/tad/Tad_New/Home.aspx

Medica
https://www.medica.com/providers/policies-and-guidelines/coverage-policies
https://www.medica.com/providers/policies-and-guidelines/um-policies-and-prior-authorization

United Healthcare
https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-coverage-sum/genetic-testing.pdf

Educational Resources

AMA CPT Practice Management:
https://www.ama-assn.org/practice-management/cpt
Review the American Medical Association's criteria for CPT Tier I, Tier II, and GSP (genomic sequencing procedure) codes, access applications, and read frequently asked questions.

ACMG Medical Genetics Practice Resources:
https://www.acmg.net/ACMG/Medical-Genetics-Practice-Resources/Medical-Genetics-Practice-Resources
Resources developed by the American College of Medical Genetics and Genomics that include clinical and laboratory practice resources and guidelines for specific disorders or uses of genetics and genomics services, as well as ACMG policy statements.

GeneReviews:
https://www.ncbi.nlm.nih.gov/books/NBK1116/
Expert-authored review articles about a variety of genetic disorders, including guidance on the use of genetic testing for diagnosis.

Choosing Wisely:
http://www.choosingwisely.org/

An online resource that seeks to advance a national dialogue on avoiding unnecessary medical tests, treatments, and procedures.

Concert Genetics:
https://www.concertgenetics.com/
Online database that contains a catalog of genetic tests available on the market, and allows you to compare gene coverage, price, and CPT codes. (Free account required)

National Comprehensive Cancer Network (NCCN) Guidelines:
https://www.nccn.org/professionals/physician_gls/default.aspx
NCCN guidelines that document evidence-based, consensus-driven management of cancer. Include algorithms or flowcharts to guide the clinical decision-making process, with reference to many germline and somatic genetic tests. (Free account required)

National Society of Genetic Counselor (NSGC) – Find a Genetic Counselor:
https://www.nsgc.org/page/find-a-genetic-counselor
Use NSGC's database to locate a genetic counselor in your area.

Glossary

Analytical validity: How well a test predicts the presence or absence of a particular genetic change or variant.

Appeal: A request submitted to a health plan to review a denied claim.

Authorization: See "**Preauthorization.**"

Clinical utility: How well the test provides information about the diagnosis, treatment, management, or prevention of a disease that will be helpful to the patient.

Clinical validity: How well the genetic change being analyzed predicts the presence, absence, or risk of a specific disease.

Co-pay: A fee paid at the time of service. This payment does not go towards the deductible.

Co-insurance: The percentage paid for a covered service after the deductible has been met.

CPT Codes: Current Procedural Terminology codes are part of the billing system. They are used by care providers and health plans to identify medical procedures and services such as lab tests. In most cases, each lab test has its own code. The system is published by the American Medical Association (AMA) and is updated annually.

Deductible: The amount paid each year before the insurance company will pay. Some services will be paid prior to the deductible being met.

Denial: When the health plan does not intend to pay. Lab tests may be denied because:

- The health plan does not have enough information from the provider to figure out if the test is a covered benefit.

- The lab test is not considered a covered benefit for a clinical condition. In some cases, a lab test is a covered benefit for some medical conditions, but not for others.
- The lab test is never a covered benefit because it is deemed "Investigational and Experimental," or useless.

External Review: When a claim is looked at by an outside agency, other than the health plan. In most cases, if an appeal is lost, the health plan has an option that allows appeal to an outside agency, which is often called an independent review organization (IRO). In many cases where medically necessary lab tests are denied, winning an appeal at an IRO is more likely and it is the member's right to appeal.

ICD Codes: International Classification of Diseases used to describe clinical features or diagnoses. Most times, a medically needed lab test will be paid for if it has the right ICD code (or codes) assigned to it on the claim form.

In-network coverage: A health plan covers care with a provider who has a contract with the insurance company. Usually this comes with a lower deductible, coinsurance and copay.

Max out-of-pocket: The maximum amount of coinsurance a member will be responsible for over the course of 1 year.

Medical Coverage Policy: Policies issued by health insurance plans that outline medical coverage criteria for a procedure or service, including lab tests.

Out-of-network coverage: A plan covers care with a provider who does not have a contract with the insurance company. Usually this comes with a higher deductible, coinsurance and co-pay. Some plans do not offer out-of-network coverage.

Peer-to-Peer Review: When the provider who ordered a medical test meets with the medical director at the health plan to discuss why a test should be covered.

Preauthorization (also called Prior Authorization): A required process that allows a provider to determine coverage and secure an approval from a payor for a lab test. This does not guarantee payment. NOT doing this before a test could result in non-payment for the test.

Predetermination: Allows the health plan to review a lab test request for medical necessity. In this process, benefit coverage is figured out before the test is done and any limits imposed by the plan can be addressed. This is done as a courtesy. A preauthorization is required by many health plans. If the payer suggests having this, go ahead and request that it be done.

PLUGS® (Patient-centered Laboratory Utilization Guidance Services) is a non-profit laboratory stewardship collaboration within Seattle Children's Hospital Department of Laboratories. Our mission is to improve laboratory test ordering, retrieval, interpretation and reimbursement.

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