Coding Variability in Genetic Testing

A summary of coding and pricing variation in commercial health insurance claims

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CONCERT GENETICS

EXECUTIVE SUMMARY

The quantity, variety, and complexity of clinical genetic tests on the market have grown rapidly over the last decade.[1,2] The elimination of patent protection on human genes, the proliferation of next-generation sequencing (NGS) technology, and the rapid discovery of gene-disease connections have all contributed to this trend. This paper will explore one result of this growth: variation in the application of billing codes for commercial insurance reimbursement.

Concert Genetics, a leader in data and digital infrastructure for the Genetic Health Information Network, analyzed 2.2 million commercial genetic testing claims from 2016-2018, representing a population of more than 35 million lives. Using a patented process of matching multi-gene, multi-code claims to a taxonomy of genetic tests, we measured code variation in genetic testing. Grouping tests according to similar domains, claims averaged between 2.0 and 18.5 codes per claim. We measured the variation of unique code combinations (or code signatures), finding that by domain, code signatures range from a low of 8 to a high of 9,931. We utilized the same methodology to analyze pricing variability, defined as variability in reimbursement, for similar tests from multiple laboratories. Finally, we measured the correlation of coding variation with reimbursement variation, finding a strong correlation. We conclude with a discussion of the impact of coding and price variation on key stakeholders in the Genetic Health Information Network.

BACKGROUND

Written into the Health Insurance Portability and Accountability Act (HIPAA) as an approved means of communicating procedures, Current Procedural Terminology (CPT®)[3] is the most commonly used coding standard for genetic tests in the United States. Code creation and maintenance is governed by the CPT® editorial panel, and over the course of a decade, molecular diagnostic codes[4] have evolved to accommodate emerging areas of testing and new technologies. When first established, few genes were tested clinically and coding was based upon the laboratory procedure(s) performed. As a wider variety of genetic tests entered the market, additional codes were developed to distinguish specific genes. In 2013, the creation of MoPath Tier 1 and Tier 2 codes shifted the basis of coding away from gene-agnostic codes toward gene-specific codes. Tier 1 codes were developed for commonly ordered single gene

[1] Phillips KA, et al. 2018. Genetic test availability and spending: Where are we now? Where are we going? Health Affairs. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5987210/

[2] Concert Genetics. April 2018. The Current Landscape of Genetic Testing: Market growth, reimbursement trends, challenges and opportunities. Available from: https://www.concertgenetics.com/resources/2018-current-landscape-genetic-testing/

[3] CPT copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

[4] Relevant codes include Molecular Pathology (81105-81408, 81479), Genomic Sequencing Procedures and Other Molecular Multianalyte Assays (81410-81471), Multianalyte Assays with Algorithmic Analyses (81490-81599), certain Cytopathology (88104-88199), certain Cytogenetic Studies (88230-88299), and Proprietary Laboratory Analyses (0001U-0061U)

tests. Tier 2 codes (81403 through 81408) were established to guide reimbursement based on the number of base pairs or exons analyzed for single-gene tests. Also in 2013, codes for laboratory-specific algorithmic tests (Multi-Analyte Algorithmic Assays, or MAAA codes) were released to provide further specificity. Additionally, gene-agnostic cytogenetic codes continued to be used for tests involving cytogenetic laboratory techniques.

Driven by the adoption of Next Generation Sequencing (NGS), the incremental cost of sequencing additional exons and additional genes plummeted. As a result, panel tests became first-line tests in many clinical settings.[5] There are currently more than 10,000 panel tests in Concert's database and nearly 65% of commercial reimbursement is for panel tests.[6] In response to the rise of NGS, specific codes for panels of genes (Genomic Sequencing Procedure, or GSP codes) were issued. GSP codes designate a single code for a panel test designed for a specific use and/or indication. Beginning in 2018, lab-specific, test-specific codes have been issued on a quarterly basis. These Proprietary Laboratory Analysis (PLA) codes were introduced in part to support changes in CMS payment policies.[7]

In summary, the pace of change in the genetic testing market has required continual evolution of the coding process. This paper seeks to quantify how uniformly (or variably) billing codes are being applied in commercial insurance reimbursement.

