



Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

Clinical Laboratory Improvement Advisory Committee

April 13, 2016

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Clinical Laboratory Fee Schedule

Current Process

- HCPCS codes
- Annual lab meeting for public pricing recommendation (crosswalk or gapfill)
- Preliminary pricing determinations ~ September
- Final pricing determination ~ November
- Reconsideration request for subsequent Annual Lab Meeting

Clinical Laboratory Fee Schedule

Current Pricing Methodology

- Crosswalk to a currently priced HCPCS code (or multiples of codes) that has the most similar methodology
- Gapfill
 - Each contractor establishes a local price based on numerous factors including laboratory input, invoices, etc.
 - CMS establishes a National Limitation Amount = median of all contractor prices.
- Once established, HCPCS code prices never change other than annual updates across the fee schedule
- Medicare contractors pay the lowest of the billed charge, the local contractor price, or the National Limitation Amount

Clinical Laboratory Fee Schedule

Future Payment System

Public Law 113-93 April 1, 2014: Protecting Access to Medicare Act (PAMA)

Proposed Rule released Oct 1, 2015

Final Rule: pending

Clinical Laboratory Fee Schedule

Future Payment System

- Laboratories are required to report private payer data
 - Regulatory definition of which laboratories are required to report
- CMS collects data and establishes rates based on the weighted median of private payer rates
- Data collected every 3 years and rates adjusted
- New tests represented by new HCPCS codes go through Annual Lab meeting and rates established through crosswalk or gapfill until private payer data available.

Clinical Laboratory Fee Schedule

Future Payment System

- Subclass of tests known as Advanced Diagnostic Laboratory Tests have separate payment rules
 - Rate is list price for 9 months then adjusted to private payer rates.
 - Private payer data collected annually

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Authority

Section 1834A(f) of Social Security Act

Public Law 113-93 April 1, 2014

Charter: April 15, 2015

Composition

Up to 15 individuals with expertise in issues related to clinical diagnostic laboratory tests including:

- representatives of clinical laboratories
- molecular pathologists
- clinical laboratory researchers
- experts in clinical laboratory science or health economics

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Objectives

- Establishment of payment rates under section 1834 A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and
- Factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.

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Duties

- Calculation of weighted medians of private payor rates for laboratory tests.
- Phase-in of reductions in Medicare payment rates based on private payer rates, as required.
- Application of market rates to establishment of Medicare payment rates.
- Evaluation and designation of tests as advanced diagnostic laboratory tests as defined in section 1834A of the Act.
- Whether to use crosswalking or gapfilling to determine payment for a specific new test.
- The factors used in determining coverage or payment processes for new clinical diagnostic laboratory tests.

Topic Restrictions

- Definition of an applicable laboratory
- Definition of a data collection period
- Treatment of discounts
- Reporting of more than one payment rate for the same payer
- Certification of data
- Definition of private payer
- Civil money penalties
- Medicare conditions of payment for clinical diagnostic laboratory tests

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- 1st Meeting: Aug 2015
 - Advised on recommendations from Jul 2015 Annual Lab Meeting

- 2nd Meeting: Oct 2015
 - Advised on Preliminary Determinations
 - Advised on proposed PAMA rule