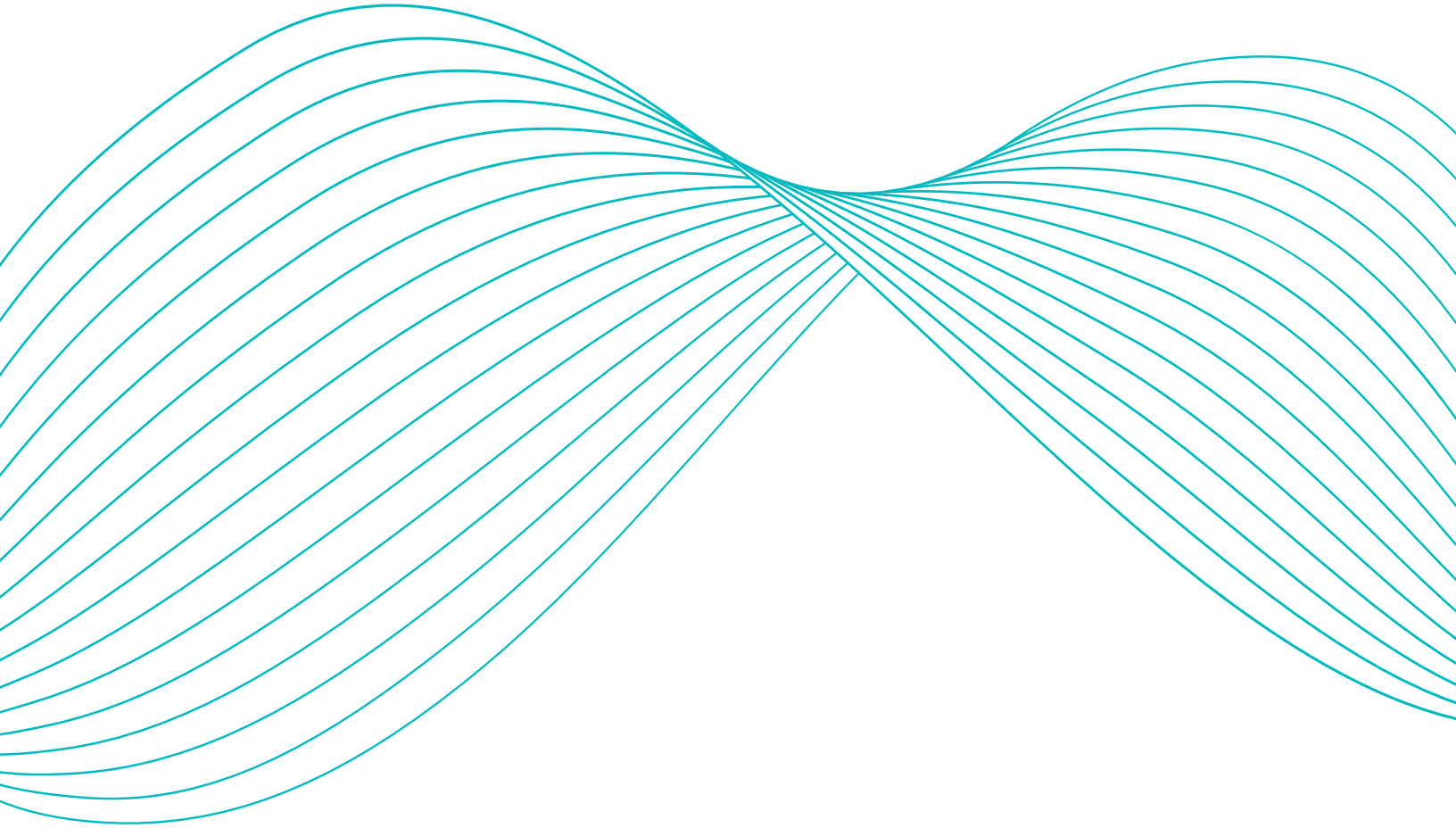
2022

# The Definitive Guide to Genetic Testing for Health Plans

## PART I. The Fundamentals

What makes genetic testing so challenging to manage, and what can health plans do about it



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# Table of Contents

## Part I: Fundamental Problems & Solution Design


**Introduction** 3

**Section 1. Defining the Problem** 6

- Fundamental Challenges
- Challenge #1 : Inability to identify the test
- Challenge #2: Rapidly changing market landscape
- Challenge #3: Fragmented approach

- Functional Challenges
- Medical Policy
- Medical Management & UM
- Claims Operations
- Payment Integrity
- Network Contracting
- Genetics / Genomics
- Finance
- Medical Economics
- Member Services & Members

**Section 2. Requirements for an Effective Solution** 11

**Conclusion** 15

**Appendix A. Taxonomy of the Problem & Solution** 16

- A grid of department-level problem & solution sets

**Appendix B. RFP Checklist** 23

- Requirements to include in a vendor evaluation

**Appendix C. List of Areas & Domains of Genetic Testing** 26

- Scope of an effective management program
- Reference medical policies

# Introduction

## The challenge and opportunity of genetic testing

The science of genetics has unlocked exciting advancements in health and life sciences. Unfortunately, the complexity of genetic testing creates confusion, burden, and waste for health insurers. Traditional solutions have failed to adequately address these challenges.

If you read no further, understand this: The lack of clear and transparent relationships between tests, billing codes, clinical evidence, and medical policy create administrative burden and waste that travels like a domino effect all the way from the health plan to the provider sitting with the patient. Any solution that does not address this root problem is unsustainable.

For the health plan, symptoms of this problem manifest across many departments.

### Medical/Clinical Policy:

Genetic testing can span a vast range of clinical presentations, and evolving evidence quickly renders policies out-of-date. Even more challenging, the nature of the testing itself has shifted (e.g., from single gene testing to multi-gene panels) leading to complexity and frustration during annual policy review. Many clinical policies focus on branded test names, but labs bill using non-specific coding, resulting in a disconnect between coverage and payment decisions that necessitates manual claim review to reach a resolution.

