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Final MoPath Prices About 26% Higher on Average, but Many Questions Remain

Final Medicare prices for 65 molecular pathology test (MoPath) codes announced Sept. 30 show some improvement over interim rates released earlier this year, but many question remains about why the remaining codes weren't priced and why Medicare contractors will be allowed to set their own prices for molecular tests in 2014.

The final Medicare prices for 65 MoPath test codes for 2014 average about 26 percent higher than the proposed rates released in May 2013. However, groups representing labs are concerned that the Centers for Medicare and Medicaid Services (CMS) priced only 65 of the 116 new MoPath CPT codes and that agency appears to be ignoring a requirement that 2014 prices be based on the median of all contractor rates.

According to CMS, only codes that are currently being paid by MACs were priced. Some codes listed in the May 9, 2013, proposed price posting are not listed in the final prices because the service is no longer being paid by the MAC. This failure to price all of the new MoPath codes leaves much uncertainty over the status of the nonpriced codes, say industry experts.

Continued on p. 2

Lab Group Seeks Meeting on MolDx

The American Clinical Laboratory Association (ACLA) is seeking a meeting with Medicare officials over the possible expansion of the Molecular Diagnostic Service Program (MolDx), a program implemented last year by Medicare contractor Palmetto GBA.

In an Oct. 6 letter to Louis Jacques, M.D., an official with the Centers for Medicare and Medicaid Services (CMS), ACLA Senior Vice President JoAnne Glisson said members of the association have received conflicting information about whether the MolDx program will be expanded to operate nationwide and about the role that McKesson Corp. will play in the MolDx program as an issuer of unique test identifiers.

While Noridian Administrative Services has taken over Medicare Jurisdiction E from Palmetto, Palmetto will continue to administer the MolDx program in that region and will also deploy the program in Jurisdiction M—formerly J11 (*NIR, Sept. 12, 2013, p. 1*).

In addition, Palmetto officials have told G2 Intelligence that they intend to work with other Medicare administrative contractors (MACs) to deploy the key elements of MolDx (test registration, new test

Continued on p. 5

Final MoPath Prices About 26% Higher on Average, *from p. 1*

CMS is allowing a 30-day reconsideration period on these final prices, so it is possible that there could be additional changes when the agency announces final amounts for the 2014 Clinical Laboratory Fee Schedule later this fall.

While final pricing for some codes improved when compared to the proposed rates issued earlier this year, many of them are still well below what labs had been paid under the code-stacking methodology. Overall, it is difficult to discern any real trend in price adjustments since some went up while others went down.

For example, while the average final Medicare payment for CPT 81206 (BCR/ABL1 gene major bp) is $187, an 87 percent increase over the average proposed (interim) price of $100, pricing for CPT 81295 (MSH2 gene analysis) dropped 64 percent to an average of $292.

Altogether, 39 tests received an average nationwide price boost over their proposed price, while 19 saw cuts and six were unchanged. Thirteen tests saw their final prices increased over what would have been paid using code-stacking methodology from Quest Diagnostics, while 24 were cut, most by double-digit percentages (*see charts on pages 4 and 5*).

Pricing released by Palmetto GBA led to increases of prices on 43 tests and price reductions on 22 others that ranged from nominal to as high as 81 percent. Some of the tests received pretty dramatic boosts over the proposed prices that had been released in the spring.

NPM1 gene analysis, CPT code 81310, was priced at a national average of $212, up 264 percent from the average proposed price of $58. It was also up 261 percent from the original code-stacked price of $59. It also fared well in California and Utah, where it is priced at $249, up 327 percent from the original proposed price.

Chimerism analysis, CPT code 81268, was priced at an average of $312, up 102 percent from the original proposed price of $150. However, it still fell far short of the original code stacking price of $1,109.

Another test that fared well from its proposed to final average price was MLH1 gene analysis familial variant, CPT code 81293. It originally had a proposed price of $91 but came in at $240, a bump of 165 percent. It also fared well in code stacking, where Medicare originally paid $94, representing a bump of 156 percent.

"The bottom line is there was some improvement," said Michael Arnold, president of the California Clinical Laboratory Association, one of the most vocal of the regional lobbying groups on the molecular coding issue. However, Arnold added that he would have liked to see the prices rise even further.

Not every code emerged unscathed. An MSH2 full-sequence gene analysis test, CPT code 81295, was priced at $292, a 64 percent reduction from the average proposed price of $809 and a 60 percent drop from the code-stacked price of $730. Palmetto cut pricing on that assay 81 percent from its original proposal, down to $153.

