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Initial Gapfill Prices Released for Molecular Pathology Codes

The affected codes include Tier 1 analyte-specific codes for high-volume procedures (CPT 81200-81383). They replace the multiple "stacking" codes (CPT 83890-83914 and 88271) used as the basis of payment for a single genetic test.

Two Medicare Administrative Contractors (MACs) were first out of the starting gate in late January when they released their gapfill payment rates for molecular pathology codes new to the 2013 Part B lab fee schedule.

Cahaba, which covers Alabama, Georgia, and Tennessee, announced its pricing for the Tier 1 molecular pathology codes on Jan. 25. Palmetto GBA announced its pricing and coverage determinations for 78 of the Tier 1 codes on Jan. 28. Palmetto covers California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands.

To industry analysts who track the large lab companies, the gapfill prices were disappointing to say the least but not unexpected. To the California Clinical Laboratory Association (CCLA), the Palmetto rates were alarming, prompting it to schedule an emergency board meeting to craft a crisis response plan. In many instances, these rates are below the costs of doing the tests. "They have no relationship to reality," said CCLA Executive Director Michael Arnold. "They will result in lab closures, lost jobs, and a reversal of recent advances in personalized medicine. Patient access to many lifesaving genetic and molecular tests may no longer be available."

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INSIDE *NIR*

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CMS Rolls Out New Medicare Bundled Payment Initiative

More than 500 organizations will begin participating in the Bundled Payments for Care Improvement initiative, the Centers for Medicare and Medicaid Services (CMS) announced Jan. 31.

Under the initiative authorized by the health care reform law, CMS will test how bundling payments for episodes of care can result in providers working together to furnish more coordinated, quality care for fee-for-service beneficiaries while lowering the costs to Medicare.

In the Jan. 31 statement, CMS announced the selection of 32 awardees in the initiative's Model 1, who will begin testing bundled payments for acute-care hospital stays as early as April 2013. In the coming weeks, CMS will announce a second opportunity for providers to participate in Model 1, with an anticipated start date of early 2014.

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Initial Gapfill Prices Released, *from p. 1*

In assigning the codes to the Part B lab fee schedule, CMS opted to use the gapfill method, which lets MACs determine the payment rates based on local pricing patterns, versus the crosswalk method, where a new code is matched to an existing code or set of codes and paid at the rate. CMS said it did not have sufficient information to establish national payment rates for the molecular pathology codes in 2013 but would use the rates that MACs set this year in determining national fees for these codes in 2014.

Gapfill Rates Lower

In its preliminary analysis of the Palmetto payment schedule, Deutsche Bank said it believes Medicare reimbursement for the 78 codes could represent a reduction of 25 percent to 30 percent for Quest Diagnostics and LabCorp in this testing segment.

For example, Palmetto will pay $57.51 for BRAF testing (CPT 81210) while Cahaba will pay $123. According to reports, labs typically were paid between $119 and $301 under the old code-stacking method. For KRAS mutation analysis (CPT 81275), Palmetto will pay $225.88 while Cahaba will pay $235. Payment under code-stacking ranged from $256 to $637.

An initial analysis by Piper Jaffray on a subset of the codes found on average reimbursement levels are 18 percent lower than the average price using code stacks from Quest and Medicare's national limitation amounts. Based on an assessment of 55 of the codes, the median decline is 25 percent, with the largest price differ-

HOW INITIAL GAPFILL PRICES STACK UP

Code	*Lab Test*	*Code Stack Price*	*Palmetto*	*%Chg*	*Cahaba*	*%Chg*
81200	Canavan Disease Mutation	$213	$94*	-56%	$123	-42%
81206	BCR/ABL1 Quantitative	$61	$108	78%	$123	102%
81210	BRAF Mutation	$259	$58	-78%	$123	-55%
81225	CYP2C19 Genotype	$290	$135	-53%	$305	5%
81226	CYP2D6 Genotype	$159	$148	-8%	$50	-69%
81227	CYP2C9 Genotype	$219	$97	-56%	$50	-77%
81235	EGFR mutation analysis	$302	$116	-61%	$123	-59%
81241	Factor V Mutation Analysis	$136	$69	-49%	$50	-63%
81243	Fragile X DNA Test	$130	$61*	-53%	$123	-5%
81255	Tay-Sachs DNA Analysis	$379	$94*	-75%	$123	-68%
81270	JAK2 Mutation Analysis	$88	$73	-18%	$90	2%
81275	KRAS Mutation Analysis	$911	$226	-75%	$235	-75%
81291	MTHFR DNA Analysis	$130	$93	-29%	$235	81%
81342	T-Cell Gene Rearrangement	$83	$148	70%	$205	148%
81350	UGT1A1 Genotyping	$83	$59*	-29%	$123	49%

**Priced, but not yet covered by Palmetto*
Source: Piper Jaffray Industry Note, Jan. 31, 2013. Prices from Palmetto and Cahaba are compared with stacked code prices from Quest Diagnostics.

ence coming from BRAF Mutation (CPT 81210) and KRAS (81275), while pricing for Warfarin (81227 + 81355) is down 13 percent.

