AMA
AMERICAN MEDICAL ASSOCIATION

Proprietary Laboratory Analyses (PLA) Codes

Tutorials for Applicants and Reviewers

Clinical Diagnostic Lab Tests (CDLT)

- The PLA subsection includes ADLTs and CDLTs.

- CDLTs are defined by the Centers for Medicare & Medicaid Services (CMS) as tests that include blood tests, urinalyses, tests on tissue specimens, and some screening and other tests that are furnished by applicable laboratories and covered under Medicare Part B. PAMA

Advanced Diagnostic Lab Tests (ADLT)

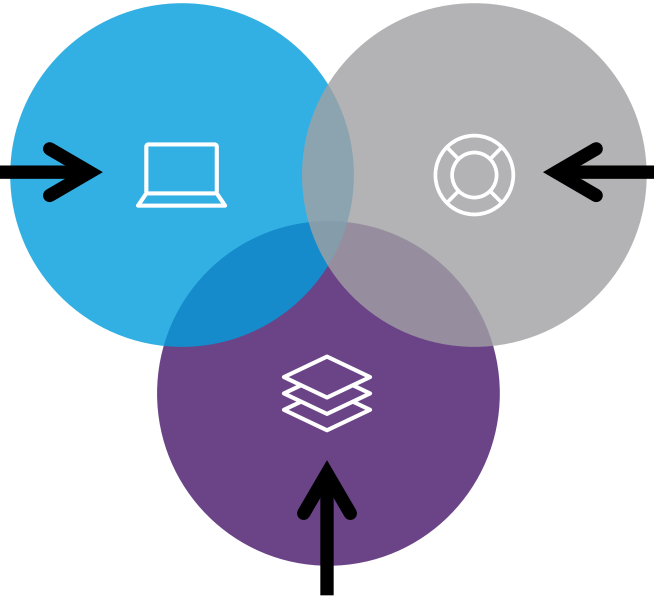
DEFINITION

PAMA defines ADLTs as a laboratory test that is “covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and that meets one of the following criteria

- Biomarkers or Proteins
  The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result;
- FDA
  The test is cleared or approved by the Food and Drug Administration (FDA);
- Health and Human Services
  The test meets other similar criteria established by the Secretary [Health and Human Services].1 ”
  (Note: Although provided for in statute, the Secretary, as of the date of this publication, has not specified additional criteria.)

PLA Codes Requirements

PLA Codes Requirements



Laboratory

PLA test codes may be requested by laboratories, who either develop a test independently, or modify a test licensed by a manufacturer (may license to multiple providing laboratories).

Code Use

These PLA codes are to be used only by the requesting laboratory (if LDT). May be licensed or marketed to multiple providing laboratories (IF cleared or approved by the FDA)

Availability

The tests included in the PLA section must be commercially available in the United States for use on human specimens.

PLA Code Requirements

- A **PLA code does not fulfill Category I code criteria. PLA codes are not required to fulfill the Category I criteria**.

- The standards for inclusion in the PLA section are:
  - The test must be commercially available in the United States for use on human specimens (electronic/paper requisition acceptable), and
  - The clinical laboratory or manufacturer that offers the test must request the code.
  - The procedure describes the service

- The report structure, per se, is not a criterion that is used to grant PLA code.

PLA Code Structure

- The descriptor nomenclature follows, where possible, existing CPT code conventions. See Appendix O of the CPT Book for examples of CPT PLA codes and descriptor, which usually follows the MAAA convention.

PLA Code Application - Descriptor

- MAAA example language
  - Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
    - Note that up to 10 analytes should be included in the descriptor
- GSP example language
  - Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP
    - Note that up to 10 analytes should be included in the descriptor

PLA Code Application – Typical Patient/Vignette

- Example: A 6-day-old male was admitted to the NICU with worsening seizures. Standard anti-epileptic treatment was not successful. The physician orders a test to identify potential actionable mutations.
  - Should not include the specific/proprietary test name
  - Should include brief clinical symptoms
  - Should include age and gender