Many Tests Not Priced

Meanwhile, some industry experts have expressed concern about what did not receive specific prices: 51 separate tests. They include ASPA gene analysis, CPT code 81200, which was paid at $213 under code-stacking; CFTR gene analyses, CPT codes 81220 to 81224; and long QT gene analysis, CPT codes 81280 to 81282.

"We are extremely concerned about the apparent lack of coverage for many of these tests, despite their current use in patient management, the availability of medical literature supporting those uses, and their inclusion in practice guidelines. In many cases, the results and interpretations provided in the reports of these medically necessary

tests are used to determine patient treatment," said Stephen Black-Schaffer, M.D., a Massachusetts pathologist who is vice chairman of the economic affairs committee of the College of American Pathologists. "CAP is concerned that many proposed contractor coverage decisions would deny beneficiaries' access to molecular testing that is necessary for their diagnosis and management."

Ignoring Statutory Requirements

Groups and labs are also concerned about statements by CMS that carriers who priced a code below the national limitation amount (NLA) could continue to reimburse for the code at that lower rate after Jan. 1, 2014, when the NLA is to take effect.

In the Sept. 30 announcement of final prices, CMS states, "If an individual MAC establishes a price that is lower than the NLA, it may continue to pay that price in 2014."

This appears to be in direct contradiction to the final Physician Fee Schedule rule for 2008, which laid out the gap-fill process. That rule, published in the Nov. 27, 2007, *Federal Register*, states that gap-filling is used when no comparable existing test is available:

> In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gap-fill amounts, if available: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.
>
> In the second year, the test code is paid at the national limitation amount, which is the median of the carrier-specific amounts.

While some contractors, such as Noridian and Palmetto, have adopted the NLA rates as their final prices, others, such as Cahaba, continue to price tests at a much lower rate. For example, while the NLA for BCR/ABL1 (CPT 81206) is $225.38, Cahaba's price is $123. And while the NLA for MSH6 gene analysis (CPT 81300) is $162.90, Cahaba is paying just $50. Cahaba administers Medicare Part B for Alabama, Georgia, and Tennessee.

The American Clinical Laboratory Association and other groups say they intend to challenge CMS's statement that it will allow MACs to pay a lower price than the NLA, noting that the statement "is inconsistent with the clear language of the gap-fill regulations, which states that after the first year payment for gap-filled tests is made at the NLA amount."

Reconsideration Requests

Reconsideration requests must be received by Oct. 30, 2013, and should be sent to *MoPathGapfillinquiries@cms.hhs.gov*.

According to CMS, the requests must include the following specific information about your test:

- ❑ Test methodology (e.g., real-time quantitative PCR, reverse-transcription PCR, flow cytometry, capillary electrophoresis, fragment analysis, etc.)
- ❑ Specific cost per sample (specify reagent, direct labor costs, indirect costs, etc.)

Once the reconsideration process is completed, the determination is final and will not be subject to further consideration. MACs will continue to determine pricing for the remainder of 2013.

The final gap-fill amounts, listed by state, are available at *www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/ClinicalLabFeeSched*. Click on "Gapfill Pricing Inquiries." The chart on the following page shows the NLA, average final prices, average proposed (interim) prices, code-stacking prices (where available), and the differences in those prices.

