

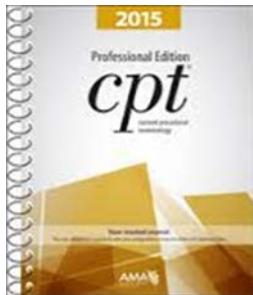


Molecular Pathology Coding Workgroup Fly-In

Your MISSION **is** *Our* MISSION

What CPT Is

Role of Current Procedural Terminology Nomenclature: Coding



CPT is a listing of descriptive terms and identifying codes for reporting medical services and procedures

The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, providing a means for harmonized communication among physicians and others in the healthcare ecosystem

CPT descriptive terms and identifying codes currently serve as the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs, and for administrative management

Providers, payers, clearing houses mandated use

HIPAA-mandated for covered entities

Technology neutral

Structure of Code Set

Category I

- Permanent codes for medical, surgical, and diagnostic services
- *Inclusion of a descriptor and its associated five-digit code number in the CPT Category I code set is based on whether “the procedure or service is consistent with contemporary medical practice and is performed by many practitioners in clinical practice in multiple locations.”*

Category III

- Temporary codes for emerging technologies, services, and procedures – quick to market and more than half move to Category I

Structure of Non-Category I CPT Pathology/Laboratory Codes

Administrative MAAA

- Does not adhere to Category I Code Criteria
- Panel tests of various types of analyses
- These tests include the use of an algorithmic analysis of the various assay results to generate a report of either a numeric score or probability
- Unique to a single clinical laboratory or manufacturer

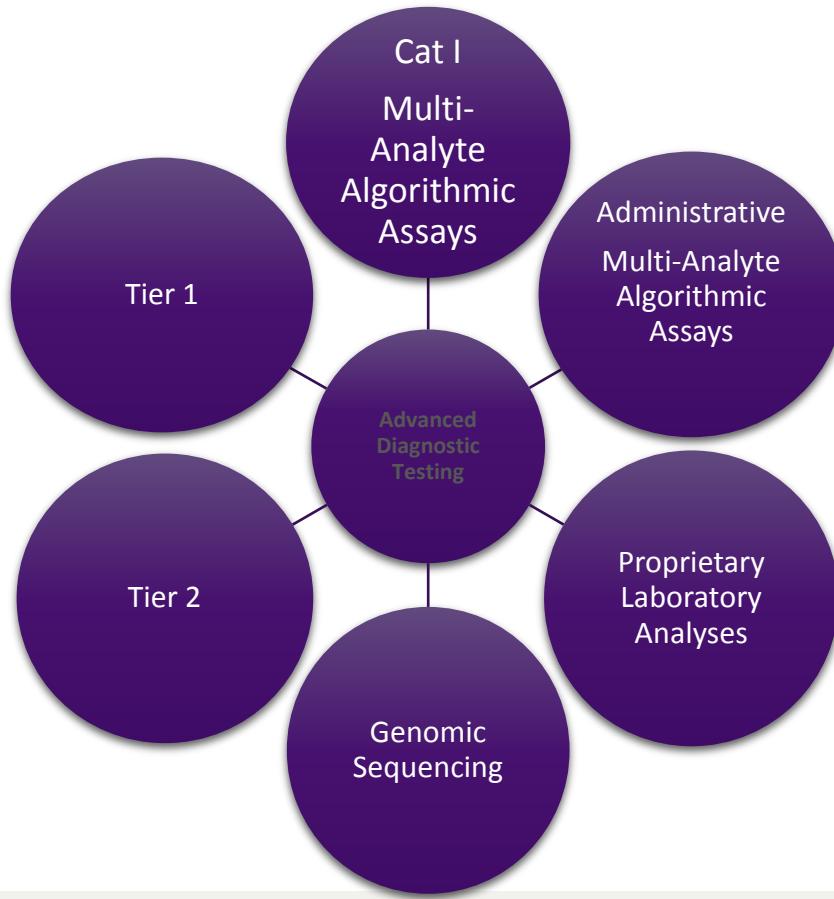
Proprietary Laboratory Analyses

- Does not adhere to Category I Code Criteria
- Unique to a single clinical laboratory or manufacturer
- Codes for labs or manufacturers that want to more specifically identify their test
- Includes MAAs, GSPs, ADLTs, and CDLTs

Code Set Criteria

General Criteria	Category I Criteria	PLA Criteria	Category III Criteria
<ul style="list-style-type: none">• Proposed code:<ul style="list-style-type: none">- Is distinct from current services- Is consistent with code set standards- Does not describe extraordinary circumstances	<ul style="list-style-type: none">• FDA clearance/approval has been received (where applicable)• Widely performed• Supported in literature• The procedure or service is consistent with current medical practice	<ul style="list-style-type: none">• Requested by the lab or manufacturer performing the test• Performed on human specimens in the U.S.	<ul style="list-style-type: none">• Performed in humans; <u>and</u>• CPT/HCPAC Advisor support; <u>or</u>• Supported in literature; <u>or</u>• Has evidence of clinical utilization

