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CMS Releases Final 2016 Gapfill Lab Payment Rates, CY 2017 Preliminary Crosswalk and Gapfill Determinations

+Insights

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The final lab payment amounts for several well-established tests fall well below current Medicare pricing. Stakeholders have until October 30, 2016, to request reconsideration of these rates.

On September 30, 2016, the Centers for Medicare and Medicaid Services (CMS) announced final gapfill payment rates for 2016, which, pending reconsideration, would be effective for 2017. CMS also released its preliminary determinations for payments for "new and substantially revised" test codes for CY2017.

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Final 2016 Gapfill Rates

In late 2015, CMS directed its Medicare Administrative Contractors (MACs) to establish payment rates for 16 molecular diagnostic tests using the gapfilling methodology. Under the gapfilling process, individual contractors establish Medicare payment rates that apply to claims in their own jurisdictions. These rates are established using information on charges and related discounts to charges, resources, payment amounts determined by other payers, and charges for other comparable/relevant tests. Using the locality-specific amounts established by the MACs, CMS determines the median of all contractor-specific rates and sets the national payment amount at that median. The national payment amount applies beginning the following year.

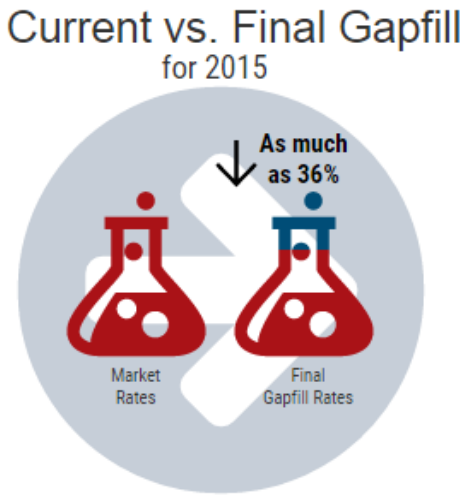
When CMS released the MACs' preliminary gapfill rates in 2016, affected labs and other stakeholders voiced strong criticism of the rates. Stakeholders argued that the proposed rates deviated substantially from current Medicare payment amounts, where established; were announced without an articulated basis for doing so; and did not accurately reflect the four criteria set forth in the gapfill regulations. With respect to a group of highly complex "multi-analyte with algorithmic analyses" (MAAA) tests, a number of MACs set preliminary gapfill rates at levels that were up to 87 percent lower than rates currently paid by Medicare. Concerns were raised that some contractors set prices for lab tests for which they never processed a claim.

In response to these concerns, CMS instructed its MACs to re-evaluate their gapfill analyses. While several MACs increased their payment amounts in response, and those increases did increase the median payment amount and resulting National Limitation Amount, the final payment amounts for a number of well-

Stakeholders may **request reconsideration** of "Final" gapfill rates **before October 30, 2016.**

established tests are significantly below current Medicare pricing by as much as 36 percent.

Although posted as "final" rates, affected stakeholders do have an opportunity to seek reconsideration of these rates, if the reconsideration request is made by October 30, 2016. It is expected that some of the affected labs will make a reconsideration request. Regardless of the outcome of that reconsideration process, CMS will again rebase payments for these tests under the new market-based payment system starting in 2018.



Preliminary 2017 Crosswalk and Gapfill Determinations

In addition to the final 2016 gapfill payment determinations, CMS released its preliminary determinations to crosswalk or gapfill new or substantially revised codes paid under the Clinical Laboratory Fee Schedule (CLFS) in 2017. CMS solicited input from the public and its own Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel at the July 2016 public meeting regarding whether CMS should set payments for these new codes using crosswalks to rates established for other codes, or assign the task of rate setting to the MACs using gapfill. Among 13 new or revised test codes, CMS chose crosswalk for all but one new code.

In general, CMS agreed with the recommendations of stakeholders and the CDLT Advisory Panel, choosing codes for crosswalk consistent with those recommended by stakeholders.

CMS proposes to crosswalk the three new presumptive drug testing CPT® codes, which were established to replace G codes created by CMS for 2016, to the same amounts applicable to the corresponding G codes in 2016. This determination reflects an understanding that the new codes are intended to establish the coding structure for presumptive drug testing in the CPT® coding system rather than having parallel systems of HCPCS codes and CPT® codes.

CMS also announced its preliminary determination in response to a reconsideration request on the G codes that were established in 2016 for definitive drug testing. Although CMS agrees with commenters that the rates established in 2016 are too low, in the preliminary determination CMS proposes crosswalks that are 15 to 21 percent less than those recommended by stakeholders and the CDLT Advisory Panel. In addition, CMS is proposing a fifth HCPCS code to report definitive testing performed using less sophisticated methods. This new code would be crosswalked to the amount for the higher level presumptive drug testing code (80307 [$79.25]).

Stakeholders and the CDLT Advisory Panel were split on their recommendations regarding code 81422 (Fetal chromosomal microdeletion(s) genomic sequencing analysis), with some suggesting a crosswalk to CPT 81435 (Hereditary colon cancer disorders), while others suggested gapfill. CMS chose gapfill and also noted that it would instruct MACs to gapfill the related code for non-invasive prenatal testing for fetal aneuploidy, 81420. This code was referred for gapfill previously, but the MACs did not establish rates for this code.

CMS will accept comments on these preliminary pricing determinations until October 30, 2016. Final determinations will be posted in November or December 2016. Those determinations will be final for 2017; however, stakeholders will have 60 days after the rates become final to request that CMS reconsider its final determinations. Reconsideration requests are reviewed by CMS at the following July public meeting, and any changes agreed to by CMS would be effective January 1, 2018.

CMS will accept comments on these preliminary pricing determinations until **October 30, 2016**. Final determinations will be posted in November or December 2016.

CMS's preliminary CY2017 pricing decision memos are available here, and the final gapfill decision document is available here**.** McDermottPlus has developed a chart of the decisions and their resulting payment rates (using current CLFS rates), available here.

For more information, please contact John Warren, Paul Radensky or Eric Zimmerman.