### Claims Operations:

Complex, stacked, and non-specific coding obscures test information, resulting in pends, manual reviews, errors, and rework. The advanced logic required to pay claims correctly in real-time cannot be programmed into many claim platforms. Even leading claim editors are unable to recognize the test represented by complex claims, leaving the plan to experiment with solutions, which are usually manual and time-consuming. Providers that vary coding to maximize reimbursement add to the confusion.

### Medical Management/UM:

For many plans, the majority of genetic tests require prior authorization. Multi-gene tests represented by multiple codes lead to complex reviews, wasting time and frustrating clinical staff. Efforts to delegate this to vendors often underwhelm expectations, with plans paying for costly services without achieving a holistic solution. UM staff are left to the subjective interpretation of when the claim should or should not be paid. Retrospective review of claims usually uncovers errors and inconsistencies.

### Payment Integrity:

The mismatch between tests and coding makes it difficult to determine whether payments were accurate and consistent with policy. Overpayments are common and difficult to recoup unless outright fraud occurred. Non-par labs submit enormous claims that can lead to member complaints about balance billing. Failure to manage this arena can invite scrutiny from state and federal auditors about the plan's ability to manage claim costs appropriately.

### Genetics / Genomics:

Organizations large enough to have dedicated specialty expertise rely heavily on these professionals to provide clinical and market insight, but the same challenges that limit transparency and force manual work for others draw down on these valuable resources. Where plans want to explore new strategic use of tests, non-specific coding impedes clarity needed to tie tests to outcomes in the data. Genomic medicine offers significant opportunity to improve quality and value, but lack clarity in diagnostics holds it, and as a result the whole market, back.

### Finance:

Managing against the prior year established budget and providing input for the future budgets to meet financial expectations are both significant challenges in an environment of failed clarity. Working with the actuarial team to price future policies is more difficult as genetic testing grows in volume, and complex coding results in unpredictable claim cost waste, driving excess burden in the budget.

### Medical Economics (ME):

At many plans, ME's goal is to assist the enterprise to match conditions against clinical utilities. In the ideal situation the department clearly explains past performance and can clearly identify use of new technology and the improvement in the paradigm. Historical trend forecasting is difficult in this non-specific, rapidly changing space. Waves of new testing are not easily factored into economic and actuarial models. Impending changes in testing may dramatically alter utilization patterns (e.g., liquid biopsy cancer screening among healthy individuals, etc.) and adjacent areas gated by testing, such as gene therapies and targeted oncology therapies, may have 10-100x the cost implications of testing.

### Network Contracting:

Facing the challenge of labs using the same code for multiple tests, negotiators try to create contracts with "average CPT pricing". This results in lose-some-win-some contracting. On certain codes, the price paid is lower than the cost of the test. In other cases, the price paid is higher. This creates misalignment and unnecessary exposure. Some carefully negotiated fee schedules often fail to achieve affordable prices for the plan because complex and highly variable coding inflates payments. Test-specific coding enables transparency for certain test types, but most testing is still vulnerable to these challenges. Meanwhile, a constant stream of new labs result in contracting professionals spending most of their days responding to new inquiries and answering for claim/billing concerns.

### Member Services & Members:

Transparency requirements demand clarity on "what test did my doctor order" and "why am I paying so much for these codes when I do not know what they represent." Without transparency, trying to act as responsible healthcare consumers, members often discover that seemingly simple questions about genetic test coverage and costs are almost impossible to answer. And, the member services area fails to assist them with this clarity, because they cannot tell the member what test was performed.

## A Unifying Solution

The critical enabler of a solution is clarity into the test itself. From that foundation, it is possible to achieve transparency, quality, and value through a systematic and efficiently run program. This paper is designed to provide a framework to assemble such a program, using the following structure.

### Section 1. Defining the Problem

Identify the underlying factors that have prevented health plans from reliably solving the challenges in this area to enable a more effective solution.

### Section 2. Requirements for an Effective Solution

Define the technical, operational, and clinical elements needed to construct an effective solution.

Part II of this whitepaper, available as a separate document here, describes the solution from Concert Genetics and experiences from customers of the company's Genetics Benefit Program.

# Section 1:
# Defining the Problem

## Identifying the underlying barriers to a more effective solution.

Genetic testing has been in clinical use for more than 20 years, yet most health plans continue to experience unnecessary waste and administrative burden associated with it. This is true even for plans that have a vendor (or multiple) engaged to manage it. Why do these problems persist?

Three fundamental challenges prevent sustainable solutions.

## Fundamental Challenges

**Challenge #1 :**
**Inability to identify the test**

**Challenge #2:**
**Rapidly changing market landscape**

**Challenge #3:**
**Fragmented approach across organizational silos**

### Challenge #1 : Inability to identify the test

There are more than 175,000 unique orderable genetic testing products on the market[1] but no widely accepted ID system to differentiate them individually. The primary coding system for billing purposes is CPT®[2], which has several hundred codes dedicated to genetic testing, most aligning to individual genes. The majority of volume is multi-gene panels represented by multiple codes in highly variable combinations. As a result, the mismatch between tests and codes causes confusion and complexity in nearly every function within a health plan that deals with genetic testing.

[1]Concert Genetics data 2022

[2]CPT® is a registered trademark of the American Medical Association

## Challenge #2: Rapidly changing market landscape

The genomics revolution has given rise to successive waves of change in genetic testing across multiple dimensions.

**Technological:**

An early generation of testing options (e.g., microarray, karyotype) was followed by sequencing techniques (e.g., Sanger sequencing) enabling single gene assays like BRCA for cancer risk and CFTR for cystic fibrosis, followed by the next-generation sequencing (NGS) breakthrough enabling large, multi-gene panels for a wide variety of indications. Today, newer techniques such as cell-free DNA sequencing are enabling current and near-future application in prenatal (e.g., non-invasive prenatal testing) and oncology (liquid biopsy).

**Evidence & Guidelines:**

Unlike drugs, genetic tests are not required to undergo clinical studies before entering the market. As a result, evidence tends to emerge over time as studies are conducted and real-world data is collected, leading to changing guidelines. This moving target creates significant burdens for the plan.