PLA code Application – Description of Procedure

- Example: DNA is extracted from FFPE tumor tissue and is subjected gene-specific PCR and next generation sequencing for EGFR and KRAS. A report is prepared by a qualified laboratory professional and is communicated to the ordering provider.
  - Must include analytes tested from which specimen type
  - Note that all analytes need to be included, unless >50

PLA Application: Required documentation for clinical laboratories

1

CLIA license number

- To ensure test is clinically available in the US

2

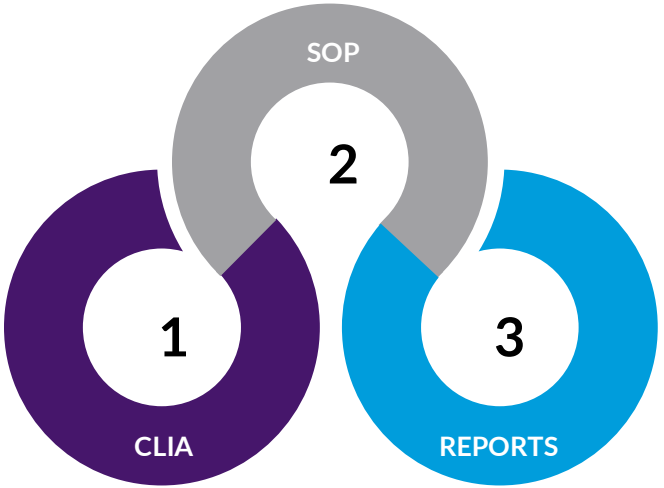
Standard operating procedure (SOP) of the test

- To ensure the testing process
- To confirm analytes and method of test for both descriptor and description of procedure

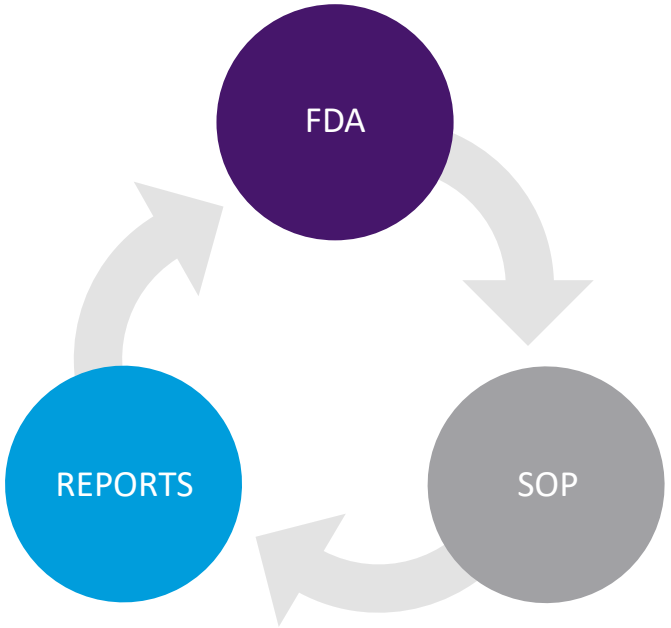
3

Clinical (patient) reports

- Ensure that all reports are anonymous or dummy reports and have no patient identifiers
- To confirm analytes and method of test for both descriptor and description of procedure



PLA Application: Required documentation for kit manufacturers



1

FDA approval letter

- To ensure test is clinically available in the US

2

Standard operating procedure (SOP) of the test/package insert

- To ensure the testing process
- To confirm analytes and method of test for both descriptor and description of procedure

3

Clinical (patient) reports (preferred)

- Ensure that all reports are anonymous or dummy reports and have no patient identifiers
- To confirm analytes and method of test for both descriptor and description of procedure

FAQ’s

Frequently asked Questions

- For new codes:
  - Is the applicant either a laboratory (LDT or FDA cleared) or manufacturer (FDA cleared). Laboratories must have a CLIA certificate (high complexity for LDT), manufacturers must provide FDA clearance.
- For revisions:
  - Is the requestor the same as the original submitter?
- How have they shown the test is orderable in the US:
  - link to order form, screen shot of electronic order form, printed order form?
- Does the proposal follow standard CPT/PLA nomenclature?