METHODOLOGY & DATA SOURCES

Since 2012, Concert has collected detailed information on clinical genetic tests offered by U.S.-based laboratories, organizing tests according to a multi-level taxonomy that enables comparison within and across groups of clinically similar tests.[8] Today, Concert's database includes 140,012[9] unique tests or Genetic Test Units (GTUs), each of which is monitored for change across twenty-five data elements. To continually validate its database, Concert cross-references additional sources, including provider, laboratory, and payer data. Concert patented a method for matching claims to individual tests and test taxonomy.[10] For this analysis, Concert analyzed a database of more than 35 million commercial lives from across all 50 states, including 2.2 million genetic testing claims with any of the relevant codes from years 2016-2018.[11]

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[5] Hooker, G. W., et al. 2017. Cancer Genetic Counseling and Testing in an Era of Rapid Change. J Genet Counsel. DOI: 10.1007/s10897-017-0099-2

[6] Panel tests represent 64.8% of allowed spend and 56.8% of claims volume in the national claims database used for the analysis performed for this paper.

[7] https://www.federalregister.gov/documents/2016/06/23/2016-14531/medicare-program-medicare-clinical-diagnostic-laboratory-tests-payment-system

[8] Test are included in the same test *category* if they use similar technologies to analyze comparable genetic markers and are used for similar clinical purposes. Categories are then grouped into *domains*, which reflect clinical areas of use.

[9] Source: Concert. August 2019. 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.

[10] Schneider, et al. 2019. Systems and Methods for Tracking, Monitoring and Standardizing Molecular and Diagnostic Testing Products and Services, US Patent #10,223,501

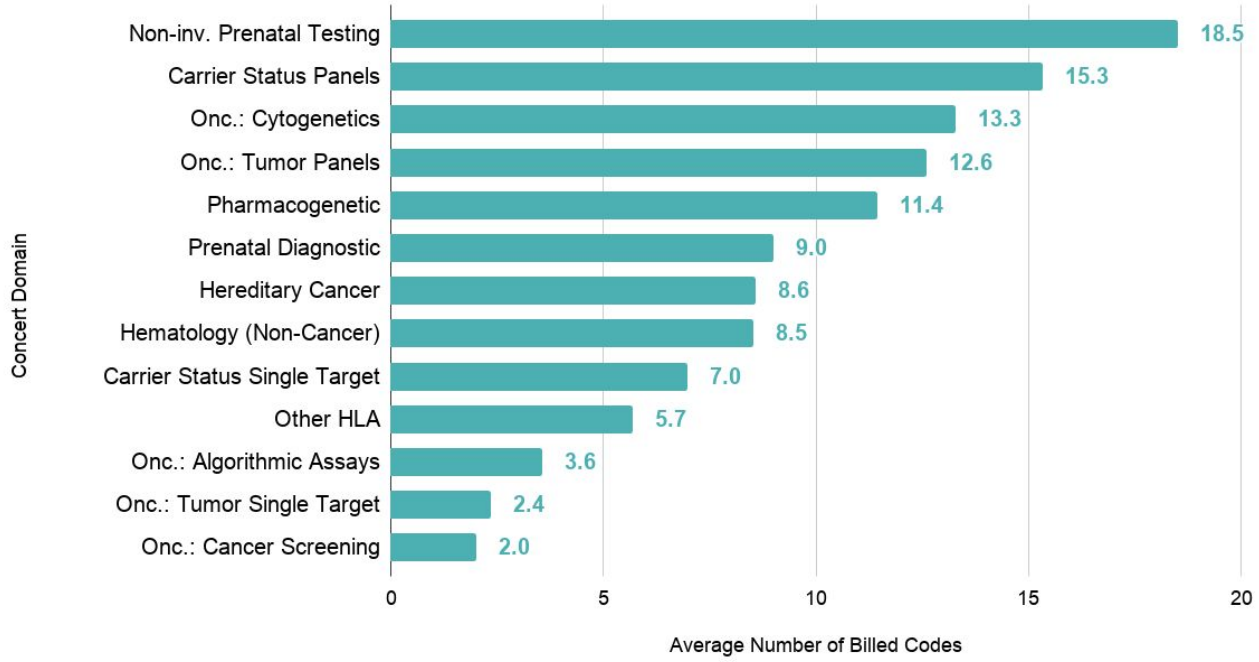
[11] For more detail on the methodology, see reference 1: Phillips KA, et al.