The CPT code set over the years has evolved into a comprehensive set of codes for emerging laboratory services to create an environment conducive for advanced diagnostic test coding



Category I Molecular Pathology Codes

Gene Specific/Genomic Test

- Adhere to Category I Code Criteria
- Biomarkers demonstrate clinical usefulness (eg, high positive predictive value, high negative predictive value)

Tier 1

GSPs/Molecular Multianalyte Assays

- Adhere to Category I Code Criteria
- Performed in lower volumes than Tier 1

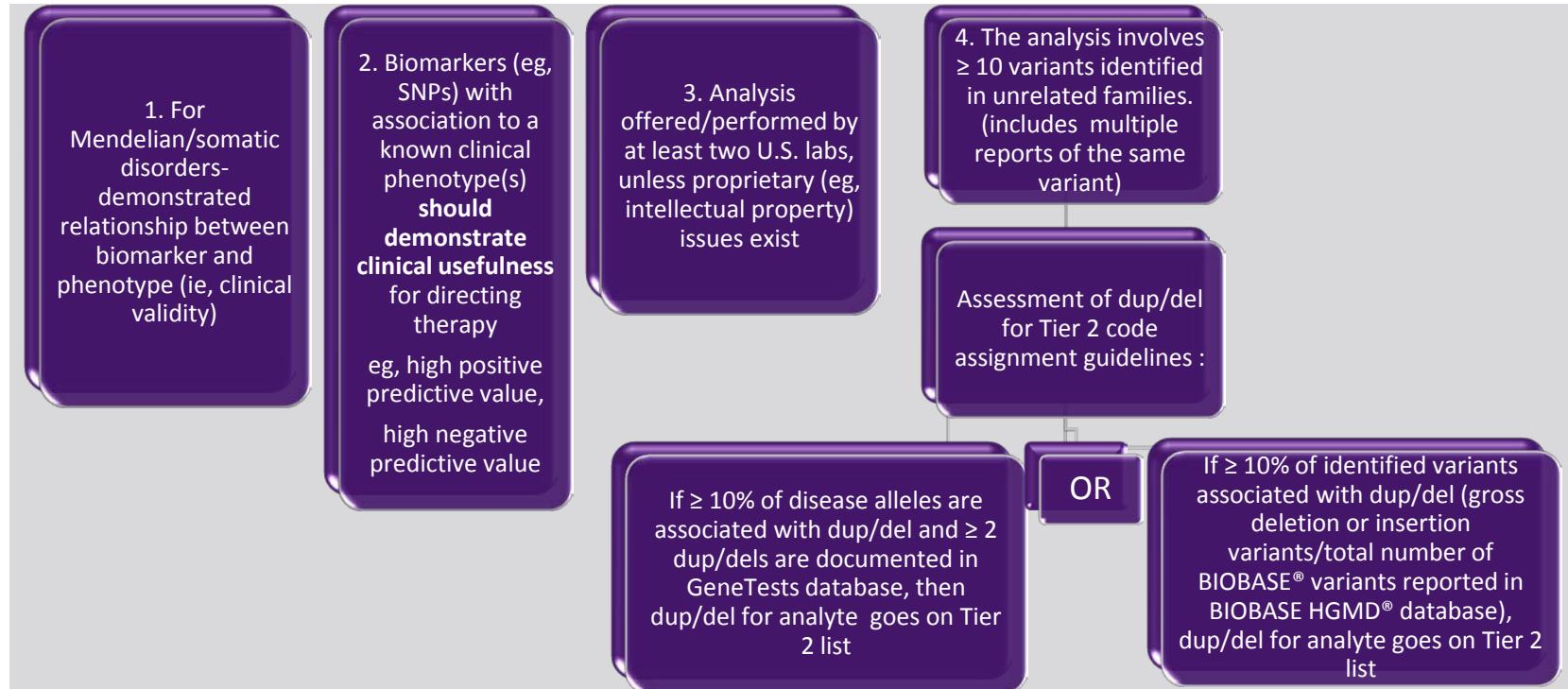
Tier 2

- Adhere to Category I Code Criteria
- Clinical molecular multianalyte DNA or RNA sequence analysis tests that simultaneously assay multiple genes or genetic regions
- Performed on nucleic acids from germline or neoplastic samples
- Use next generation or massively parallel sequencing technologies
- Target specific combinations of genes or genetic material, or assay the exome or genome