**Labs & Test Options:**

Recent testing methodologies, such as NGS and cell-free DNA, have lowered the barrier to entry for new labs, leading to rapid market entry and significant noise for plans. Quality, cost, and value vary significantly, and most plans lack a comprehensive view.

## Challenge #3: Fragmented approach across organizational silos

As the above factors manifest in different departments, the natural inclination for functional leaders is to address issues with point solutions: delegated entities for UM, claim editors for payment integrity, etc. However, these solutions don't address adjacent issues, leaving portions of the problem unsolved, or simply transferring them to a delegated entity, adding administrative cost and member/provider abrasion. As a result, 20 years into the genomic revolution, health plans still do not have a comprehensive approach to this critical area.

## Functional Challenges

The root cause challenges described in the previous section manifest as symptomatic problems within the departments of the health plan. Following is an abridged description of challenges that manifest within each function of the health plan. For the complete table, see **Appendix A. Comprehensive Solution Map**.

| | Test Identification | Changing Landscape | Organizational Silos |
|---|---|---|---|
| **Medical / Clinical Policy** | Most tests ordered are multi-gene panels represented by multiple codes, yet most medical policies are organized and searchable by codes. This mismatch leads to intractable confusion about which policy applies to a given situation. | Test ordering has shifted from single-gene tests to panels, which themselves change constantly. New technologies such as cell-free DNA emerge and proliferate. Guidelines and evidence change more rapidly than policies can be updated. | Policy changes have unintended consequences. Coverage of panel tests opens the plan to variable billing codes, but gene/code-specific policy burdens MDs with complex, time-consuming reviews. Delegation offloads the burden, but other areas (network contracting, claims) live with the consequences of unclear policy. |
| **Medical / UM** | Inability to identify genetic tests in claims was often the original reason these codes were placed on prior auth lists. However, the waste and frustration of a complex review process offsets savings. First-line reviewers struggle to locate the correct criteria, leading to escalations and frustrated, burnt-out MDs. | New tests enter the market and gain adoption quickly. New codes are released quarterly. Policy and criteria rarely keep pace, which leaves clinical staff to make medical determinations without clear criteria, or in most cases, specialty training. | The limitations of a UM solution for genetic testing crop up in many places. For example, claims arrive with prior auth numbers and variable combinations of codes that may or may not have been authorized, and which are expensive to pend for review. Again, delegation alleviates the UM workload, but other departments pay the price. |
| **Claims Operations** | Without knowing the specific test, the plan is forced to either pay or deny the claim with incomplete information and risk appeal, or route it for records request and manual review—all costly options. Claim editing vendors are not in a better position to identify the test. | The pace of change makes manual configurations burdensome to maintain. The same lab/test may be billed differently from claim to claim, and plans don't have systems to track the 'right way.' Pending every claim for manual review is not an option. | Without alignment with network and medical policy, claims operations can't ensure configurations accurately reflect lab contracts, coverage criteria, and coding rules. The cycle of denials and appeals draws down on resources. |

| | Test Identification | Changing Landscape | Organizational Silos |
|---|---|---|---|
| **Payment Integrity** | Claims are difficult to decipher and align with policy, whether pre-pay or post-pay. Standard fraud detection tools often identify most labs as suspicious because they can't differentiate between the complex coding inherent to genetic testing and outright fraud. | A fast-moving market often means the plan has incurred significant waste before an issue is identified. Small inappropriate payments lead to "death by a thousand cuts" when recovery is impractical. | Effective payment integrity requires alignment between departments to achieve a successful result, but a single source of truth to enable this alignment is rarely available. |
| **Network Contracting** | The relative value of a lab or proprietary test is often known by the lab but not the plan, putting the plan at a distinct disadvantage. Plans that contract based on billing codes (without specifying the test) see savings erode as the lab selects/combines codes that favorably impact lab revenue. | Network teams often feel inundated with new labs seeking to get in network. Once in network, labs change their test catalogs frequently. This places pressure on network teams to focus disproportionate time on this area. | It's almost impossible for a plan to maintain correct coding for many thousands of tests. Establishing coding standards requires coordination between departments and a central system of record, which is cost-prohibitive to assemble, and even more difficult to implement across UM, claims, etc. |
| **Genetics / Genomics** | Few health plans can afford to hire and retain dedicated clinical genetics/genomics staff. Those that can still face the intractable challenge of identifying tests represented by complex claims. Staff can help with both pre-service and post-service reviews but are quickly overwhelmed by the volume. | The pace of change in the market is fast across a large range of clinical specialties, and genetics experts end up being spread thin across them. | Fundamental changes such as the shift from single genes to panels require updating policies and other documentation that fall outside the scope of individual clinical experts. Meanwhile, for those that come from a clinic setting or laboratory, adapting to health plan operations can be difficult, leading to retention challenges. |

| | Test Identification | Changing Landscape | Organizational Silos |
|---|---|---|---|
| **Finance** | The waste that arises from challenges with test identification eats away at operating margins in ways that are often hidden from view. Spread across departments and aggregated across many codes, the net effect is consumption of scarce administrative resources with no easy way to measure and address. | Changing ordering patterns, new billing codes, and a fragmented provider market make this space difficult to parse, preventing finance leaders from achieving the granular view they need to provide guidance. | Because traditional solutions do not unify the key functional areas in the plan, finance leaders do not have a single dashboard view into performance indicators. |
| **Medical Economics** | The same tests are represented differently over time, and medical economists do not have access to a method to level set, which makes year-over-year trend analysis and forecasting difficult. | Genetic testing is a competitive market, which should drive price declines, but the complexities of the market can prevent this from happening. | Economists supporting the plan's management of this area encounter the same coordination challenges as the other functional departments, making results difficult to achieve. |
| **Member Services & Members** | Members inquiring about test coverage and cost often find themselves stuck in the same quagmire as everyone else: Coverage can depend on the billing codes that the lab uses, and those billing codes depend on what the plan covers. | Members are often surprised to learn their genetic test is much more expensive than a typical "lab test." Despite new legislation focused on preventing surprise bills, genetic testing is an area where such bills are common. | Members ultimately pay the price for fragmentation in this space, as they work to get access to high-quality care at affordable costs, and as they shoulder rising premiums. |

# Section 2:
# Requirements for an Effective Solution

## Technical, operational, and clinical factors needed for an effective solution

Health plans must address the three fundamental challenges in a way that aligns department-level operations and enables end-to-end effectiveness.