FINAL MEDICARE MOLECULAR PATHOLOGY PRICES							
HCPCS/ CPT	DESCRIPTOR	NATIONAL LIMIT	AVERAGE FINAL	CODE STACKED PRICE*	% CHG. FROM STACKED	PROPOSED AVERAGE	% CHG. FROM AVG. PROPOSED
81206	BCR/ABL1 gene major bp	$225.38	$187	$61	207%	$100	87%
81207	BCR/ABL1 gene minor bp	$199.08	$168	$61	175%	$87	93%
81208	BCR/ABL1 gene other bp	$221.09	$205			$149	38%
81210	BRAF gene analysis	$180.60	$162	$259	-38%	$88	84%
81211	BRCA1, BRCA2 gene analys.	$2,795.09	$2,842	$3,340	-15%	$2,845	0%
81212	BRCA1, BRCA2 185delAG	$178.04	$182			$181	1%
81213	BART testing	$587.12	$598	$700	-15%	$598	0%
81214	BRCA1 full sequence analysis	$1,449.01	$1,457			$1,457	0%
81215	BRCA1 full gene known fam.	$93.94	$91			$90	0%
81217	BRCA2 gene known fam. Var.	$93.94	$91			$90	0%
81225	CYP2C19	$294.00	$275	$290	5%	$223	23%
81226	CYP2D6	$455.00	$405	$159	154%	$278	46%
81227	CYP2C9	$176.40	$153	$219	-30%	$126	21%
81235	EGFR	$332.50	$279	$302	-7%	$185	51%
81240	F2 gene analysis	$67.64	$62	$136	-55%	$43	45%
81241	F5 gene analysis	$84.00	$77	$136	-43%	$73	6%
81245	FLT3 gene analysis	$167.17	$153	$344	-56%	$97	38%
81256	HFE gene analysis	$89.84	$84	$95	-12%	$70	20%
81261	IGH gene rearrangement	$272.15	$250	$154	62%	$164	52%
81262	IGH direct probe	$60.00	$60			$54	11%
81263	IGH variable region somat	$404.83	$367	$227	62%	$253	45%
81264	IGK gene rearrange analys	$205.26	$197			$122	61%
81265	IGK short tandem repeat	$295.60	$286	$777	-63%	$404	-29%
81267	Chimerism analysis, post trans.	$285.17	$257	$1,109	-77%	$155	66%
81268	Chimerism analysis, post trans. with cell selection	$358.47	$312	$1,109	-72%	$155	102%
81270	JAK2 gene analysis, variant	$126.00	$119	$88	35%	$82	45%
81275	KRAS gene analysis, variants	$198.97	$238	$911	-74%	$234	2%
81291	MTHFR gene analysis	$60.00	$64	$130	-51%	$87	-27%
81292	MLH1 gene analysis; full seq.	$651.12	$710	$900	-21%	$836	-15%
81293	MLH1 gene analysis, fam var.	$261.02	$240	$94	156%	$91	165%
81294	MLH1 gene analysis; dup del	$192.12	$228	$270	-15%	$486	-53%
81295	MSH2 gene analysis, full seq	$152.86	$292	$730	-60%	$809	-64%
81296	MSH2 gene analysis; fam var.	$130.51	$127	$94	36%	$95	35%
81297	MSH2 gene analysis; dup/del	$152.86	$201	$270	-25%	$536	-62%
81298	MSH6 gene analysis; full seq.	$290.01	$421	$870	-52%	$714	-41%
81299	MSH6 gene analysis; fam. Var.	$162.46	$152	$94	62%	$90	68%
81300	MSH6 gene analysis; dup/del	$162.90	$178	$270	-34%	$484	-63%
81301	Microsatellite instability anal	$398.03	$371	$321	16%	$313	19%
81310	NPM1 gene analysis, exon 12	$249.01	$212	$59	261%	$58	264%
81315	PML/RARalpha translocation	$284.97	$230	$160	44%	$105	119%

HCPCS/ CPT	DESCRIPTOR	NATIONAL LIMIT	AVERAGE FINAL	CODE STACKED PRICE*	% CHG. FROM STACKED	PROPOSED AVERAGE	% CHG. FROM AVG. PROPOSED
81316	PML/RARalpha com single	$434.65	$260			$123	111%
81317	PMS2 gene full seq analysis	$787.19	$830	$1,130	-27%	$722	15%
81318	PMS2 known familial variant	$186.01	$173			$90	91%
81319	PMS2 gene dup/del var	$223.34	$216	$462	-53%	$431	-50%
81321	PTEN gene analysis, full seq	$605.24	$610			$582	5%
81322	PTEN known fam var	$58.84	$89			$63	42%
81323	PTEN dup/del	$88.26	$151			$90	67%
81332	SERPINA1 gene-A1 antitrys	$60.00	$63	$94	-33%	$70	-10%
81340	TCR gene rearrange amp	$287.17	$260			$147	77%
81341	TRB gene rearrange direct	$68.16	$66			$46	44%
81342	TRG (T cell antigen recept)	$276.98	$258	$83	212%	$157	64%
81370	HLA class I and II typing	$552.75	$528			$533	-1%
81371	HLA verif typing	$330.84	$317			$326	-3%
81372	HLA class I typing, low res	$303.64	$303			$311	-3%
81373	HLA class I locus, low res	$153.08	$154			$157	-2%
81374	HLA class I one antigen equi	$100.00	$106			$113	-7%
81375	HLA clas II typing, low res	$303.43	$288			$283	2%
81376	HLA class II, one locus low res	$168.00	$161			$158	2%
81377	HLA class II one antigen equ	$126.20	$121			$122	-1%
81378	HLA class I and II typing high res	$475.00	$460			$465	-1%
81379	HLA class I typing, high res	$461.00	$447			$432	3%
81380	HLA class I one locus, high res	$243.64	$237			$236	1%
81381	HLA class I, one allele	$130.00	$114			$118	-3%
81382	HLA class II typing, one locus	$170.00	$170			$170	0%

Sources: CMS, Piper Jaffray. All CPT codes copyright American Medical Association.
*Code stack price from Quest Diagnostics.