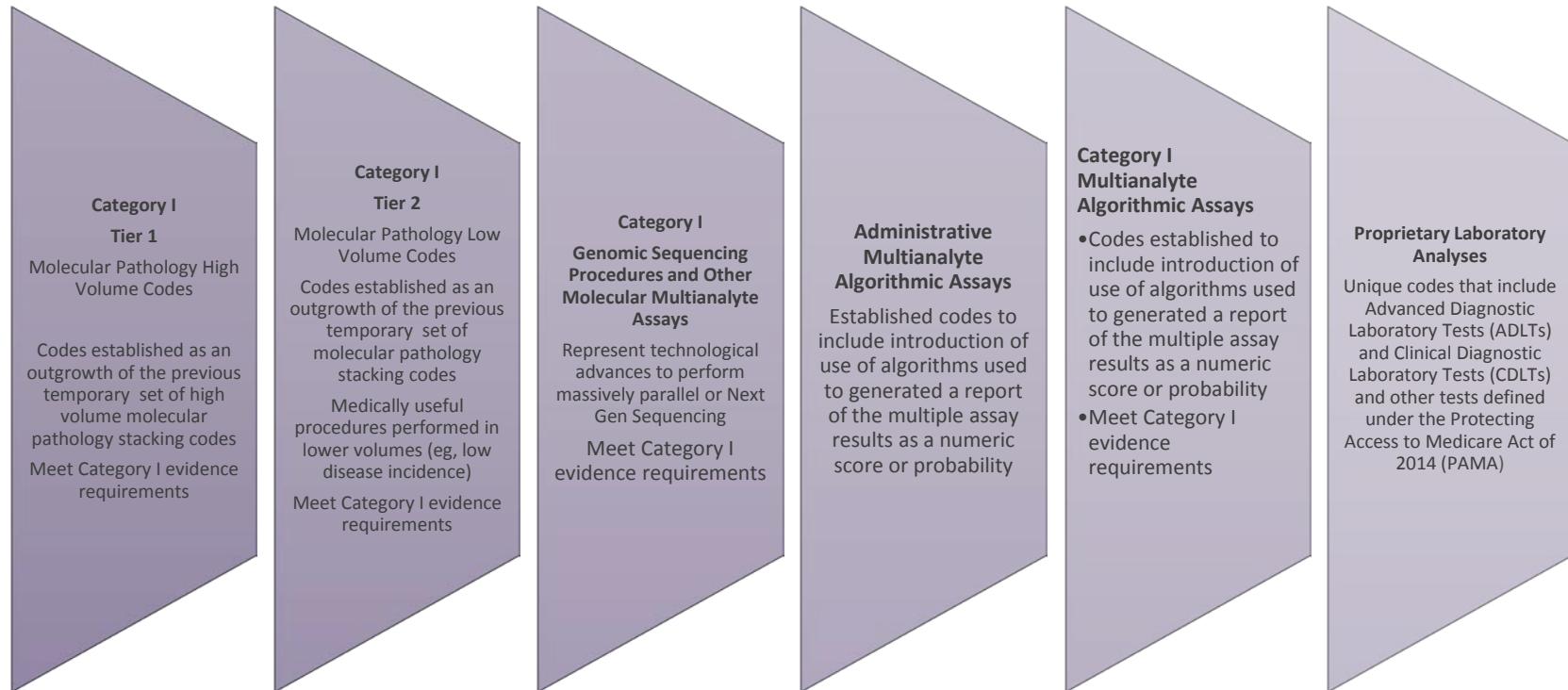
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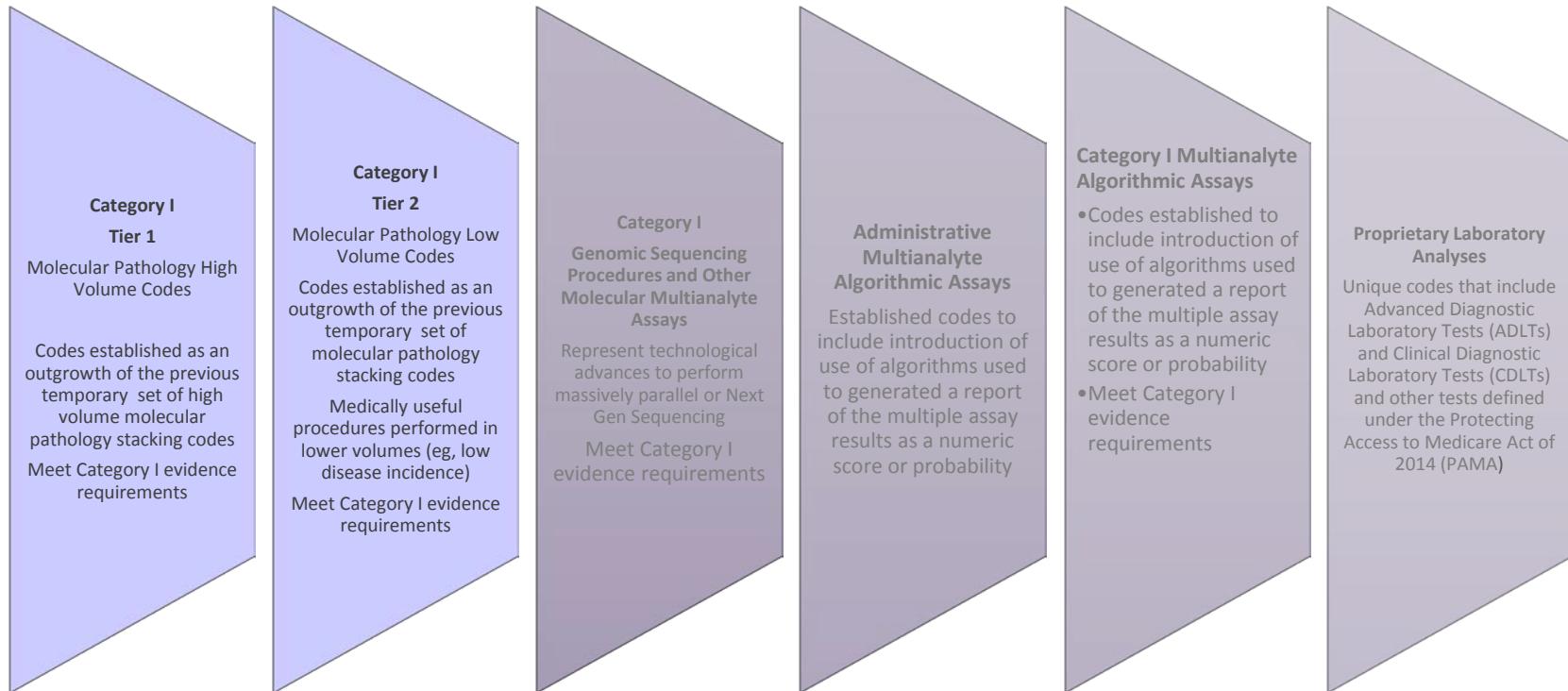
Specific Molecular Pathology Criteria