## Requirements to Solve Fundamental Challenges

### 1. Comprehensive Test Registry & Data Platform

*A solution to the test identification problem*

Solving test identification requires an ability to track the tests on the market, standardize the way they are represented in coding, and link this data with the other assets, such as medical policy, contracts, and fee schedules.

### A. Individual test catalog, organization, and identification

To make accurate coverage and payment decisions, the plan needs to know what test was performed. To know that, it must have visibility into the tests on the market.

#### Fundamental Requirement 1a

- The plan has access to a database of genetic tests. For each test, it includes the clinical purpose, genes, and unique ID. It is searchable and organized according to a taxonomy (e.g., similar tests are categorized, categories are grouped into larger domains). It covers all major areas of testing, including reproductive/prenatal, pediatric/rare disease, hereditary cancer, oncology, pharmacogenomics and system-specific testing (e.g., cardiology, neurology). See appendix for full list of testing areas and domains.

### B. Coding standardization & updates

To make consistent coverage and payment decisions, each test must be billed the same predictable way each time.

#### Fundamental Requirement 1b

- The plan or its delegate has a systematic method to apply billing codes to the tests in its database according to guidance from AMA, CMS, and other relevant authorities (e.g., panel tests are assigned panel codes; proprietary tests with PLA codes are assigned those codes). This method incorporates new tests as they are introduced at least monthly, new codes as they are released quarterly (e.g., PLA codes), and it outputs documentation (e.g., a searchable table) the plan and labs can access at any time.

### C. Link with other content

To operationalize these capabilities, the plan or its delegate must have a system to link tests and coding standards to other critical content.

#### Fundamental Requirement 1c

- The plan or its delegate maintains links between the test database and its medical policies and payment policies. Every test has one medical policy that governs coverage and one correct way to code and bill it. This information can be accessed by staff (e.g., clinical staff reviewing a prior authorization or claim) at any time.

## 2. Authoritative Evidence & Coverage Logic

*A method to keep pace with the changing landscape to deliver evidence-based decisions*

Keeping pace with the changing landscape requires policy, payment rules, and provider network strategies that adapt continuously rather than waiting on annual or multi-year cycles.

### A. Policy & coverage criteria organization

To consistently apply policy, each test must have only one (1) policy, and one (1) set of coverage criteria, to govern it. Policies must be organized by the same taxonomy as the test catalog so that each new test that comes onto the market and is added to the catalog has a clearly associated policy.

#### Fundamental Requirement 2a

- The plan or its delegate maintains medical policies that cover all major areas of genetic testing (see appendix for list) and are organized by the same taxonomy as the test catalog, by categories/domains rather than genes. Each test has one policy and one set of criteria within that policy to govern it.

### B. Evidence & guideline curation

In order to provide consistent coverage decisions that do not get overturned on appeal, medical policies must incorporate the latest evidence and guidelines. For well-grounded decisions and peer-to-peer discussions, references must be provided for the specific coverage criteria (to answer the question of why a specific coverage decision was made).

#### Fundamental Requirement 2b

- The plan or its delegate curates guidelines and performs comprehensive evidence reviews where guidelines do not exist for all major areas of genetic testing. These are reflected in updated policy documents and coverage criteria at least twice a year. References and citations are provided at the level of coverage criteria for easy access rather than as a large block at the end of long policy documents.

### C. Test catalog updates

To avoid confusion associated with new laboratories and tests entering the market, the database of tests that the plan accesses must incorporate new tests proactively, without awaiting submissions from labs.

#### Fundamental Requirement 2c

- The test database is actively maintained. Labs are not required to submit their test catalog data for inclusion. New tests are added, existing tests are updated (e.g., as genes are added to panels), and outdated tests are removed.

## 3. Integrated Approach to Automation

*A cohesive approach to align & automate operations across departments*

Achieving success in genetic testing requires alignment in strategy, performance measures, and sources of information, with a roadmap to integrate the agreed-upon approach into the workflow and systems of record.

### A. Unified approach to panel tests

Many of the problems in genetic testing, are coordination problems, the only way to succeed is through a unified approach. The plan's approach to panel tests is a good litmus test.

#### Fundamental Requirement 3a

- The plan has a unified approach to managing multi-gene panel tests. For any given panel, the correct coding for the test, the criteria that determines coverage, whether prior auth is required, and the cost (allowed amount) for that test is known and agreed-upon up front between departments.

### B. Unified performance measurement

To track the effectiveness of the program, performance measurement must include indicators of medical cost, administrative cost, and the accuracy of authorization and payment decisions.

#### Fundamental Requirement 3b

The plan has access to regular performance measurement metrics including the following:

- Average number of codes compared to benchmark by type of test
- Average allowed cost compared to benchmark cost by type of test
- Administrative indicators (denials, appeals, overturns, pended claims) by type of test
- Violations of coding standards by labs
- Payments against policy

### C. Automated enforcement

To maintain effective performance and reduce administrative burden, key elements of the program need to be hard-wired into plan operations. Integration, but it does take time and attention, which is why the plan needs a roadmap for success.

#### Fundamental Requirement 3c

The health plan has a roadmap to integrate the program into its systems of record, including at least the following:

- Test IDs and associated coverage criteria integrated into prior authorization and care management software
- Claim edits based on coding standards and coverage criteria delivered into claims payment process

## Functional Requirements

To take effect at a practical level, solutions must align with the needs, systems and operations of key functional areas. Defining requirements for these ensures solutions achieve the desired effect.

