The Concert Coding Engine

A solution for transparent and consistent coding of genetic tests

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CONCERT GENETICS

EXECUTIVE SUMMARY

The genetic testing market has grown and evolved rapidly, with more than 170,000 clinically orderable genetic tests now on the market.[1] Amidst this growth, one persistent challenge has been ambiguity and inconsistency in how genetic test claims should be coded. Concert has demonstrated that variation in coding leads to administrative burden, error, waste, and variation in pricing.[2]

In response to these challenges, Concert developed a novel method to translate each genetic test into a single code or code combination. This method, delivered as the Concert Coding Engine, operates according to concise guiding principles, relies on finite data elements, and generates a repeatable output. The resulting coding standards are intended to eliminate ambiguity in how tests should be coded, leading to more efficient and consistent reimbursement for tests.

Since its launch in 2019, the Concert Coding Engine has been implemented widely. Many health plans have instituted requirements for labs to code according to the Concert coding standards for reimbursement, leading to outcomes that benefit plans, labs, and most importantly, health consumers. In addition, while the Coding Engine does not require the use of a unique test identifier, many health plans have also adopted the Concert Genetic Testing Unit (GTU).[3] The GTU aligns each test with the correct code(s) to further increase transparency and reduce administrative friction.

This paper describes the Coding Engine, including the objectives, guiding principles, data inputs, underlying logic, limitations of the current implementation, and results of implementation. It concludes with a brief discussion on how stakeholders access and deploy the Concert Coding Engine and the results of those implementations.

[1] Concert data. 170,355 GTUs as of January 2024. Concert uses the term Genetic Testing Unit (GTU) for any orderable combination of analytes (e.g., genes or other targets) and techniques at a specific point in time, sold by a laboratory as a single item in the laboratory's catalog. The decline in the number of GTUs previously shared by Concert elsewhere (i.e., 175,000+) is largely due to laboratory consolidation.
[2] Concert. September 2019. Coding Variability in Genetic Testing: A summary of coding and price variation in commercial health insurance claims. https://www.concertgenetics.com/resources/coding-variability-in-genetic-testing/
[3] Concert. October 2021. The Genetic Testing Unit (GTU): A unique identifier for every genetic test, accessible by all. https://www.concertgenetics.com/resources/concert-genetic-testing-unit-gtu/

OBJECTIVES & GUIDING PRINCIPLES

The overarching goal of a data-driven coding solution for genetic testing is to advance precision medicine through transparency and efficiency. The desired outcomes are the following:

1. Accurate determination of insurance coverage and price, minimizing surprise bills received by patients
2. Predictable reimbursement according to market-based pricing, reducing administrative and financial costs for laboratories and health plans
3. Consistent application of medical policy with minimal human intervention, limiting time-consuming manual reviews (including prior authorization)

The Concert Coding Engine standardizes the coding process for genetic testing, allowing stakeholders to arrive at a single way to code each test on the market. To support these ends transparently, Concert utilizes the following principles to guide maintenance of the Coding Engine:

1. There is a single, repeatable way to code each genetic test on the market.
2. The relevant unit for coding is the test performed. The test performed is the test for which a patient receives a result, not a subset or component of the test performed; for example, a multi-target (e.g., multi-gene) panel test is one unit. Concert maintains a five-digit alphanumeric identifier, the GTU, to uniquely identify each test.
3. Test attributes (targets, techniques and, for panel tests, clinical application), not attributes like a patients' medical or family history, are the basis for assigning codes. Each test attribute and unique identifier is publicly available.[4]
4. The Current Procedural Terminology (CPT®)[5] Code Book and supporting guidance can (and must) be translated into data structures that can be matched with known test attributes.
5. Choose simplicity over complexity, whenever possible. Panel codes are used whenever applicable. Single target codes will ONLY be used when a multi-target test does not meet criteria for any panel code. A maximum number of codes will be applied.

CODING ENGINE

Overview

The Coding Engine is a software application that transforms test attributes into a specific code or set of codes. The Coding Engine consists of three core elements: a database of genetic tests

[4] Users are invited to review Concert's genetic test database at www.app.concertgenetics.com at no charge. Users may report any test data errors via the website or directly to Concert Genetics. Most tests are updated on a bi-weekly basis.

[5] CPT copyright 2024 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

(and test attributes), expert-curated coding guidance, and a logic-driven algorithm for mapping tests to codes. Each of these elements is described below.