Evolution of the CPT Set of Advanced Diagnostic Test Codes



Evolution of the CPT Set of Advanced Diagnostic Test Codes



Molecular Pathology Procedures Tier 1 and Tier 2 Codes

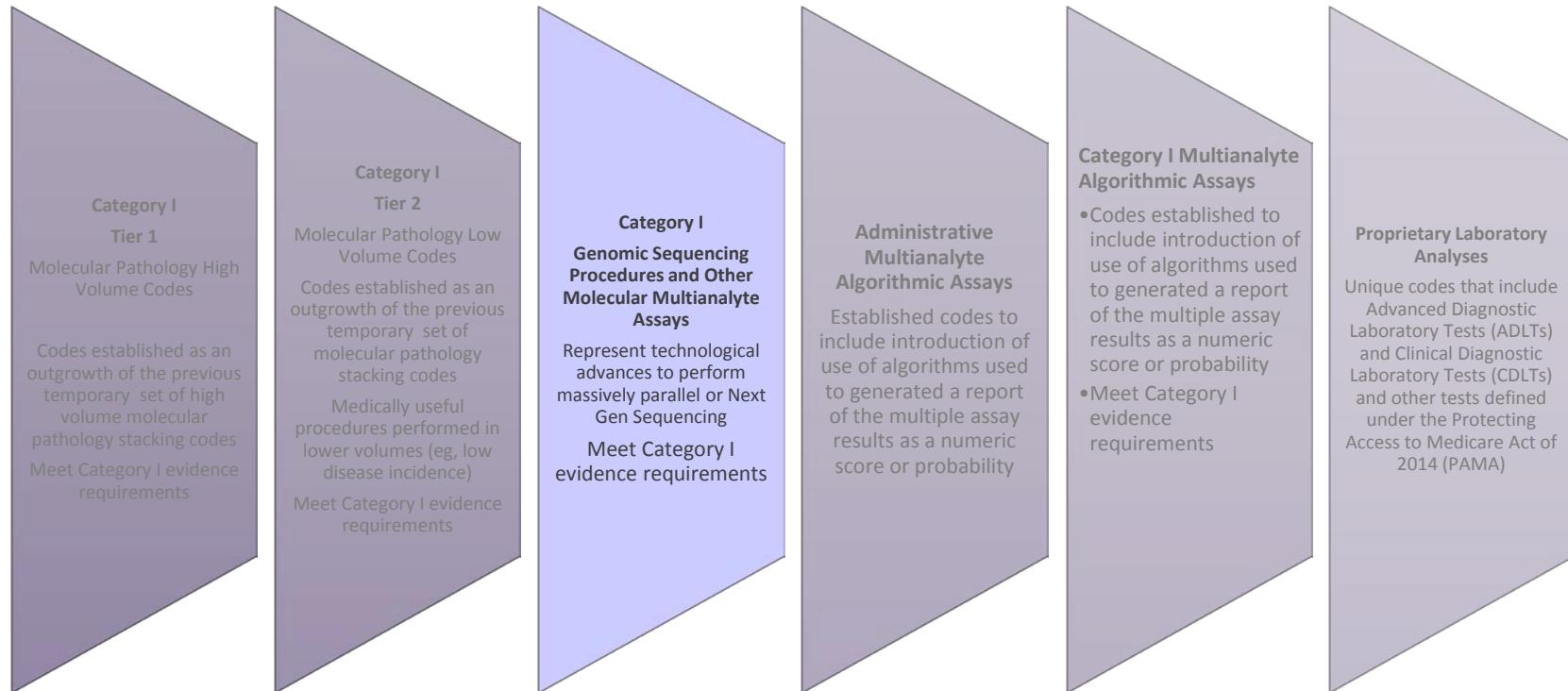
Applications for new or revised Tier 1 and Tier 2 Molecular Pathology codes must satisfy Category I CPT code criteria, as well as these Parameters Specific for Category I Requirements for Molecular Pathology:

- In the case of Mendelian and somatic disorders, there is a demonstrated relationship between biomarker and phenotype (ie, clinical validity)
- Biomarkers (eg, SNPs) that have an association but not a proven causative effect to a known clinical phenotype(s) should have demonstrated clinical usefulness (eg, high positive predictive value, high negative predictive value, directing therapy/management).
- Analysis is offered in at least two U.S. laboratories are performing the analysis unless proprietary (eg, intellectual property issues exist)
- The analysis involves ≥ 10 variants identified in unrelated families. Multiple reports of the same variant may be included.

Tier 2 Molecular Pathology Procedures

- Describe low volume gene tests (eg, low disease incidence) not listed in the higher volume Tier 1 molecular pathology codes (81161, 81200-81383).
- Listed in groupings of resource-based levels of:
 - technical resources, and
 - interpretive complexity

Evolution of the CPT Set of Advanced Diagnostic Test Codes



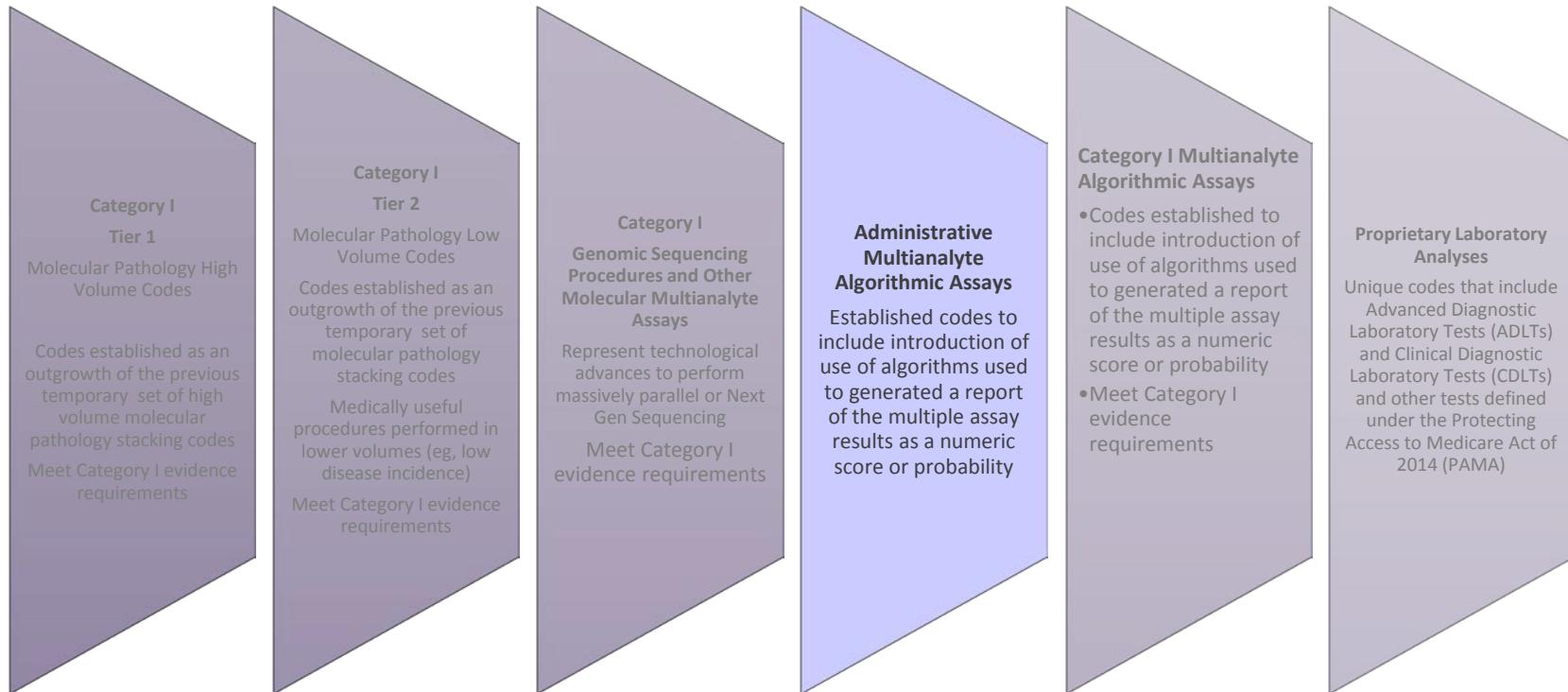
Genomic Sequencing Procedures (GSP) and Other Molecular Multianalyte Assays (MMA)