For a full breakdown of department-level requirements and a checklist of requirements to include in a vendor RFP, see:

- **Appendix A. Comprehensive Solution Map**
- **Appendix B. RFP Checklist.**

For further information about the concepts discussed in this whitepaper, contact connect@concertgenetics.com.

# Conclusion

In the coming years, genetic test availability and utilization will rise, driven by the rapid release of new tests, the development of clinical applications for genomic sequencing, and the accumulation of clinical and economic data to support their evidence-based use. The implication of this trend extends beyond the tests themselves to the targeted therapies, gene therapies, and other precision medicines indicated by their use. Genetic testing management will become the lynchpin of precision medicine management, which will be orders of magnitude more impactful and expensive. Health plans need to prepare for this now.

As discussed in this paper, effective response requires a unified approach that begins with a single source of truth for test identification and extends to technical and operational implementation across many key health plan departments. This paper provides a concrete set of requirements to enable this level of unification. Part II of this paper (available here) describes a specific solution that meets these requirements, providing a clinical, technical, and operational roadmap for its implementation

## Appendix A. Comprehensive Solution Map

A grid of department-level problem & solution sets

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Medical / Clinical Policy** | Test Identification | To be useful, medical policies must align coverage criteria to services as identified by CPT® codes. Initially, most CPT codes represented a single gene and most medical policies followed the same organizational structure. Over time, more genes became clinically relevant, outdating the policies. In practice, most tests are multi-gene panels represented by multiple codes in highly variable patterns. For this reason, many health plans (and their delegates) have a large legacy set of policy documents that do not align to current test usage, leading to a situation in which policy leaders and front-line clinical staff routinely struggle to reconcile these new valuable tools to policy. | • Policy is organized like the testing market. Criteria is established by test, not CPT code nor gene. Every test aligns to one (1) set of criteria.<br>• Authoritative mapping between test catalog and policy/criteria is maintained and searchable.<br>• Evidence and references are provided at the criteria level to support decision-making, rather than all at the end of a policy document.<br>• Panel tests are covered where evidence supports it.<br>• Policies are updated at least 2x per year. |
| | Changing Landscape | The migration from single-gene testing to panel testing is one of many dimensions along which the changing landscape affects policy. Another is the rapid introduction and adoption of new methodologies, such as cell-free DNA testing, which gave rise to both non-invasive prenatal testing (NIPT) and liquid biopsy for oncology. A third dimension is the introduction of new panel tests in new combinations. A fourth is the emergence of new guidelines and evidence, which is difficult to compare and catalog. The pace of change necessitates frequent updates, which are often too costly to justify (especially for an area that represents 1-2% of spend), let alone justifying a complete reorganization of policies as major market shifts occur. | |
| | Fragmentation | Solutions developed in isolation for medical policy have unintended consequences for other departments. Favorable coverage of multi-gene panel tests opens the plan to variable billing practices and high costs. However, issuing gene/code-specific policy and covering only those with evidence of clinical value forces labs to bill multiple codes even when one (the panel code) would do, burdening medical directors with complex time-consuming reviews. As clinical evidence mounts for new gene-disease associations, bills inevitably rise. Delegating this function to a vendor alleviates the burden, but other functions still have to live with the consequences of unclear policy. | |

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Medical Management / UM** | Test Identification | Inability to identify genetic tests in claims was the original reason many of these codes were placed on prior auth lists. Introducing a pre-service checkpoint made intuitive sense, but it has failed on a couple of fronts. First, genetic testing prior auth does not happen pre-service. The sample is almost always drawn and sent to the lab, which is submitting the auth request. Second, mismatch between tests, policies, and codes generally requires labs to obscure the test by billing multiple single-gene or non-specific codes. Finally, the waste and frustration of the review process drives costs that offset any savings. Whether the plan maintains one long policy or dozens of individual ones, first-line reviewers struggle to locate the correct criteria, leading to escalations and frustrated, burnt-out MDs. | • Prior authorization requirements are established by test, not by just billing codes. A list of tests/categories that require PA can be viewed by ordering providers and labs.<br>• Each PA request identifies the specific test, not just the billing codes This should include the test name and a unique test ID that front-line staff can use to search/find the correct policy and criteria.<br>• Every test has one correct way to bill it. Codes included on the PA request can be checked against coding standards for that test. Coding standards should include the following:<br>  ◦ Panel tests are represented by the panel code (if one exists)<br>  ◦ Proprietary tests are represented by the PLA code (if one exists)<br>  ◦ No more than 5 billing codes should ever be used to represent a single genetic test<br>• Each PA approval should document the approved codes (in alignment with the coding standards) so these can be incorporated into claims payment accuracy. |
| | Changing Landscape | Even in situations where test-code-policy alignment allows for efficient reviews, change is likely coming. New tests enter the market; new codes are released; policies and processes cannot adapt quickly enough. The workload mounts. | |
| | Fragmentation | Frustration with the limitations of a UM solution for genetic testing crops up in many places. Member-facing teams field complaints of enormous surprise bills from both in- and out-of-network labs. The claims team receives claims with prior auth numbers and innumerable combinations of codes that may or may not have been authorized, and which are expensive to pend for review. Just as with policy, delegation alleviates the workload for clinical/UM staff, but other departments pay the price. | |