Frequently asked Questions

- **Our test has a technical component, but this is followed by interpretation and reporting by a laboratory medical director (MD or PhD)**
    - If there is a technical component it could have a specific PLA code but if evaluation and reporting requires a professional service, then it's not really appropriate for a PLA code – it would be a service on the PFS.
- **Do we need to wait until our test in completely validated and orderable for use before applying for this code?**
    - If the test qualifies for a PLA code – it would still need to be orderable for patients in the us before a code application can be considered.

Frequently asked Questions

- **Can the applicant leave the PLA descriptor open so that they can add genes as assay/or need changes?**
  - No. We generally do not have “open” pla codes. descriptor needs to be as clear and specific as possible
- **Can a PLA code be modified?**
  - Depends. Minor editorial change are acceptable. Major changes that significantly alter the existing PLA code will need a new code
- **Do the applicants need accreditation by CAP/JCO or other accreditation agencies?**
  - CLIA certification is sufficient. All laboratories that perform tests need to have a CLIA certificate **or** a certificate of accreditation from one of the approved accrediting agencies (eg, CAP, COLA, JCO etc.) with high enough complexity to cover the test.

Frequently asked Questions

- **Can a manufacturer request a PLA code if not FDA cleared/approved?**
  - No. Manufacturers of FDA cleared test/kit can apply for and have a PLA code based on the FDA approval/clearance. the test could be provided in any appropriate complexity CLIA **lab** (report of any such lab would suffice).
  - Manufacturers of non-FDA approved assays may sell reagents (not licensed test/assay). The laboratory performing the test must validate the assay and must be a high complexity lab (in this case the assay is an LDT)

Frequently asked Questions

- **How detailed should the SOP be?**
  - The main purpose of asking for the sop is to check whether the test is accurate for what the applicant indicates that they are doing.

- **Should the applicant be required to provide the algorithm for verification?**
  - Since PLA is proprietary, the applicant is not required to disclose the algorithm, but the elements that are part of the test/assay that are specified in the descriptor should generally be provided. If there is any reason to suspect that the test is not available or is a “sham”, more details should be requested from the applicant.

Frequently asked Questions

- If a test receives as a CPT code (PLA or Cat I) based on an LDT version of a test, is a new code required once the same version of the test is cleared or approved by the FDA?
  - A new code would generally not be required following FDA clearance, for a PLA from the same provider. different provider would need to request their own PLA code for the same test. If Category I, it could be proprietary (MAAA) or generic.

PLA Review Process

PLA Timeline: A Brief Overview

Initial Review

AMA staff will review all PLA submissions and forward applications to TAG

TAG Review

The TAG review applications and forward recommendations to the CPT Editorial Panel