Coverage Denials an Issue

Reimbursement rates are not the issue if the test is not covered in the first place under Palmetto's MolDx program. Darren Lehrich, an analyst with Deutsche Bank, notes that only 53 of the 78 codes priced by Palmetto thus far appear to be covered under Medicare based on Palmetto's review of available literature.

The lower gapfill payments will prove problematic for many labs, an industry source told NIR*, coming as it does alongside the scheduled 2 percent Medicare sequestration cut in March and the 52 percent cut already imposed on Medicare reimbursement for the technical component of CPT 88305, the most commonly ordered surgical pathology code.*

Among the tests denied coverage are Fragile X DNA testing, Apolipoprotein (Apo) E genotype testing to assess risk of cardiovascular disease, PTEN tumor suppressor gene testing, and UGT1A1 gene analysis testing used to guide therapy selection for colorectal cancer.

According to Palmetto, the majority of denials are due to lack of evidence of clinical utility. Palmetto wants to see published studies demonstrating that physicians actually make clinical decisions based on test results.

Labs performing tests that have been denied coverage by Palmetto must seek payment from the patient's private insurance carrier or from the patient.

Rina Wolf, vice president of commercialization strategies, consulting, and industry affairs for Xifin Inc., a revenue management firm based in San Diego, is advising clients who are affected by this pricing to submit their concerns, along with supporting documentation as to their costs and any potential impact on access to these tests, to Palmetto.

BRACAnalysis Testing

For BRACAnalysis testing (CPT 81211), Cahaba set pricing at $2,900, which is 13 percent below what the test developer, Myriad Genetics, had been paid previously. Palmetto has not established a payment rate for that code since the testing is performed outside its jurisdiction. Myriad submits claims to Noridian, the MAC in Utah, for payment, not Cahaba, notes Amanda Murphy, an analyst with investment banking firm William Blair. However, Cahaba rates may be factored into the overall median calculation that CMS uses to calculate 2014 reimbursement for the new molecular diagnostic codes.

Gapfill Timetable

CMS has given its MACs until April 1 to complete gapfill pricing for the molecular pathology codes new to the Part B lab fee schedule.

CMS will post the rates on its Web site by April 1 for a 60-day period of public comments (not reconsideration requests).

Later, when CMS finalizes the gapfill rates, it will accept reconsideration requests on the gapfill amounts for 30 days.

Once the reconsideration process is completed for a cycle, the CMS determination is final and not subject to further reconsideration.

Source: CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html*.

CMS Finalizes Physician Payment 'Sunshine' Rule

A final rule, released Feb. 1 by the Centers for Medicare and Medicaid Services (CMS), requires medical device and drug manufacturers to report payments to physicians and teaching hospitals.

The rule also authorizes CMS to make publicly available information about ownership or investment interests that physicians (or their immediate family members) have in these manufacturers and group purchasing organizations (GPOs).

The data collection is to begin Aug. 1 and the reporting period will run through December 2013. The data must be reported to CMS by March 31, 2014, and the agency plans to post the information on its Web site by Sept. 30, 2014.

The disclosure and transparency requirements, which implement Section 6002 of the health care reform law, are intended to reduce the potential for conflicts of interest that could result in financial incentives that bias medical judgment and patient care.

"Disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper," CMS said in the rule. "Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts."

Penalties for Noncompliance

The final rule requires that manufacturers must report annually "all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) to covered recipients."

"You should know when your doctor has a financial relationship with the companies that manufacture or supply the medicines or medical devices you may need," said Peter Budetti, CMS deputy administrator for program integrity, in a Feb. 1 statement. "Disclosure of these relationships allows patients to have more informed discussions with their doctors."

Those who violate the reporting requirements will be subject to civil monetary penalties, capped annually at $150,000 for failure to report, and $1 million for knowing failure to report. CMS and the Health and Human Services Office of Inspector General reserve the right to audit, evaluate, or inspect manufacturers and GPOs for compliance.

In addition, manufacturers and GPOs must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities. This does not apply, however, to ownership or investment interests held by teaching hospitals.

In certain cases, research payments made under a product research or development agreement will be delayed from publication on the public Web site, CMS said. "Publication of a payment or other transfer of value will be delayed when made in connection with research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply or clinical investigations regarding a new drug, device, biological, or medical supply."