FINDINGS

1. Multi-code claims are prevalent across genetic testing; some claims contain hundreds of codes.

With the prevailing code system largely based on individual genes and techniques, multi-gene and multi-technique tests introduce an inherent challenge: Which code(s) to bill? In this analysis, summarized in the table below,[12] we find that in every domain, claims average more than one billing code per claim. Five domains averaged more than ten codes per claim.

Fig 1. Average Number of Codes Per Claim by Domain of Genetic Testing



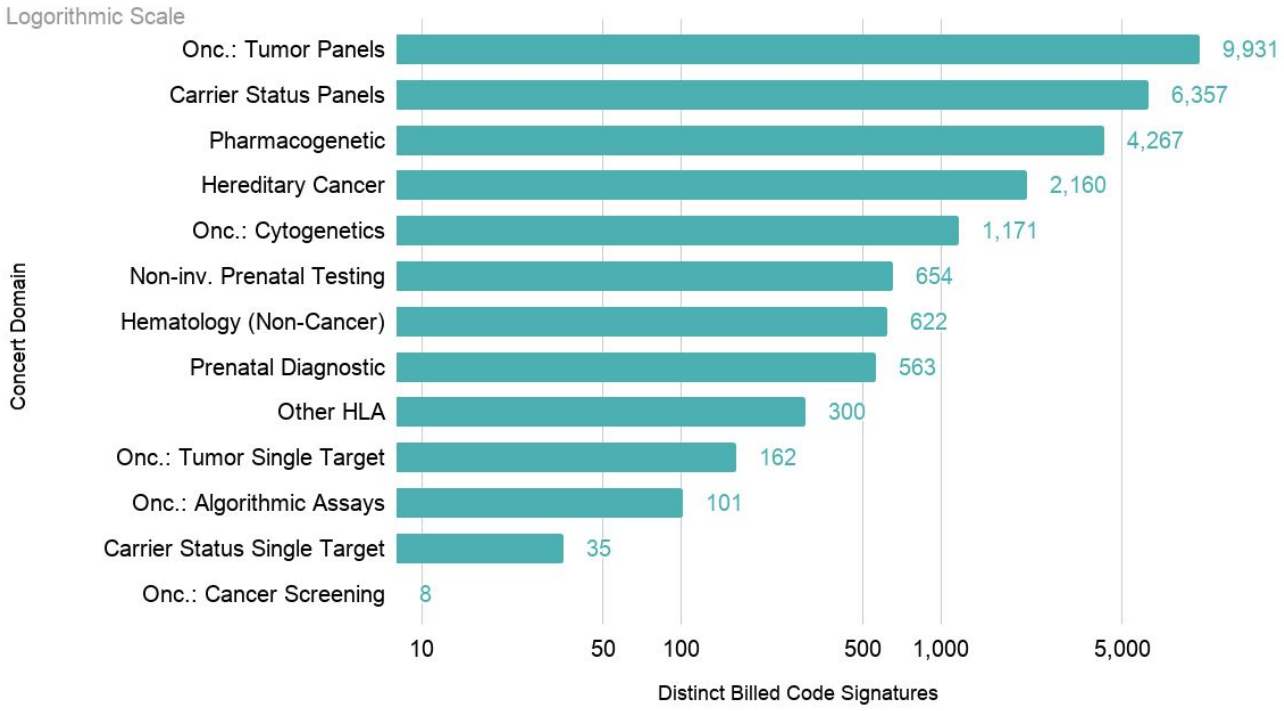
In extreme cases, a claim may contain hundreds of codes. Most of the domains in the chart above contained at least once instance of a claim with more than 100 codes.

[12]This and all following charts are limited to those domains that had claims volume above a cutoff threshold. As a result, 13 of Concert's 30+ domains are shown.

2. Code combinations for similar tests vary widely.

Not only do claims contain numerous codes, but the number of unique combinations of codes (code signatures) is also very high.[13] Shown below is the count of unique code combinations found in each domain.