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Claims Operations** | Test Identification | Without knowing the specific test, the plan is limited to either paying the claim or routing it for records requests and manual review, both of which are costly. Claim editing vendors are generally not in a better position than the plan to identify the test that was billed. | • Pre-pay claim edits can be delivered into the plan's claim process without establishing a separate data feed, e.g., edits can be delivered to/through the plan's existing primary or secondary claim editor.<br>• Pre-pay claim edits recognize the type of test performed. Editing must be able to interrogate the entire claim, including multiple lines, and return logic based on the type of test performed.<br>• Edits enforce coding standards. Edits should refer to standards to ensure inappropriate coding practices do not result in overpayment. These edits will include:<br>  ◦ Unbundled codes billed when panel code exists<br>  ◦ Procedure code restricted to specific laboratories<br>  ◦ Missing or incomplete diagnosis code<br>• Edits are applied based on policy/coverage. These edits will include:<br>  ◦ Test is investigational or experimental<br>  ◦ Test is inconsistent with patient age<br>  ◦ Test is not supported by diagnosis<br>  ◦ Test is not supported by family history<br>• Tests are uniquely identified in claims. Ideally, a test-specific identifier is available and required on claims, at least those that contain non-specific billing codes. |
| | Changing Landscape | The pace of change (new codes every quarter, new tests every day, and significant policy changes every year or sooner) means that manual configurations are burdensome to maintain. Due to ambiguity in the coding system, the same lab/test may be billed differently from claim to claim, and nobody can track the 'right way' to code most tests. | |
| | Fragmentation | Without communication between network and medical policy, claims operations can't have confidence that changes to configurations don't run counter to the lab specific contracts or changing coverage criteria. The resulting cycle of denials and appeals draws down on resources. | |
| **Payment Integrity** | Test Identification | Payment integrity faces all the challenges of claims operations, albeit compounded by the fact that the plan has already paid the claim. Post-pay claims are equally difficult to decipher and align with policy. | • Post-pay claim analysis identifies the type of test performed–does not just rely on billing code-level analysis.<br>• Payments against policy are identified. Once the test is identified, payments against policy should be identified to determine opportunities to remediate.<br>• Lab billing is analyzed at the test/claim level. Analysis should identify billing behavior inconsistent with coding standards and network agreements.<br>• Investigations and recovery efforts are based on systematic lab billing behavior. Plenty of evidence is available for a strong case. |
| | Changing Landscape | Emergence of new laboratories and rapid changes in billing patterns often mean the plan has incurred significant waste before the plan can identify the issue. Standard tools to flag cases for investigation often flag all labs, unable to differentiate complex billing inherent to genetic testing from outright fraud. | |
| | Fragmentation | Effective payment integrity requires alignment between departments to achieve a successful result, but ground truth is difficult to achieve in genetic testing. In addition, the cost of each inappropriately paid genetic testing claim is often small enough that the effect is "death by a thousand cuts," and recovery is impractical. | |

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Network Contracting** | Test Identification | Contracting decisions are often guided by the value of the lab and its test catalog relative to the existing network, yet reliable data on this is difficult or impossible to obtain. Once contraction begins, the unit of service is the test, and the plan's failure to explicitly understand test attributes, comparable services and market pricing will put contracting at a distinct disadvantage with respect to the contracting lab. Plans that contracting based on billing codes (without specifying the test) will see contracting savings quickly erode as the lab will select more favorable codes or stack codes as the lab products evolve. | • Every test has one correct way to code and bill it. These coding standards are transparent and applicable to all labs, not just par labs. Labs are obligated to adhere to coding standards, e.g., either payment policy or par contract (or both) establish this requirement.<br>• The value of a test/lab is objectively determined based on market data. Price benchmarks are available by test, not just by code.<br>• Standard fee schedule is based on market rates, not just Medicare rates, which are often outdated. This fee schedule is used for most labs.<br>• Pricing by test (not just code) is transparent in contracts. The combination of coding standards and a market fee schedule should make the price of every test transparent.<br>• Quality information is collected. A standard set of quality information, beyond CAP and CLIA, should be collected and stored for all labs.<br>• The tools and data to establish a preferred laboratory program is available if the plan decides to establish one. |
| | Changing Landscape | Network teams often feel inundated with new labs seeking to get in network. Without an independent perspective on which labs are important, it's easy to err on the side of contracting with too many or too few. Once in network, labs change their test catalogs much more frequently than contracts are typically renegotiated. This places pressure on network teams to keep up, and causes challenges for other departments if they don't. | |
| | Fragmentation | With over 300 labs providing 175,000 tests, it's impossible for a plan to maintain an accurate understanding of the products on the market and therefore the correct means of coding each test. Establishing coding standards requires coordination between departments and a central system of record, which is cost prohibitive to assemble. To add to the complexity, coverage often differs between lines of business (generally driven by advancements in Medicare NCDs and LCD) and may even change during the life of the contract. Finally, contracting teams want to know if a lab is under investigation, but as stated before, that can be most genetic labs (even high-quality ones). All of these moving targets make it difficult for the network team to establish successful agreements for the plan and its members. | |

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Genetics / Genomics** | Test Identification | Few health plans can afford to hire and retain dedicated clinical genetics/genomics staff. Those that can still face the intractable challenge of identifying tests represented by complex claims. Staff can help with both pre-service and post-service reviews but are quickly overwhelmed by the volume. Tracking and test identification systems that scale require not just clinical expertise, but also software and data science, at which point it becomes cost prohibitive to do within a single organization. | These requirements align directly with the fundamental requirements outlined in the paper.<br><br>**1a:** Access to a database of genetic tests<br><br>1b: Systematic method to apply billing codes to the tests in its database according to relevant authorities<br><br>**1c.** Links between the test database and its medical and payment policies<br><br>**2a:** Medical policies that are organized by the same taxonomy as the test catalog<br><br>**2b:** Guidelines and evidence are incorporated into updated policy at least twice a year and references are provided at the criteria level.<br><br>**3a.** Unified approach to managing multi-gene panel tests across departments<br><br>**3b:** Access to regular performance measurement metrics including the following:<br>• Avg. number of codes per claim by test<br>• Average allowed cost by test<br>• Administrative indicators (denials, appeals, etc) by test<br>• Violations of coding standards by lab<br>• Payments against policy<br><br>**3c:** Roadmap to integrate the program into its systems of record, including:<br>• Test IDs and associated coverage criteria integrated into PA platform<br>• Claim edits based on coding standards and coverage criteria delivered into claims payment process |
| | Changing Landscape | The pace of change in the market is fast across a large range of clinical specialties and genetics experts end up being spread thin across them, compounded by the increasing number of providers claiming to provide impactful information to the clinician, via their select panel. | |
| | Fragmentation | Fundamental changes such as the shift from single genes to panels requires updating policies and other documentation that fall outside the scope of individual clinical experts. Meanwhile, for those that come from clinical or lab environments, translating market realities into terms health plan departments understand and can act upon is difficult. | |

