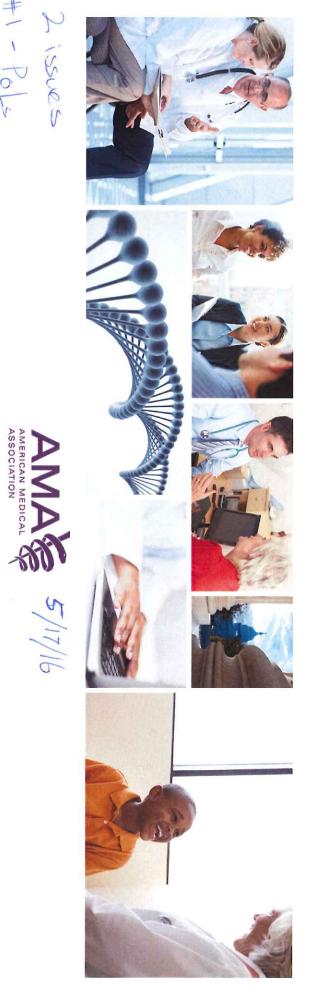
Protecting Access to Medicare Act

Coding Solution



Support low threshold picclusions increases such prices to use flevibility to

Protecting Access to Medicare Act of 2015

Coverage
Determinations

Medicare
Contractors

Coding

Data Reporting

Pricing

Exercise



PAMA §216 Coding Provisions

ADLTs

CDLTs

FDA Cleared or Approved

Not limited to Single Laboratory

Single Laboratory AND

May be currently reported with a CPT Category I or III code

MAAA Like Criteria **OR**

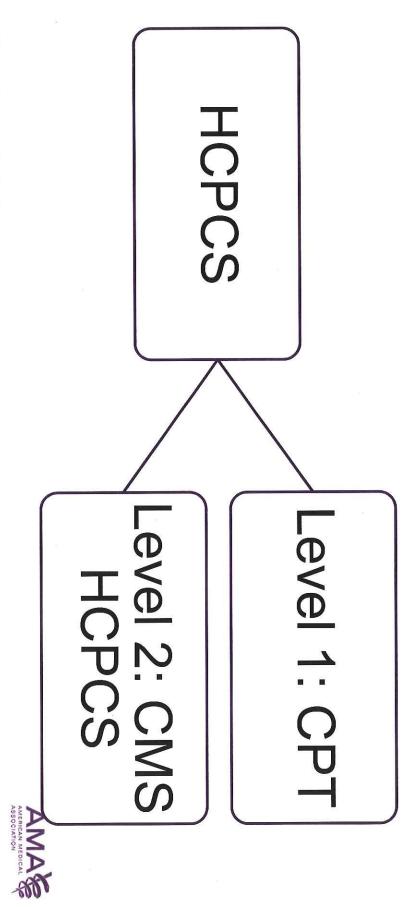
FDA Cleared or Approved Tests **OR**

Secretary's Discretion

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HCPCS





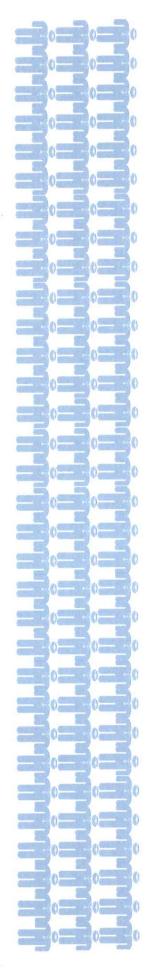






CPT Advisors

- CPT Advisory Committee
- More than 100 Medical Specialty Societies with membership in the AMA House of Delegates
- CPT Health Care Professionals Advisory Committee (HCPAC)
- Organizations representing non-physician healthcare professionals





Participants, Process, Modernization

Submit Application

- Open to Public
 Encourage Interaction with Medical
 Specialties

Access to Workgroup Meeting Deliberations & Recommendation

 Open to Public and Free Meetings **Public CPT**



Access to Meeting Deliberations & Comments/

Rationale

- Applicant
- Interested Stakeholder
 Medical Specialties

Public/Stakeholders (including Medical Specialties) Testimony and Comment at CPT Editorial Panel