Sources of Genetic Test Data

The Coding Engine utilizes Concert's database of genetic tests as its source of tests and test attributes. While any sufficiently detailed database could be substituted, Concert's database has three primary benefits. First, Concert maintains an accurate current and historic snapshot of the entire market with minimal administrative burden on the laboratory industry. Second, Concert maintains a high level of detail – not only all targets and techniques, but more than 20 other data elements – on each test in the database. Third, Concert combines additional data sources (e.g., claims, orders) to further validate and estimate the frequency of gene utilization across the market. Each of these elements contributes to the accuracy and reliability of the Coding Engine.

Sources of Coding Guidance

The Coding Engine requires the following data assets, each of which must be assembled and synchronized with the CPT® Code Book:[6]

Table 1: Required Data Elements

Data Table	Fields
PLA/MAAA Code Table	PLA or MAAA Code Lab Name Test Name
Tier 1 Code Table	Tier 1 Code Gene Name (HGNC Standard) Technique
Tier 2 Code Table	Tier 2 Code Gene Name Technique
Genomic Sequencing Procedure (GSP) Code Table	GSP Code Genes or Genomic Target Technique(s) Clinical Indication
Gene Priority Score	All genes and techniques (sequencing, del/dup, targeted mutation) ordered by frequency of use (Concert database)

[6] The following code sections of the CPT® code book are relevant for the Coding Engine: Tier 1 Molecular Pathology , Tier 2 Molecular Pathology, Multi-Analyte Algorithmic Assays, Genomic Sequencing Procedures, Proprietary Laboratory Analysis Codes.

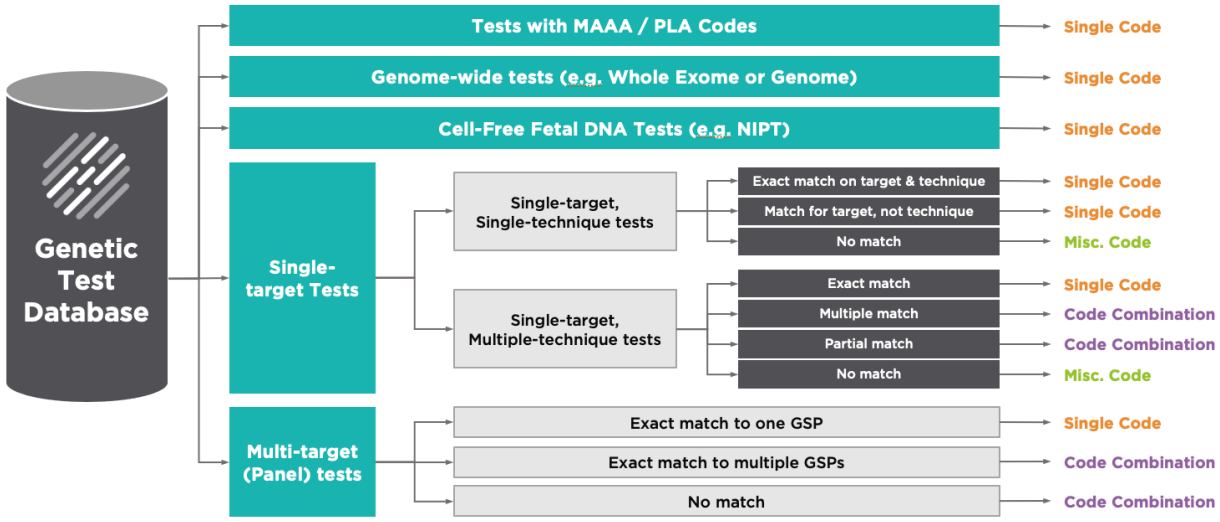
Coding Logic

The Coding Engine is driven by an algorithm based on logic that maps tests to codes. The logic is as follows:

1. Tests with MAAA/PLA codes. If the test has a specified MAAA or PLA code, assign that code.
2. Genome-wide tests. If the test covers the whole exome or genome, code as appropriate for the technique to match the exome, genome or microarray code(s).
3. Cell-free fetal DNA tests. If the test is designed to examine circulating cell-free fetal DNA (also known as non-invasive prenatal testing), it will be matched to the appropriate corresponding code or codes (aneuploidy and/or microdeletions).
4. Single-target (e.g., Single-gene) tests.
    a. Single-target, single-technique tests. Assign the appropriate Tier 1 or Tier 2 code based upon the specific target and technique provided.
        i. Exact match on target and technique – If there is an exact match, this code will be mapped.
        ii. Match for target, not technique – If there is a target match, but a technique mismatch, a code may be used if the technique specified in the test supersedes the available code (e.g., If there is a targeted mutation code specific to a gene, but not a sequencing or del/dup code, the targeted mutation code can be used).
        iii. No match – If there is no target or technique match, or if there is a target match, but a different technique in the specified test, use the miscellaneous code.
    b. Single-target, multiple-technique tests. Assign the appropriate Tier 1 or Tier 2 codes, assigning multiple codes for distinct techniques performed. The broadest code will be assigned first to minimize the total number of codes. Sequencing codes and targeted mutation codes for the same gene will not be used in combination with one another.
        i. Exact match – If there is only one code to cover both sequencing and deletion/duplication analysis, that code will be used before using individual single gene - single technique codes.
        ii. Multiple match – If there are multiple codes for different techniques applied to the same target and those differing techniques are each performed, those codes may be used in conjunction with one another. Deletion/duplication analysis performed on NGS sequence data is considered a unique technique.
        iii. Partial match – If there is a Tier 1 or Tier 2 code for one of the techniques included in the test, but not for the other, the test may be coded with one Tier 1 or Tier 2 code and one unit of the miscellaneous code.
        iv. No match – Use the miscellaneous code.

5. Multi-target (panel) tests. Compute all target-technique combinations and match to similarly computed GSP target-technique combinations.
    a. Exact match to one GSP – Assign GSP code.
    b. Exact match to multiple GSP codes – Two GSP codes may be used if they represent different techniques for the same targets, (e.g., 81435 and 81436). If these codes represent the same technique, the more specific of the indications for testing will be used.
    c. No match – If there is no match, individual single gene codes may be used. All target-technique combinations will be mapped to the appropriate codes. Codes will be sorted by technique (Sequencing>Del/Dup>Exon>Targeted Mutation) and then by priority of gene frequency in the market. The first 4 single gene codes will be applied, with any remaining codes represented by a single miscellaneous code.

Figure 1: Logic Flow



Summary Statistics and Limitations

The Coding Engine currently assigns discrete code combinations to 152,444 tests in Concert's database of 170,355 tests. The Coding Engine assigned 1,301 unique code combinations for this universe of tests, contrasting starkly with more than 36,000 unique code combinations observed in a large database of genetic testing claims.[7] This suggests that the broad adoption of the Concert coding standards currently underway in the market will greatly simplify and streamline the coding and reimbursement process for genetic testing.

[7] Concert Genetics. September 2019. Coding Variability in Genetic Testing: A summary of coding and price variation in commercial health insurance claims.

USE OF THE CODING ENGINE & RESULTS

The coding standards assigned by the Concert Coding Engine are accessible by all stakeholders via the Concert website. Laboratories view and use the output of the engine on their own tests at no charge. Health plans and their delegates license and implement payment policy and payment accuracy solutions based on the Coding Engine for a fee.

As of this publication, health plans representing more than 30 million members are using Concert's coding standards to bring transparency and predictability to reimbursement. Laboratory providers representing more than 85% of genetic spend nationally have agreed to adhere to these standards in accordance with health plan payment policy.[8] Results include the following:

- One health plan reported a 50% reduction in the volume of prior authorizations in genetic testing. Greater consistency in coding enabled the removal of many genetic testing codes from its prior authorization list.
- Another plan experienced a 33% reduction in the number of codes billed per testing claim in its Commercial and Medicaid lines of business following the implementation of Concert's coding standards.
- A third plan saw 50% reduction in codes per claim in its Commercial and Medicare Advantage lines of business following implementation of the payment policy.

CONCLUSION

Concert developed the Coding Engine in response to a market need for consistency and transparency in the way genetic tests are represented by codes. Through implementation of the Coding Engine, millions of health consumers now benefit from greater transparency and consistency in insurance reimbursement of molecular diagnostics.

Concert remains committed to working with all stakeholders to improve the Coding Engine, and, more importantly, to advance the digital infrastructure necessary for the success of precision medicine.

[8] Based on Concert analysis of genetic testing claims from 55 million members