Lab Group Seeks Meeting on MolDx, *from p. 1*

evaluation, inclusion of the test ID on the claim). Glisson notes that ACLA has heard anecdotally that CMS intends for the MolDx program to operate in all MAC jurisdictions and for Palmetto to maintain its role with the program going forward.

"To date, there has been no official notice that this is the direction CMS intends to take," she writes. "We seek clarification from you about CMS's intention and, if the program were to become national in scope, about the timeline for such an expansion to other MAC jurisdictions. It is not clear whether coverage policies would be the same in each jurisdiction under such a national program. We also would like to discuss the sorts of functional divisions between coverage and payment that would arise in other MAC jurisdictions if the MolDx program were to expand."

ACLA also continues to have "misgivings about the seemingly ad hoc development of the program's policies, procedures, and coverage decisions and about the use of articles to announce coverage decisions, rather than LCDs," which does not give laboratories and other stakeholders an opportunity to comment on noncoverage decisions.

Palmetto has also used the articles to establish its own coding for covered tests, often disregarding the test-specific molecular pathology CPT codes and instead insisting

that tests be billed with "not otherwise classified" codes. "This means that while a laboratory uses test-specific CPT codes to submit claims for all other payors (and in other MAC jurisdictions), in MolDx jurisdictions it will have to use the NOC code that Palmetto tells it to," writes Glisson. "This is an administrative burden, and currently there is no way to appeal Palmetto's decision about the proper code to use."

Takeaway: The potential expansion of Palmetto's Molecular Diagnostic Service Program has created great uncertainty in the laboratory industry and potentially could adversely impact Medicare beneficiaries' access to molecular diagnostic tests.

Payment Reforms Must Spread Beyond Medicare

The results from the first year of the Centers for Medicare and Medicaid Services' (CMS's) Pioneer accountable care organization (ACO) demonstration show that in order for ACOs to succeed, value-based payment models need to expand quickly to other payers beyond Medicare, according to an article in the Oct. 2 *Journal of the American Medical Association.*

The Pioneer program demonstrates that for the experiment to ultimately succeed, "value-based payment and patient incentives to reward clinicians and health care organizations that offer more real value to patients must spread rapidly to other payers. Otherwise, the very delivery systems that are improving cost and quality may drop out of these important experiments," the article said.

The lead author was John Toussaint, chief executive officer of Thedacare Center for Healthcare Value, in Appleton, Wis.

ACOs are groups of doctors and hospitals organized to improve coordination of care for their patients. Under the Affordable Care Act, ACOs have been established for Medicare beneficiaries in what is known as the Medicare Shared Savings Program.

The Pioneer program is administered under the Center for Medicare and Medicaid Innovation at CMS and is designed for health care organizations and providers that have experience coordinating care for patients across care settings. First-year results, announced in July, found all 32 of the Pioneers successfully met quality measures for the first performance year, with all earning incentive payments for their reporting accomplishments. By contrast, less than half performed well enough against cost benchmarks to share in savings for the program.

According to Toussaint's article, "How the Pioneer ACO Model Needs to Change: Lessons From Its Best-Performing ACO," many hospitals participating in the Medicare ACO programs are still caring for patients under a traditional fee-for-service model operated by private insurance and Medicaid, without any shared savings or incentives for high-value care. They are also using the same care processes for efficiently managing the privately insured patients as they are for Medicare patients.

As a result, when a hospital achieves savings by reducing its overall volume of services, such as decreasing patient readmissions, overall revenues still decline. So, every time a hospital admission is avoided for a fee-for-service patient, it means less revenue with no chance to share savings, Toussaint said in the article.

"Unless all payers quickly move to value-based payment systems or give insurers incentives to preferentially use health care organizations that provide greater value to patients, more organizations (especially those unable to shift costs to other payers) will discontinue participation in both of Medicare's ACO programs and other

related arrangements," Toussaint said in the article. "That is why (in most markets) commercial insurers, self-funded employers, and state administrators of Medicaid must join with Medicare to discuss health system incentives that are based on value for patients, not just shared savings."