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Finance** | Test Identification | The waste that arises from the plan's challenges with test identification eats away at operating margins in ways that are often hidden from view. Spread across departments and aggregated across many codes, the net effect is consumption of scarce administrative resources with no easy way to measure and address. Meanwhile, opportunities to improve unit cost are missed. No single laboratory (or provider) can provide the full range of genetic tests. Fierce competition is valuable if it can lead to declining prices, but it also presents problems for plans trying to manage genetic testing. | • Medical cost reporting is available by category/type of test, including cost and volume of tests, not just codes, that allow for review against budget.<br>• Administrative cost reporting is available by category/type of test, including the administrative cost of staff time and vendors, for review against budget.<br>• Forecasting is based on test- and speciality-level trends, incorporating current growth rates and scientific and clinical market factors. |
| | Changing Landscape | Changing ordering patterns, new billing codes, and a fragmented provider market make this space difficult to parse, preventing finance leaders from achieving the granular view they need to provide guidance. | |
| | Fragmentation | Because no solution spans the key functional areas in the plan, finance leaders do not have a single dashboard view into performance indicators that measure the plan's success. | |
| **Medical Economics** | Test Identification | Waves of new technology and clinical adoption happen quickly and often front-run the release of billing codes to identify these new tests. The same tests are represented differently over time, and medical economists do not have access to a method to level set, which makes year-over-year trend analysis and forecasting difficult. | • Claims data is enriched to identify the type of test performed. Sorting through coding confusion to identify the test performed enables clinical utility and economic value analysis.<br>• Mapping between conditions, tests, and treatments is available. Data will link clinical situations and therapies to the tests members should receive to enable clinical utility and economic value analysis. |
| | Changing Landscape | Genetic testing is a competitive market, which should drive price declines, but the complexities of the market can prevent this from happening. | |
| | Fragmentation | Economists supporting the plan's management of this area encounter the same coordination challenges as the other functional departments, making results difficult to achieve. | |

| Function | Fundamental Challenge | Description | Solution Requirements |
|---|---|---|---|
| **Member Services & Members** | Test Identification | Members inquiring about test coverage and cost (and the member services team they contact) often find themselves stuck in the same quagmire as everyone else: Coverage can depend on the billing codes that the lab uses, and those billing codes depend on what the plan covers. | • Ideally, the type of test is identified in the EOB. In many cases, billing codes do not indicate the test performed, leaving both the member and member-facing staff to guess.<br>• Cost estimator tools for genetic tests are available. Members should be provided cost estimates for tests based on market rates, using contracted rates and coding standards to calculate expected costs. |
| | Changing Landscape | Members are often surprised to learn their genetic test is not performed at their hospital nor a lab they recognize, and that it is much more expensive than a typical “lab test.” Despite new legislation focused on preventing surprise bills, genetic testing is an area where such bills are common. Quality varies widely between labs, and members have little control over which lab is selected. | |
| | Fragmentation | Members ultimately pay the price for fragmentation in this space, as they work to get access to high-quality care at affordable costs, and as they shoulder rising premiums. | |

## Appendix B. RFP Checklist

Specific requirements & questions to include in a vendor search

### Genetic Test Information

- ☐ Vendor maintains a database of genetic tests.
  - ☐ Vendor provides a unique ID for each test.
  - ☐ Database includes fields for the clinical purpose, genes, of each test.
  - ☐ Database includes par- and non-par labs.
  - ☐ Vendor proactively updates database (does not wait for lab submissions to add new tests)
  - ☐ Vendor provides a search interface for health plan customers that links tests to policy, coverage criteria, and correct coding.
  - ☐ Tests are organized into a taxonomy for comparison to one another (e.g., similar tests are organized into categories, categories are grouped into specialities/domains)

### Coding Standards

- ☐ Vendor maintains coding requirements for tests
  - ☐ Method to apply billing codes to the tests in its database according to guidance from AMA, CMS, and other relevant authorities (e.g., panel tests are assigned panel codes; proprietary tests with PLA codes are assigned those codes).
  - ☐ Method incorporates new tests as they are introduced, and it outputs documentation (e.g., a searchable table)
  - ☐ Vendor provides documentation for each test's correct coding that the plan and lab can access at any time.
  - ☐ Vendor maintains coding for new tests as they enter the market
  - ☐ Vendor incorporates new codes as they are release (at least quarterly)
  - ☐ Vendor provides a search interface that shows correct coding for every test
  - ☐ Vendor provides a link between every genetic test and the corresponding policy and criteria for that test.

### Medical Policies

- ☐ Vendor provides evidence-based medical policies for all major domains of genetic testing.
  - ☐ Policies at a minimum cover the following domains of testing:
    - ☐ Hereditary Cancer Susceptibility
    - ☐ Oncology, including:
      - ☐ Algorithmic Testing
      - ☐ Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)
      - ☐ Cytogenetic Testing
      - ☐ Molecular Analysis of Solid Tumors
      - ☐ Hematologic Malignancies
      - ☐ Cancer Screening
    - ☐ Pharmacogenetics
    - ☐ Exome and Genome Sequencing
    - ☐ Inherited Disorders, Intellectual Disability, and Developmental Delay
    - ☐ Reproductive Medicine & Prenatal, including
      - ☐ Carrier Screening
      - ☐ Non-Invasive Prenatal Screening (NIPS)
      - ☐ Preimplantation Genetic Testing
      - ☐ Prenatal Diagnosis (via Amniocentesis, CVS, or PUBS) and Pregnancy Loss