Resolving Disputes

The law requires CMS to provide covered recipients at least 45 days to review and dispute the information related to them that was submitted by device and drug

manufacturers and GPOs. CMS will notify them when the reported information is ready for review. Any disputed transfer of value will be resolved directly between the recipient and the relevant manufacturer or GPO, CMS said. In response to comments requesting additional time to resolve disputes initiated late in the 45-day period, the agency said it finalized a 15-day opportunity to resolve disputes before the information is published publicly, following the 45-day review and correction period.

Proposal Floated to Overhaul Medicare Physician Payments

A plan to repeal the sustainable growth rate (SGR) formula that determines the annual update to the Medicare physician fee schedule is being circulated for feedback by Republicans on the House Ways and Means Committee.

The SGR has triggered physician fee cuts over the past decade that Congress has repeatedly stepped in to block. In place of the SGR, the plan would freeze fees during the transition to a performance-based payment system using quality measures endorsed by physicians and medical societies.

Proposal's Three-Phase Approach

Phase 1: The SGR would be fully repealed, and Medicare payments for physicians would be frozen for a set period of time (unspecified).

Phase 2: Physician fee schedule payment updates would be based on performance of meaningful, physician-endorsed measures of care quality and participation in clinical improvement activities, such as reporting clinical data to a registry or employing shared decisionmaking tools.

Phase 3: This involves further reform of Medicare's fee-for-service payment system to account for the efficiency of care provided. After several years of quality-based payments, physicians who perform well on quality measurement would be afforded the opportunity to earn additional payments based on the efficiency of care they deliver.

Cost Is Key Question

The Medicare overhaul proposal is clear up front that SGR repeal must be budget-neutral, that is, fully paid for and not increase the deficit, but does not specify how this would be done. This has been a key obstacle to SGR reform efforts in past Congresses. The proposal notes that the Congressional Budget Office has estimated the cost of SGR repeal at $245 billion over 10 years.

SGR Triggers Short-Term Fixes

The SGR formula, included in the 1997 Balanced Budget Act, limits the yearly increase in costs per Medicare beneficiary to the nation's annual growth in gross domestic product. Because of the size of reimbursement cuts that would be required, Congress has resorted to a series of short-term fixes over the last decade. The latest fix, passed Jan. 1, cancels a cut of 26.5 percent that had been scheduled to take effect for 2013 and continues the freeze on fees.

Hearings on a permanent fix reportedly could be held soon by the Ways and Means health subcommittee. Its chairman, Rep. Kevin Brady (R-Texas), said in a Jan. 15 statement that he intends to draft legislation to repeal the SGR.

New Medicare Bundled Payment Initiative, *from p. 1*

The initiative includes four models of bundling payments, varying by the types of health care providers involved (hospitals, physicians, post-acute facilities, and other providers as applicable) and the services included in the bundle. The participating provider organizations will agree to provide CMS a discount from expected payments for the episode of care, and then the provider partners will work together to reduce readmissions, duplicative care, and disease complications.

The Jan. 31 announcement also marks the start of Phase 1 of Models 2, 3, and 4. In Phase 1 (January-July 2013), over 100 participants partnering with over 400 provider organizations will receive new data from CMS on care patterns and engage in shared learning in how to improve care. Phase 1 participants are generally expected to become participants in Phase 2, in which they opt to take on financial risk for episodes of care starting in July 2013, pending contract finalization and completion of CMS's standard program integrity reviews.

To see the list of awardees for Model 1 and participants for Phase 1 of Models 2, 3, and 4 go to *http://innovation.cms.gov/initiatives/bundled-payments*.

Bundled Payment Models

- **Retrospective Acute-Care Hospital Stay Only (Model 1):** Episode of care is defined as the inpatient stay in the hospital. Medicare will pay the hospital a discounted amount based on the payment rates established under the Part A diagnosis-related groups. Medicare will continue to pay physicians separately for their services under the Part B fee schedule. Under certain circumstances, hospitals and physicians will be permitted to share gains arising from the providers' care redesign efforts.

- **Retrospective Acute-Care Hospital Stay Plus Post-Acute Care (Model 2):** Episode of care includes the inpatient stay, and all related services during that time. It will end either 30, 60, or 90 days after discharge. Participants can select up to 48 different clinical condition episodes.

- **Retrospective Post-Acute-Care Only (Model 3):** Episode of care is triggered by an acute-care hospital stay, and the provision of post-acute-care services with a participating skilled nursing facility, inpatient rehabilitation facility, long-term care hospital, or home health agency will begin within 30 days of discharge. It will end 30, 60, or 90 days after initiation of the episode. Participants can select up to 48 different clinical condition episodes.