- Must meet Category I code criteria
- Are DNA or RNA sequence analysis methods
- Simultaneously assay multiple genes or genetic regions relevant to a clinical situation.
- May target specific combinations of genes or genetic material, or assay the exome or genome.
- Performed via GSP, polymerase chain reaction [PCR] methods and microarrays
- Represent discrete genetic values, properties, or characteristics in which the measurement or analysis of each analyte is potentially of independent medical significance or useful in medical management.
- Do not represent algorithmically combined results to obtain a risk score or other value, which in itself represents a new and distinct medical property that is of independent medical significance relative to the individual, component test results

Genomic Sequencing Procedures

- Technology is commonly referred to as next generation sequencing (NGS) or massively parallel sequencing (MPS).
- Performed on nucleic acids from germline or neoplastic samples.
- Examples include:
 - Aneuploidy analysis of cell-free circulating fetal DNA,
 - Gene panels for somatic alterations in neoplasms, and
 - Sequence analysis of the exome or genome to determine the cause of developmental delay.
 - Are designed to evaluate the genetic material in totality or near totality to:
 - Identify sequence (base) changes,
 - Identify copy number, structural changes, and abnormal zygosity patterns.
 - “Re-query” or re-evaluate the sequence data (eg, complex phenotype such as developmental delay is reassessed when new genetic knowledge is attained, or for a separate unrelated clinical indication).

