

including recommendations from the Advisory Panel on CDLTs described in paragraph (e) of this section, and a request for written public comments within a specified time period on the proposed determination; and

(2) Final determinations of the payment amounts for tests, with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public.

(3) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section, CMS will provide an explanation of how it took into account the recommendations of the Advisory Panel on CDLTs described in paragraph (e) of this section.

(4) On or after January 1, 2018, in applying paragraphs (d)(1) and (2) of this section and §414.509(b)(2)(i) and (iii) when CMS uses the gapfilling method described in §414.508(b)(2), CMS will make available to the public an explanation of the payment rate for the test.

(e) CMS will consult with an expert outside advisory panel, called the Advisory Panel on CDLTs, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists researchers, and individuals with expertise in laboratory science or health economics, in issues related to CDLTs. This advisory panel will provide input on the establishment of payment rates under §414.508 and provide recommendations to CMS under this subpart.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41099, June 23, 2016]

#### **§414.507 Payment for clinical diagnostic laboratory tests.**

(a) *General rule.* Except as provided in paragraph (d) of this section, and §§414.508 and 414.522, the payment rate for a CDLT furnished on or after January 1, 2018, is equal to the weighted median for the test, as calculated under paragraph (b) of this section. Each payment rate will be in effect for a period of one calendar year for ADLTs and three calendar years for all other CDLTs, until the year following the next data collection period.

(b) *Methodology.* For each test under paragraph (a) of this section for which

applicable information is reported, the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.

(c) The payment amounts established under this section are not subject to any adjustment, such as geographic, budget neutrality, annual update, or other adjustment.

(d) *Phase-in of payment reductions.* For years 2018 through 2025, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

(1) 2018—10 percent of the national limitation amount for the test in 2017.

(2) 2019—10 percent of the payment rate established in 2018.

(3) 2020—10 percent of the payment rate established in 2019.

(4) 2021—0.0 percent of the payment rate established in 2020.

(5) 2022—0.0 percent of the payment rate established in 2021.

(6) 2023—15 percent of the payment rate established in 2022.

(7) 2024—15 percent of the payment rate established in 2023.

(8) 2025—15 percent of the payment rate established in 2024.

(e) There is no administrative or judicial review under sections 1869 and 1878 of the Social Security Act, or otherwise, of the payment rates established under this subpart.

(f) For a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in §414.508(b)(1) and (2).

(g) For ADLTs that are furnished between April 1, 2014 and December 31, 2017, payment is based on the crosswalking or gapfilling methods described in §414.508(a).

[81 FR 41099, June 23, 2016, as amended at 85 FR 85028, Dec. 28, 2020; 87 FR 70225, Nov. 18, 2022]

#### **§414.508 Payment for a new clinical diagnostic laboratory test.**

(a) For a new CDLT that is assigned a new or substantially revised code between January 1, 2005 and December 31, 2017, CMS determines the payment amount based on either of the following:

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(1) *Crosswalking*. Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the local fee schedule amounts and national limitation amount of the existing test.

(ii) Payment for the new CDLT code is made at the lesser of the local fee schedule amount or the national limitation amount.

(2) *Gapfilling*. Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the CDLT and routine discounts to charges;

(B) Resources required to perform the CDLT;

(C) Payment amounts determined by other payors; and

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(ii) In the second year, the test code is paid at the national limitation amount, which is the median of the contractor-specific amounts.

(iii) For a new CDLT for which a new or substantially revised HCPCS code was assigned on or before December 31, 2007, after the first year of gapfilling, CMS determines whether the contractor-specific amounts will pay for the test appropriately. If CMS determines that the contractor-specific amounts will not pay for the test appropriately, CMS may crosswalk the test.

(b) For a new CDLT that is assigned a new or substantially revised HCPCS code on or after January 1, 2018, CMS determines the payment amount based on either of the following until applicable information is available to establish a payment amount under the methodology described in § 414.507(b):

(1) *Crosswalking*. Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, mul-

multiple existing test codes, or a portion of an existing test code.

(i) CMS assigns to the new CDLT code, the payment amount established under § 414.507 of the comparable existing CDLT.

(ii) Payment for the new CDLT code is made at the payment amount established under § 414.507.

(2) *Gapfilling*. Gapfilling is used when no comparable existing CDLT is available.

(i) In the first year, Medicare Administrative Contractor-specific amounts are established for the new CDLT code using the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges;

(B) Resources required to perform the test;

(C) Payment amounts determined by other payors;

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and

(E) Other criteria CMS determines appropriate.

(ii) In the second year, the CDLT code is paid at the median of the Medicare Administrative Contractor-specific amounts.

[81 FR 41100, June 23, 2016]

#### **§ 414.509 Reconsideration of basis for and amount of payment for a new clinical diagnostic laboratory test.**

For a new CDLT, the following reconsideration procedures apply:

(a) *Reconsideration of basis for payment*. (1) CMS will receive reconsideration requests in written format for 60 days after making a determination of the basis for payment under § 414.506(d)(2) regarding whether CMS should reconsider the basis for payment and why a different basis for payment would be more appropriate. If a requestor recommends that the basis for payment should be changed from gapfilling to crosswalking, the requestor may also recommend the code or codes to which to crosswalk the new test.

(2)(i) A requestor that submitted a request under paragraph (a)(1) of this