In both Models 2 and 3, the bundle will include physicians' services, care by post-acute providers, related readmissions, and other related Part B services included in the episode definition, such as clinical laboratory services; durable medical equipment, prosthetics, orthotics, and supplies; and Part B drugs. A target price will be set based on historical fee-for-service payments for the participant's Medicare beneficiaries in the episode and will include a discount. Payments will be made at the usual fee-for-service rates, after which the aggregate Medicare payment for the episode will be reconciled against the target price. Any reduction in expenditures beyond the discount reflected in the target price will be paid to the participant and may be shared among its provider partners. Any expenditures above the target price will be repaid to Medicare.

"The objective of the bundled payment initiative is to improve the quality of health care delivery for Medicare beneficiaries, while reducing program expenditures, by aligning the financial incentives of all providers," said acting CMS Administrator Marilyn Tavenner.

- **Acute-Care Hospital Stay Only (Model 4):** CMS will make a single, prospectively determined bundled payment to the hospital that would cover all services furnished during the inpatient stay. Physicians and other practitioners will submit "no-pay" claims to Medicare and will be paid by the hospital out of the bundled payment. Related readmissions for 30 days after hospital discharge will be included in the bundled payment amount. Participants can select up to 48 different clinical condition episodes.

Forging Ahead With Other Payment Model Demonstrations

In addition to rolling out the bundled payment initiative, the CMS Center for Medicare and Medicaid Innovation is fielding other payment model demonstrations authorized by the health care reform law.

As of Feb. 3, CMS will begin accepting letters of intent to participate in an end-stage renal disease (ESRD) seamless care initiative. Interested organizations must include a dialysis facility, a nephrologist, and one other Medicare provider or supplier that serves at least 200 beneficiaries. Those that succeed in offering high-quality care that lowers the total Parts A and B cost of care for ESRD beneficiaries will have the opportunity to share in Medicare savings. ESRD beneficiaries constitute 1.3 percent of the Medicare population and account for an estimated 7.5 percent of Medicare spending, totaling over $20 billion in 2010. These high costs are often the result of underlying disease complications and multiple comorbidities, which often lead to high rates of hospital admission and readmissions, as well as a mortality rate that is much higher than the general Medicare population.

On Jan. 10, CMS approved a major expansion of the Medicare Shared Savings Program to 106 new accountable care organizations (ACOs). This brings the total number of ACOs established since 2012 to more than 250, serving about 4 million Medicare fee-for-service beneficiaries (*NIR 13, 2/Jan. 24, p. 2*). ACOs are legal entities formed by physicians and health care providers to furnish coordinated, quality care and disease-management programs to beneficiaries (5,000 at a minimum). ACOs share the risk and rewards for keeping patients healthy. Beneficiaries in ACOs can choose health care providers within or outside their ACO.

While Medicare continues to pay individual health care providers and suppliers for specific items and services as it currently does under Part A and Part B reimbursement, CMS sets a benchmark on per capita spending for each ACO against which its performance is measured to assess whether it qualifies to receive shared savings or to be held accountable for losses.

In June 2012 CMS launched the Independence at Home demonstration project involving 15 independent practices and three consortia. It is testing the use of home-based primary care teams to improve health outcomes, forestall the need for care in institutional settings, and lower Medicare expenditures for Medicare beneficiaries with multiple chronic conditions (serving at least 200 eligibles). The teams are led by physicians or nurse practitioners, and members include physician assistants, pharmacists, social workers, and other staff.

The project will award incentive payments to participants that meet designated quality measures and reduce Medicare costs. To qualify for an incentive payment, the practice's expenditures for participating beneficiaries must be lower than the calculated target expenditure, which represents the expected Medicare fee-for-service spending on participating beneficiaries in the absence of the demonstration.

For more on the portfolio of payment model demonstrations under way or being planned, go to *www.innovation.cms.gov*.

Surveying Lab, Physician E-Health Data Exchange

How well clinical laboratories exchange health information electronically with test ordering physicians is the subject of a survey that the Office of the National Coordinator for Health Information Technology launched in late January. Results are to be posted on its Web site this summer.

The College of American Pathologists and the College of Healthcare Information Management Executives are urging their members to participate if selected for the survey.

More than 2,700 hospital-based clinical labs and about 2,000 independent labs are among those in the study's random sample that are invited to participate. The survey will concentrate on two measures: the percentage of laboratory facilities that are able to send structured lab results electronically to ordering physicians and the percentage of lab results now being sent electronically to ordering physicians.

The data will be used to support the work of the State Health Information Exchange Cooperative Agreement Program by providing a baseline of information exchange required and targeted help to those behind the nationwide average. For labs in the study, the survey is expected to take no more than 20 minutes to complete.

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