

On May 9, 2013, CMS posted contractor submitted gapfill prices and allowed for a 60 day public comment period. CMS shared all comments received with the Medicare Administrative Contractors (MACs). On September 30, 2013, CMS posted National Limitation Amounts (NLA) for 2014 followed by a 30-day reconsideration period. On November 29, 2013, CMS posted the final NLAs.

On September 30, 2013, CMS posted a NLA of \$2,700 for CPT code 81211—a test for the BRCA 1&2 gene. On November 29, 2013, CMS posted an NLA of \$1,438.14 for CPT codes 81211 and 81214, a test for the BRCA 1 gene only. The NLA for code 81211 was based on the median of MAC submitted prices and will be effective for tests performed on or after January 1, 2014.

Prior to a Supreme Court decision earlier this year, only one laboratory was providing tests for the BRCA gene. Following the Supreme Court decision, additional laboratories began providing the test. The MACs received data on the pricing by the laboratories offering the test. Based on the new information, the MACs submitted pricing information for CPT code 81211 that resulted in an NLA of \$1,438.14.

As the public has not had the opportunity to provide comment on the new NLA for 81211, we are providing an additional public comment period through January 27, 2014. At present, it is our understanding laboratories are offering the CPT code 81211 test for prices that range from approximately \$900 to \$2900. As CPT code 81214 is similar to CPT code 81211, the additional 15-day comment period will apply to both CPT codes 81211 and 81214.

Please submit comments and justifications for the requested prices to [MoPathGapfillInquiries@cms.hhs.gov](mailto:MoPathGapfillInquiries@cms.hhs.gov) no later than January 27, 2014. CMS will not consider any comments that are not sent to this email address. Please note that the NLA may change as a result of comments received through this process. Medicare contractor comments may also form the basis for a change in the NLA. If there are any revisions to the pricing for 81211 or 81214, these revisions will be effective prospectively, from April 1, 2014.

CPT 86152 was inadvertently omitted from both the September 2013 and the November 2013 CLFS files and is now reflected in this updated file. CMS will also be accepting comments on the pricing of this code, to be consistent with the overall gapfill process. Please submit comments to [MoPathGapfillInquiries@cms.hhs.gov](mailto:MoPathGapfillInquiries@cms.hhs.gov) no later than January 27, 2014. CMS will not consider any comments that are not sent to this email address. Please note that the NLA may change as a result of comments received through this process. Medicare contractor comments may also form the basis for a change in the NLA. If there is any revision to the pricing for 86152, the revision will be effective prospectively, from April 1, 2014.

Only the following codes will be subject to public comment through January 27, 2014:

- 81211 (BRCA1&2)
- 81214 (BRCA1 full seq)

- 86152 (cell enumeration using immunologic selection and identification in fluid specimen)