- Open to Public
- Applicant
 Interested Stakeholder
- Medical Specialties
- Access to Application

- Applicant
 Interested Stakeholders
- Medical Specialties



CPT Codeset Structure

Category I

 Permanent codes diagnostic services surgical, and for medical,

Category II

report quality performance Codes used to

Category III

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

Administrative Code MAAA

- •Multianalyte
 Assays with
 Algorithmic Analyses
- Generally available for patient care
- Typically unique to a single laboratory or manufacturer

PLA Section

 Designed to meet the requirements of the PAMA provisions



















Coding Overview Protecting Access to Medicare Act (PAMA) §216:

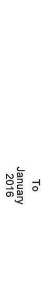
PAMA requires a new coding infrastructure to report clinical diagnostics laboratory tests with requisite specificity

The proposed rule allows the coding solution to be:

HCPCS Level I CPT 9 **HCPCS** Level II CMS G codes

Initial Public Engagement

Protecting Access to Medicare Act (PAMA) Enacted April 2014 Public Panel Discussion of PAMA Coding Strawman Proposal October 2014 Public Panel Discussion of PAMA Coding Strawman Proposal February 2015 PAMA
Proposed
Rule Issued
by CMS
September
2015 Public Panel Discussion of PAMA Coding Options and Proposed Rule October 2015 Panel Approval of New PLA Section of CPT First Public Panel Session for the New PLA Section December 2015 PLA
Documents
Publicly
Posted for
Review and
Distributed
to
Stakeholder Second Public Panel Planning Session for the New PLA Section January 2016 Public Panel Discussion of New PLA Section of CPT



December 2015

s

February 2016

November 2015



New CPT Proprietary Laboratory Analyses Section A lieu of Grodes

Attributes

- One code for the life of the test
- Available to any clinical laboratories or manufacturers who want to specifically identify their test
- Must be requested by the lab or manufacturer
- Test performed on human specimens
- Published quarterly
- Retirement requested by the applicant
- Not CPT Category I or Category III code



Overview of the New PLA Section

CPT Provides a Sustainable Coding Infrastructure

CMS Responsible for ADLT Adjudication

CPT Editorial Panel Responsible for Codification

Offers Consistent National Coding-one code for the life of a test



General Concepts for Introductory Guidelines

Pathology & Laboratory Subsection Title: Proprietary Laboratory Analyses

0 that are proprietary analyses, and non-proprietary analyses provided on a Proprietary Laboratory Analyses (PLA) codes represent clinical laboratory tests

proprietary platform.

- 0 using a proprietary test licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration (FDA)). These analyses can be provided either by a single ("sole-source") laboratory or
- 0 Includes Advanced Diagnostic Laboratory Tests (ADLTs) and Clinical Diagnostic Act of 2014 (PAMA). Laboratory Tests (CDLTs) as defined under the Protecting Access to Medicare



General Concepts for Introductory Guidelines

- the same service These PLA codes should not be reported with any other CPT code(s) for
- 0 may be reported with a specific PLA code Similarly, other CPT code(s) should not be used to report services that
- 0 clinical laboratory or manufacturer PLA codes are specified by the procedure's proprietary name and

PLA Application Overview

Requirements

- Test must be commercially available in the U.S. for use on human specimens
- Code must be requested by the lab or manufacturer performing the test
- ✓ Test is, or will be, listed on the CLFS

Documentation, if applicable

- FDA clearance or approval
- Sole-source laboratory



PLA Application Overview

- Additional information requested (similar to other lab CCPs)
- ✓ Proposed descriptor language
- ✓ Procedure description*

✓ Clinical use*

* Used primarily for CPT descriptor refinement, not to confirm validity of code request.



PLA Advisory Group Specifics

Charge

appropriate and consistent descriptor language and to provide additional Review and make recommendations to the CPT Editorial Panel regarding code assistance in maintenance of this code set change proposals related to the new clinical laboratory test section, to assure

Composition

- Co-chairs (2), at least one of whom is a current CPT Editorial Panel member;
- One current member of the Pathology Coding Caucus
- One current member of the Molecular Pathology Advisory Group;
- One insurance representative;
- Ad hoc Rotating members (5)