Fig 2. Number of Distinct Code Signatures Observed Within Each Domain



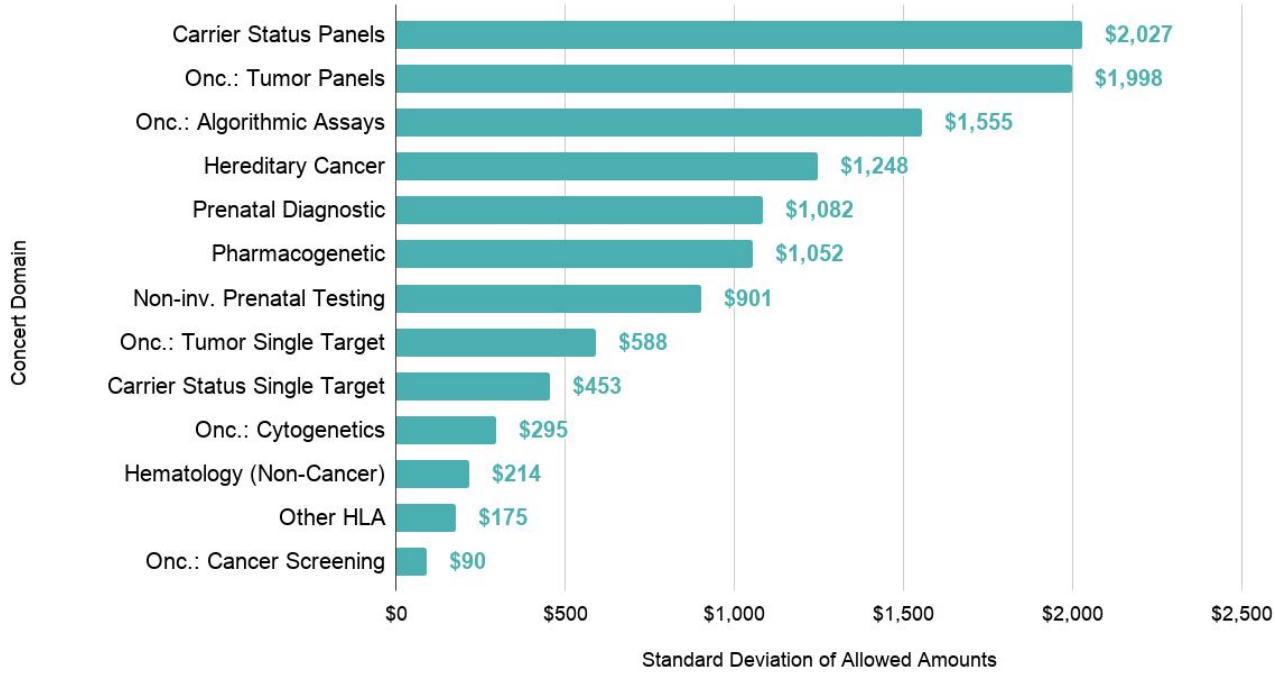
[13] More than 36,000 unique code combinations were observed across all 30+ domains.

3. Reimbursements for similar tests vary widely.

To better understand the economic impact of highly variable, multi-code claims, we also measured reimbursement variation.[14] Relative to a mean reimbursement amount of roughly $1,000 across all claims, variability in most domains is high.