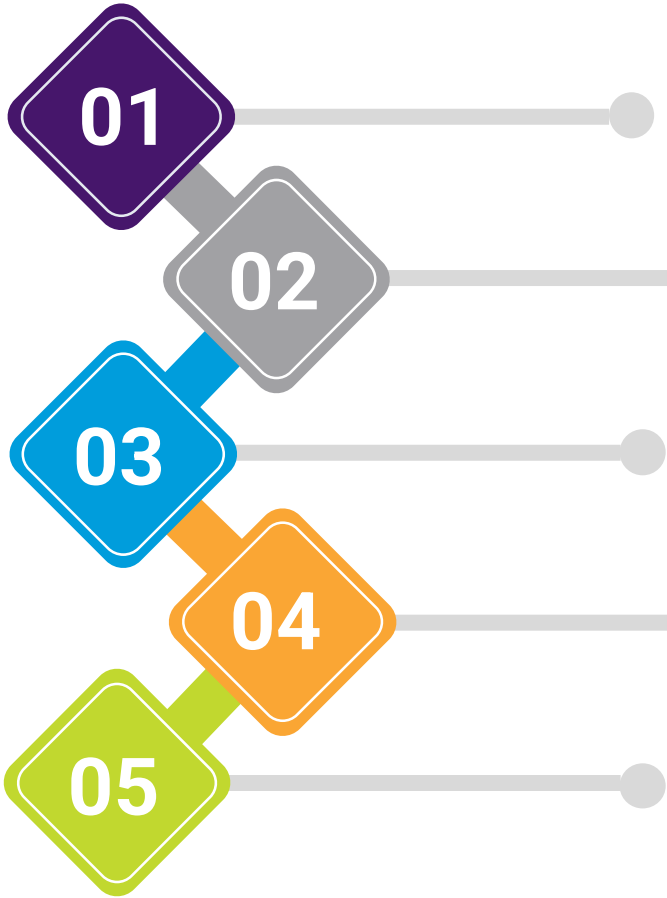
Panel Review

Panel will review TAG recommendations and will vote on whether to approve codes

After the Meeting

AMA staff will prepare approved recommendations for publication

PLA Application Initial Review



Initial Review

After submitting your application, AMA Staff will review the application to check that it is complete.

Deficiencies

AMA staff will contact the applicant if there are any deficiencies with the application.

Address & Resubmit

Applicants should resubmit deficiencies within 2 business days.

Late Resubmissions

Applicants that do not respond to deficiency requests, or that respond late could have their application pushed to the next cycle.

Completed Applications

Complete applications are forwarded to the PLA Technical Advisory Group (TAG) for their review.

Initial Review

- During this period, AMA staff will contact you to confirm names of applicants and contact details and provide any additional participants for the PLA discussion.
- Additionally, you will need to confirm your test name, laboratory name and manufacturer name with how it should be published, if approved.

Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG) Review

CREATIVE SLIDE

TAG Review

The TAG review all applications usually within a 2-week period.
During this review period, if the TAG have questions or concerns about your application, AMA staff will contact you.

TAG Recommendations

The TAG will disclose their recommendations to you, in most cases a Code Descriptor, Typical Patient and Description of Procedures. If you agree with the TAG recommendations, your application is placed on a consent calendar.

Incomplete Applications

If the TAG believe that your application does not meet PLA criteria, AMA staff will contact you.

TAG Discussion

At the end of the review period, the TAG hold a discussion for remaining issues.

TAG discussion

- Due to the volume of PLA applications, all recommendations are placed on a consent calendar. Items can be extracted from the calendar for further discussion if needed.
- During this discussion, any remaining items are addressed. This also includes any items that are extracted from the consent calendar.
- If the TAG have questions or concerns for the applicant, AMA staff will contact the applicant so they can join the discussion.
- Not all applicants will be contacted to join the discussion.
- If you are not contacted by AMA Staff your application moves to Panel Review.

CPT Editorial Panel Review

Panel Review

- The Panel review all TAG recommendations either during the in-person CPT Editorial Panel meetings in February (Q1) or May (Q2) or on a virtual discussion in August (Q3) and November (Q4).
- If the Panel have questions or concerns regarding your application, AMA staff will reach out to you.

Panel Discussion

- The Panel review all the PLA applications as a consent calendar.
- The Panel can extract any application from the consent calendar for further discussion.
- All applications on the consent calendar (unless extracted) are voted together.

Panel Discussion

- If the PLA applications are addressed during the in-person Panel meeting, the consent calendar will have a Tab number assigned.
- This Tab is added to the regular CPT Editorial Panel meeting agenda along with other CPT Applications (eg, Category I codes).
- Extracted applications during the in-person meeting are placed on the CPT Editorial Panel meeting agenda for discussion.
- If PLA applications are addressed during the virtual Panel meeting, then only PLA applications are discussed.

After the Panel meeting

- At the conclusion of the Panel meeting, AMA staff will contact you regarding your application.
- Please contact Thilani.Attale@ama-assn.org if you have any questions regarding your PLA application.

Other information

- Publication and effective date – book/web (add calendar)
- Billing and pricing

Publication and Effective date

	Winter	Spring	Summer	Fall
Application Submission Deadline	Early December	Early March	Early June	Early September
Panel Vote	February CPT Editorial Panel Meeting	May CPT Editorial Panel Meeting	August Virtual Panel Meeting	November Virtual Panel meeting
Publication Date	April 1st	July 1st	October 1st	January 1st
Effective Date	July 1st	October 1st	January 1st	April 1st

Billing and pricing

Please contact Centers for Medicare & Medicaid Services (CMS) and other payors to present your rationale for pricing. The AMA is only responsible for facilitating code creation.

The link below should help you with payment information.

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html

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