Evolution of the CPT Set of Advanced Diagnostic Test Codes



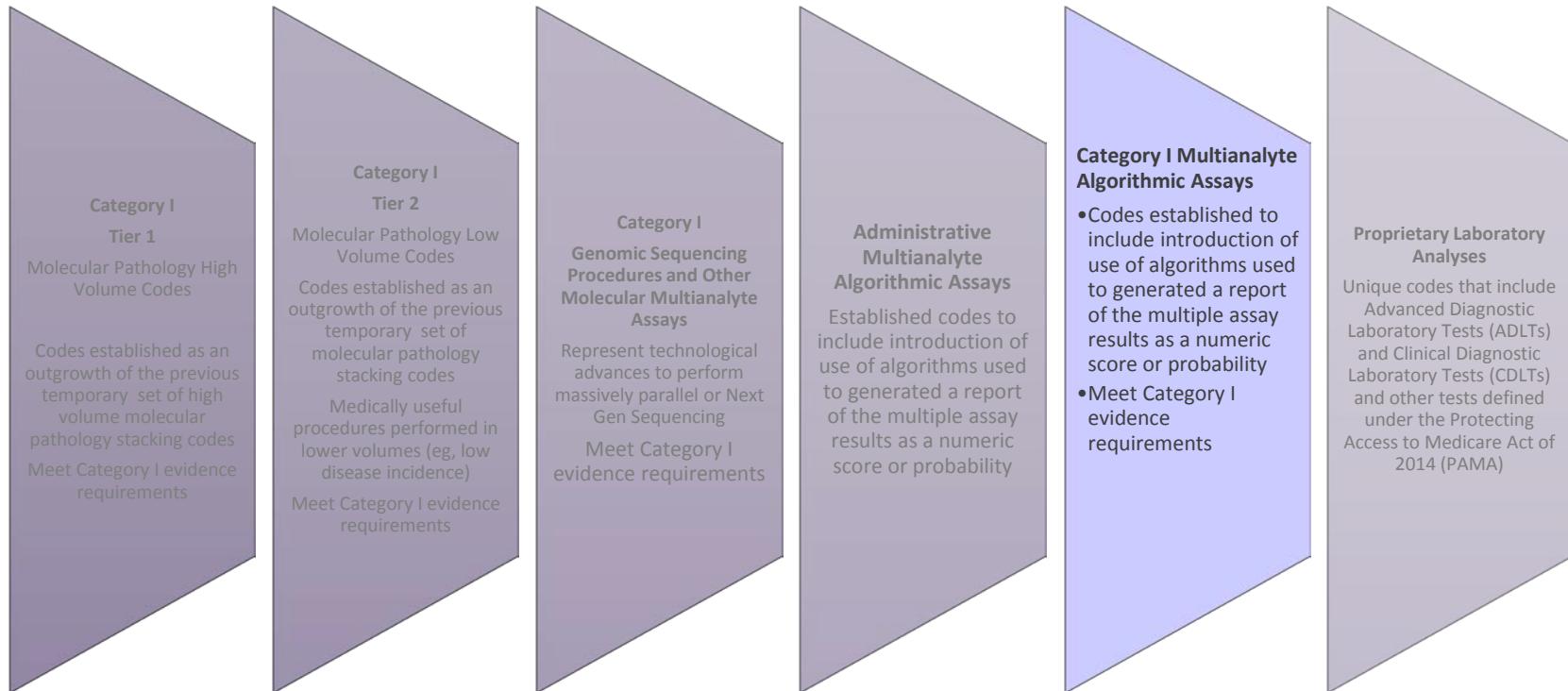
Administrative Multianalyte Assays with Algorithmic Analyses (MAAA)

Administrative MAAA Codes

Administrative code set facilitates accurate reporting of MAAA services that are not assigned Category I codes

- Analysis must be generally available for patient care
- Include proprietary name of test
- Are typically unique to a single clinical laboratory or manufacturer
- Codes include all analytical services required for the algorithmic analysis (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection) in addition to the algorithmic analysis itself.
- 5-digit, alphanumeric codes ending with the letter 'M'.
- Located in Appendix O of CPT code set

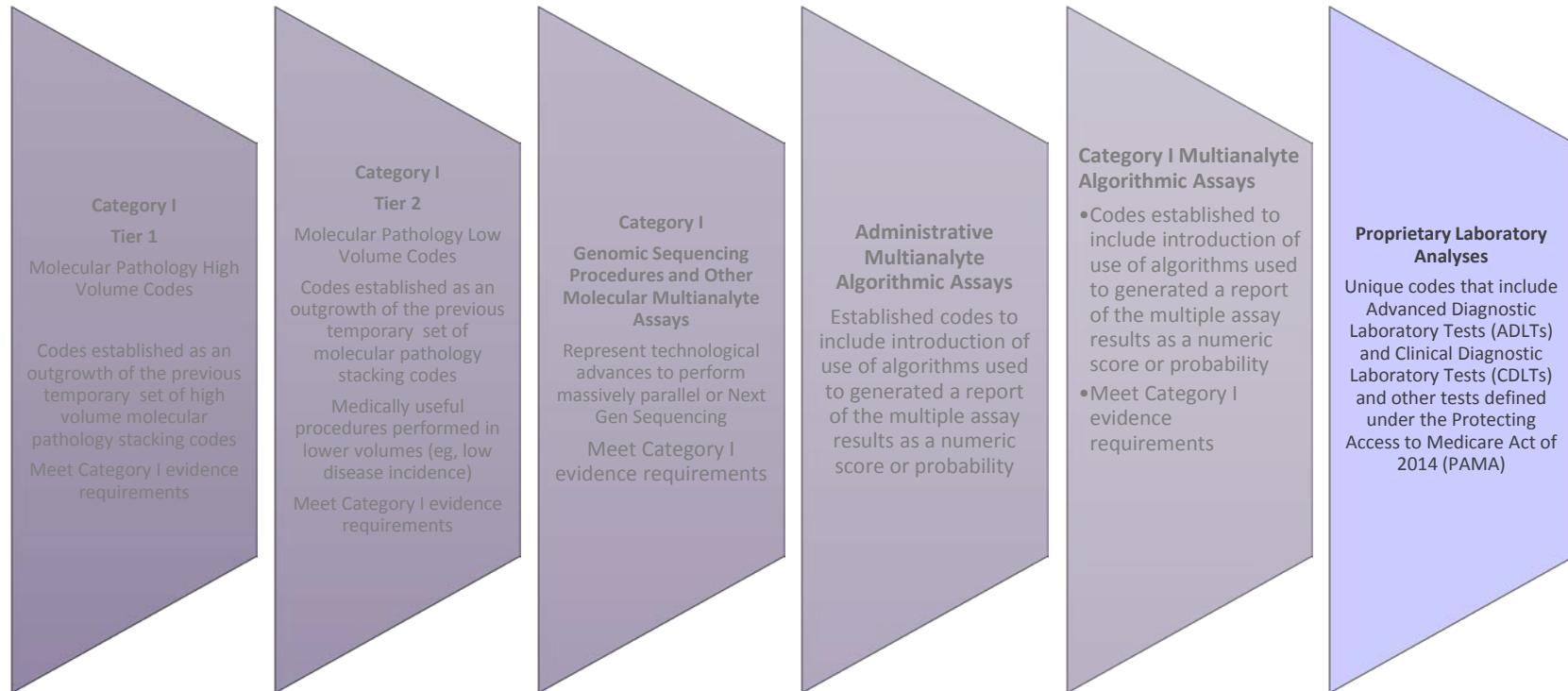
Evolution of the CPT Set of Advanced Diagnostic Test Codes