Fig 3. Standard Deviation of Reimbursements Observed Within Each Domain

Mean allowed amount across all genetic testing is approx. $1,000

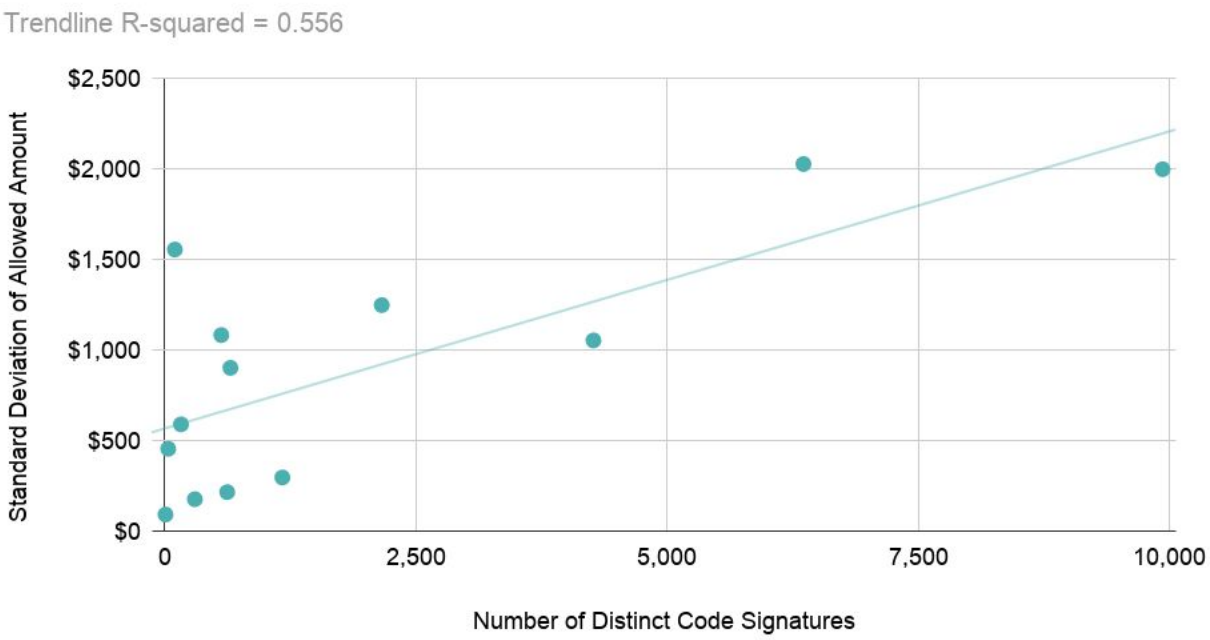


[14] Reimbursement variation is calculated as the standard deviation in the allowed amount for claims within each domain. The term "allowed amount" refers to the total cost of a medical service combining the health insurer's financial responsibility with the member's.

4. Coding variation correlates with price variation.

We also measured the correlation between code and reimbursement variation, finding that these two variables correlate with an R^2 of 0.556. The following chart illustrates the relationship between the number of distinct code combinations observed and the variation in reimbursement amounts within each genetic testing domain.

Fig 4. Correlation Between Code Variation and Price Variation



Code variation is just one factor contributing to price variation, even within similar testing domains. Differences in quality, service, and brand also impact price variation. That said, this analysis suggests that highly variable, multi-code claims likely contribute to variation in payments.

IMPLICATIONS & CONCLUSIONS

As the financial guarantor of the health care system, health insurers are impacted by any factor that contributes to limitations in transparency or higher prices. In extreme cases, code variation provides justification for further restrictive methods, most notably prior authorization. More subtly, complex coding requires time and energy to accurately apply policy in genetic testing, leading to additional administrative costs for health insurers and beyond.

Coding variability – and resulting counter measures from health plans – contributes to review processes that are costly or impractical to embed within the provider workflow. Providers are trying to make the right decision for their patients with minimal hassle from within an existing workflow,[15] and increasingly they rely upon laboratories for administrative support. Some laboratories have invested in in-house prior authorization capabilities, while others have outsourced this activity to third parties. While these laboratory-provided services (including obtaining prior authorizations) are of great value to patients and ordering providers, they add incremental costs (both administrative and switching) that ultimately must be borne by the patient, health insurer, or employer.

In the broad context of precision medicine, the coding system is a critical component in data connection and data analysis across the Genetic Health Information Network. Data ambiguity – the inability to precisely track a test, order, and result, and to tie that information with longitudinal patient history – is one of the central obstacles to a data-driven learning system.[16] Solutions that reduce coding variation will not only bring short-term benefit (lower out-of-pocket expenses, lower premiums, fewer surprise bills, and less confusion in determining coverage), but will advance precision medicine by improving the accuracy and interoperability of genetic data. This will ultimately lead to insights that accelerate healing and improve health through precise, personalized care.

[15] https://www.mobihealthnews.com/content/joshua-barrett-and-dan-gebremedhin

[16] Bustamante, Carlos D et al. 2017. Building the Digital Infrastructure to Enable Genetic Medicine: Recommendations from a Multi-Stakeholder Summit. DOI: 10.31219/osf.io/ntka2