Toussaint said strong federal-state and public-private partnerships will be needed to coordinate all payers in each region across the country and ensure that high-value care is rewarded consistently.

Takeaway: Shared-savings models will fail unless all payers move to value-based payment systems.

EHR Donation May Be Illegal in Massachusetts

Massachusetts has become the ninth state to issue an opinion asserting state authority to regulate the practice of donations of electronic health record (EHR) software to physicians by laboratories.

The state Department of Public Health on Sept. 16 issued an opinion saying that state law is "implicated when a clinical laboratory makes an EHR donation to a referring physician." The department noted that a decision on a violation of the law is "fact-specific and made after a review of the particular investigative findings."

Eight other states have issued similar rulings: New York, New Jersey, Missouri, Connecticut, Pennsylvania, Tennessee, Washington, and West Virginia.

Under a current exception to the anti-kickback statute, clinical laboratories are allowed to cover up to 85 percent of the cost of a physician's EHR software. However, physicians and labs have long been at odds over the issue, with some labs and pathology practices complaining that they are essentially blackmailed into donating the EHR software or else risk losing the physicians as referral sources.

The EHR exception expires at the end of 2013, but the Department of Health and Human Services (HHS) has proposed extending the safe harbor until the end of 2016. However, HHS indicated that it might consider restricting protected donors, with a specific eye on clinical labs as high-risk donors that could be excluded from future protections.

CAP Seeks Carve-Out

The College of American Pathologists (CAP) has urged HHS to carve out laboratories and pathologists from the proposed extension. In a letter sent to HHS earlier this year, CAP urged caution in using the exception to further incentivize additional interoperability as the laboratory and pathology communities have seen significant abuses of these exceptions.

"The divergence between current laboratory EHR donation practices and those originally contemplated and intended under the safe harbor when established in 2006 is significant," said CAP. "It results in negative effects on access to health care services, quality, competition, cost to the federal health care programs, and overutilization."

CAP also has expressed concern about the extraordinary expenses labs face managing and sharing patient data electronically with each client's individual EHR system interfaces and urged HHS to identify funding streams to cover the costs of multiclient laboratory interfaces and maintenance.

Takeaway: In the absence of a federal carve-out for the EHR exception, the College of American Pathologists is pursuing state rulings that would help protect labs that feel pressure to donate EHR software to physicians.

LDT Regulation Appears to Be Stalled

Whatever happened to the lab-developed test (LDT) regulation being put together by the Food and Drug Administration (FDA)? According to the top official in the FDA's Office of In Vitro Diagnostics and Radiological Health, the guidance may have stalled.

Speaking at the 2013 American Association for Clinical Chemistry (AACC) annual meeting in Houston this summer, Alberto Gutierrez, Ph.D., said intense lobbying by industry groups has stalled progress on the guidance and changed the tone of FDA's previously open discussion with stakeholders, according to an AACC report from the meeting.

"At one time I thought the agency could put a proposal on the table, and we could have a discussion," said Gutierrez. "Three years later, I can tell you only that I can't tell you that it's not going to happen; I can't tell you that it's going to happen—it's out of my hands. I have no idea whether the agency will be able to put together a proposal for this or not."

Gutierrez still believes LDT regulation is needed and offered recent examples of problems, including the ongoing use of the BD SurePath test for human papillomavirus screening, which is approved only for Pap testing.

Times Calls for Release of Guidance

Gutierrez's comments at AACC came not long after the *New York Times* editorial board called on the FDA to release the LDT draft guidelines as quickly as possible, charging that "an alarming number of diagnostic medical tests have never been tested for safety and accuracy."

According to the July 7 editorial, if a diagnostic test is made by a traditional device manufacturer, the FDA reviews its safety and effectiveness before approving it for marketing. However, if a test is developed by a clinical laboratory for use at its own facilities, it can be sold without a premarket review.

"That bifurcated approach made sense in years past when a medical center might develop a diagnostic test for its own doctors and patients," said the *Times*. "But the landscape has changed with the advent of more sophisticated tests and the rapid expansion of commercial laboratory companies."

The *Times* editorial fails to recognize that LDTs are already regulated under the Clinical Laboratory Improvement Amendments.

Takeaway: Despite pressure both for and against the LDT draft guidance, little appears to be happening with the regulation.

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