- ☐ Aortopathies and Connective Tissue Disorders
- ☐ Cardiac Disorders
- ☐ Epilepsy, Neurodegenerative, and Neuromuscular Conditions
- ☐ Eye Disorders
- ☐ Gastroenterologic Disorders
- ☐ Hearing Loss
- ☐ Hematologic Conditions (Non-Cancerous)
- ☐ Immune, Autoimmune, and Rheumatoid Disorders
- ☐ Kidney Disorders
- ☐ Lung Disorders
- ☐ Aortopathies and Connective Tissue Disorders
- ☐ Cardiac Disorders
- ☐ Epilepsy, Neurodegenerative, and Neuromuscular Conditions
- ☐ Eye Disorders
- ☐ Gastroenterologic Disorders
- ☐ Hearing Loss
- ☐ Hematologic Conditions (Non-Cancerous)
- ☐ Immune, Autoimmune, and Rheumatoid Disorders
- ☐ Kidney Disorders
- ☐ Lung Disorders

**Utilization Management**

- ☐ Vendor either provides delegated UM services or supports the following aspects of plan's UM program:
  - ☐ Prior authorization requirements are established by test, not by code. Codes are not specific enough to determine whether prior auth is needed.
  - ☐ Tests are uniquely identified in prior auth requests. A test-specific ID is required in PA submissions.

**Claims & Payment Integrity**

- ☐ Vendor supports claim payment accuracy with pre-pay claim editing.
  - ☐ Pre-pay claim edits recognize the type of test performed. Editing interrogates the entire claim (not just one line/code) and returns edits based on this identification.
  - ☐ Edits are applied based on coding standards. Edits ensure inappropriate coding practices do not result in overpayment.
  - ☐ Edits are applied based on clinical/coverage information.
  - ☐ Edits are applied based on vendor's unique test ID.
  - ☐ Edits can be provided through the plan's claim editing vendor of choice; no technical integration specific to genetic testing is required.
  - ☐ Edits apply to par and non-par labs.
  - ☐ Each edit includes a remark, rationale & evidence to support it. Documentation and expertise is available to support appeals.

- ☐ Vendor provides post-pay payment integrity intelligence and services.
  - ☐ Post-pay claim analysis identifies the type of test performed, interrogating multiple lines of a claim to make that determination, rather than only editing based on only code-specific rules (one line at a time).
  - ☐ Payments against policy are identified.
  - ☐ Lab billing integrity reports are provided. Analysis identifies billing behavior inconsistent with coding standards and network agreements to remediate.
  - ☐ Recovery-specific data and support is provided.

**Network Contracting**

- ☐ Vendor provides a mechanism (e.g., payment policy) to require adherence to coding standards and quality information submission from par and non-par labs.
- ☐ Vendor provides price benchmarks at the test-level and code-level.
- ☐ Vendor supports lab contracting efforts with market intelligence, such as the relative value of a lab/test relative to existing par options.
- ☐ Vendor supplies test-specific coding standards so the plan can understand test prices arising from CPT code rates / fee schedule.
- ☐ Vendor provides a standard market-based fee schedule that does not rely solely on a percent of Medicare rates.
- ☐ Vendor enables collection of quality information from labs.

**Genetics Expertise**

- ☐ Vendor provides genomics expertise in (multiple) key specialties, including Oncology, Pediatrics / Rare Disease, and Prenatal / Reproductive

**Member Services & Members**

- ☐ Vendor identifies the type of test represented by a claim and can provide this data to support member services and EOB.
- ☐ Vendor provides cost benchmarking to support member-facing cost estimating.

**Performance Measurement & Financial Analysis**

- ☐ Vendor provides regular performance measurement metrics including the following:
  - ☐ Average number of codes compared to benchmark by type of test
  - ☐ Average allowed cost compared to benchmark cost by type of tests
  - ☐ Administrative indicators (denials, appeals, overturns, pended claims) by type of test
  - ☐ Violations of coding standards by lab
  - ☐ Payments against policy
- ☐ Vendor provides claim data enrichment services (e.g., identify the test represented by a claim to support further analysis) to support medical economics, financial & actuarial teams

## Appendix C. Concert Areas & Domains of Genetic Testing

**An overview of the types of tests using Concert's taxonomy**

Any genetic testing solution must cover all major areas of genetic testing in order to be effective. Following is an abridged list of the Areas and Domains of testing in Concert's taxonomy.

Note, the full Concert catalog contains more than 175,000 unique orderable tests, each with a unique GTU identifier code, organized into more than 50,000 categories, which roll up into these Domains and Areas.

| Areas | Domains |
|---|---|
| **Hereditary Cancer** | • Hereditary Cancer Susceptibility |
| **Oncology** | • Algorithmic Testing<br>• Cancer Screening<br>• Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)<br>• Cytogenetic Testing<br>• Molecular Analysis of Solid Tumors and Hematologic Malignancies (Tumor DNA testing) |
| **Pharmacogenetic** | • Pharmacogenetics |
| **Rare Disease** | • Exome and Genome Sequencing for the Diagnosis of Genetic Disorders<br>• Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay<br>• Biochemical / Metabolic |
| **Reproductive Medicine/Prenatal** | • Non-Invasive Prenatal Screening (NIPS)<br>• Preimplantation Genetic Testing<br>• Prenatal Diagnosis (via Amniocentesis, CVS, or PUBS) and Pregnancy Loss<br>• Prenatal and Preconception Carrier Screening |
| **System/ Specialty Specific** | • Aortopathies and Connective Tissue Disorders<br>• Cardiac Disorders<br>• Epilepsy, Neurodegenerative, and Neuromuscular Conditions<br>• Eye Disorders<br>• Gastroenterologic Disorders<br>• Hearing Loss<br>• Hematologic Conditions (Non-Cancerous)<br>• Immune, Autoimmune, and Rheumatoid Disorders<br>• Kidney Disorders<br>• Lung Disorders<br>• Metabolic / Endocrine / Mitochondrial Disorders<br>• Skeletal Dysplasias |
| **Healthy Person Testing** | • Disease Risk: Healthy Person Testing |
| **Identity** | • Identity and Forensics<br>• Transplant |
| **Other** | • Cytogenetics: Germline<br>• Other Molecular<br>• Protein and Hormone Analyte Tests |

Concert's complete test catalog and reference medical policies can be viewed by creating a free account at https://app.concertgenetics.com