Category I Multianalyte Assays with Algorithmic Analyses (MAAA) Codes

- Multianalyte Assays with Algorithmic Analyses (MAAAs) are procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (eg, proteins, polypeptides, lipids, carbohydrates).
- Algorithmic analysis uses the results of these assays as well as other patient information (if used) is then performed and typically reported as a numeric score(s) or as a probability.
- In order to report an MAAA code, the analysis performed must fulfill the code descriptor **and**, if proprietary, must be the test represented by the proprietary name listed in Appendix O of CPT code set.
- **Category I** MAAAs must meet Category I CPT code criteria

Evolution of the CPT Set of Advanced Diagnostic Test Codes



Proprietary Laboratory Analyses (PLA)

- Alpha-numeric CPT codes with a corresponding descriptor
- Available to labs or manufacturers for more specific identification of their tests.
- Criteria requires
 - evidence of performance on human specimens, and
 - request for code by the clinical laboratory or the manufacturer that offers the test.
- PLA codes include (but are not limited to)
 - Advanced Diagnostic Laboratory Tests (ADLTs) and Clinical Diagnostic Laboratory Tests (CDLTs) as defined under the Protecting Access to Medicare Act of 2014 (PAMA) including:
 - Multianalyte Assays with Algorithmic Analyses (MAAA),
 - Genomic Sequencing Procedures (GSP).

Preparatory Conference Calls – Specialty Societies

- Clinical usefulness:
 1. Do these GSPs/MMAs (codes 81410-81471) have any clinical usefulness?
 2. Do these tests have any unique clinical usefulness, that is not achieved by existing tests?
 3. Can you define clinical scenarios where these tests would be used preferentially, to the exclusion of existing tests?
 4. Is there peer reviewed published data to support clinical usage of these tests?
- Guidelines:
 1. Does your society have (or is developing) guidelines, recommendations, or opinions informing its members on the clinical usage of these tests?
- Panel composition:
 1. Can your society make a recommendation for what components should be included in broad panels designed to address the clinical usages cited above?

Preparatory Conference Calls – Payers

1. Are there any GSP/MMA (Molecular Multianalyte Assays) codes (81410-81471) that you include in your test menu?
2. Other than the issue of code granularity, what are the needs of payers for GSP/MMA codes and their usage guidelines?

Preparatory Conference Calls – Labs

1. In general, how do you determine what elements or entities are included in a panel test?
2. Is the clinical usefulness of every element in a GSP/MMA panel test supported by peer-reviewed literature?
3. As a group, are the laboratories who perform GSP/MMA panel tests in agreement on their composition?
4. Do the laboratories who offer GSP/MMA panel tests have concordance on the composition of panels and the clinical indications for their usage?
5. What is the incidence of clinical scenarios where a specific GSP/MMA panel test would be indicated?
6. Can you identify the clinicians who use these GSPs/MMAs and the professional societies who represent them?

Genomic Sequencing Panel CPT Codes

Basic principles*

Target genes on a GSP must have clinical validity for the condition/ clinical presentation the GSP is designed for

Descriptor should list specific target genes which are examples of clinically valid targets, and include language such as: " and additional clinically valid target genes".

- Literature references in the CCP should support the clinical validity
 - This could include studies which demonstrate clinical validity of genes, or clinical or laboratory guidelines from specialty societies or curated databases which address this

There must be a specified minimum number of target genes, and an upper limit of the number of target genes.

*Contributed materials - submitted by David B. Flannery, MD, American College of Medical Genetics and Genomics

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