Molecular Pathology Reimbursement: Taking Action In A Time Of Crisis

Part II of a two-part webinar series on the current crisis in molecular pathology reimbursement

June 11, 2013
Disclaimer

This webinar is intended strictly as an educational resource for laboratory geneticists to help them understand the mechanics of billing and reimbursement and advocate for reasonable levels of reimbursement for molecular genetics laboratory services. ACMG does not warrant the accuracy, completeness, or timeliness of the information presented. Adherence to the information or suggestions contained in the webinar is completely voluntary and does not assure improved reimbursement or compliance with legal requirements, and the ACMG expressly disclaims any responsibility therefor.

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Ms. Tang’s expertise is in working with medical technology innovators to develop short- and long-term reimbursement strategies that optimize market access. In addition to her work in reimbursement strategy development, Ms. Tang has successfully advocated for positive payer coverage policies, secured new billing codes, and established favorable payments for a wide range of technologies. Having previously worked in a molecular biology lab at the Lawrence Berkeley National Laboratory, she holds a special interest in molecular diagnostics, and to date has worked with numerous labs and companies to respond to the reimbursement challenges facing the industry today.
Webinar Objectives

✓ Recap the current status of Medicare gap-filling for molecular pathology (MoPath) codes
✓ Recognize what laboratories can do to influence rate-setting outcomes
✓ Understand how to provide cost data to payers to support accurate rate-setting
✓ Learn about how you can support ACMG’s rate-setting advocacy efforts
Current Status of Medicare Gap-Filling
Proposed MAC Gap-Fill Rates Were Released On May 9, 2013

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<th>Test</th>
<th>CPT Code</th>
<th>Palmetto</th>
<th>Novitas</th>
<th>First Coast</th>
<th>Cahaba</th>
<th>NGS/WPS</th>
<th>Noridian/CGS/NHIC</th>
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<td>$58.31</td>
<td>$50.00</td>
<td>N/A</td>
<td>N/A</td>
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</table>

1 [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html)
Comments Are Due to CMS by July 8, 2013

- Many of the MACs coordinated on their MoPath fee schedule rates
  - Noridian, CGS, Novitas, and WPS used Palmetto’s payment rates for many or nearly all of the MoPath codes
  - With a few exceptions, NGS and NHIC have the same fee schedule

- The public has until July 8, 2013, to provide comments to CMS regarding the interim MAC payment rates and/or rate-setting rationale
  - Commenters should provide comments to both CMS and their local MACs
  - Information that should be provided includes cost, test methodology, and any other information that could help CMS and the MACs revise their pricing for particular codes

Send all comments to MoPathGapfillInquiries@cms.hhs.gov
The Downstream Effect of Medicare Gap-Filling

- As the single largest payer in the country, the rates set by Medicare often heavily influence Medicaid and private payer reimbursements as well.
  - These payers often benchmark their own payment rates to Medicare fee schedule amounts (e.g., X% of Medicare rates).
- This means that even if Medicare is not a significant payer for your lab, the outcome of the Medicare gap-filling process is likely to affect you as well.
- Medicaid and private payers may also be undertaking activities similar to gap-filling to establish payment rates for the MoPath codes.

Medicare gap-filling outcomes are likely to impact other payer reimbursements as well.
The Role of Laboratories in Rate-Setting Advocacy
Take Action Now

Laboratories hold the key to ensuring a favorable outcome in the rate-setting process

- Payers such as CMS urgently need to hear from laboratories in order to understand whether or not their payment rates are appropriate.
- In addition to providing positive or negative feedback on current rates, laboratories should also provide any of the following information to payers to support appropriate rate-setting recommendations:

  ✓ Charges for the test and routine discounts to charges
  ✓ Cost of resources required to perform the test
  ✓ Payment amounts determined by other payers
  ✓ Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant
2013 Medicare Gap-Filling Timelines

Key gap-filling milestones are aligned with critical windows for labs to influence rate-setting outcomes

- CMS Proposed Rates Published; Comment Period Begins: May 9, 2013
- 60 Day Comment Period to CMS Ends: July 8, 2013
- CMS Releases Final Gap-Fill Payment Rates for MoPath Codes
- 30 Day Reconsideration Period Ends
- 1/1/2014

Most Important Time for Advocacy Efforts

Continued Surveillance and Outreach is Imperative

Conduct Any Additional Outreach and Prepare for Implementation
The Period From Now through July 8 is a Critical Window For Medicare Advocacy

**Methods:**

**Outreach**
- Proactively reach out to key payer targets to provide appropriate rate-setting recommendations

**Surveillance**
- Actively monitor payment rates issued or paid by payers

**Response**
- Provide feedback (positive or negative) in response to rate-setting decisions

**Timing:**

**Now-July 2013**
- Submit comment letters to CMS and your local MAC by July 8, 2013
- Submit relevant data to support accurate rate-setting

**July-Sep 2013**
- Continue actively engaging your local MAC
- Monitor updates to payer/MAC fee schedules and respond accordingly

**Sep-Dec 2013**
- Monitor and respond to the final gap-fill rates (to be released in Sep 2013)
- Continue payer outreach efforts as needed
Identify Key Payer Targets For Advocacy Efforts

- Because time is of the essence, your advocacy efforts should be tailored to make the most impact – this starts with identifying the key payer targets for your lab.
- We recommend targeting the following payers:
  - Your top 5 payers in terms of billing volume and/or revenue
  - CMS and your local MAC
    - Even if Medicare is not a significant payer for your lab, the outcome of the Medicare gap-filling process will impact Medicaid and private payer reimbursements as well
  - Payers that have provided inadequate payments for MoPath codes to date

Don’t wait for payers to reach out to you. Be proactive and reach out to them.
Suggested Rate-Setting Inputs For Each Test of Interest

1. **Test Information**
   - Relevant clinical information (including clinical utility evidence)
   - Annual testing volume

2. **Charges & Costs**
   - Charges for the tests (and routine discounts to charges)
   - Cost of resources used in performing the test

3. **Payments**
   - Any favorable payment rates established by other payers
   - Previously received payment amounts (based on former code stacks)
Key Takeaways

- There is still time to influence payer rate-setting for the MoPath codes, and active laboratory participation is critical to success.
- In order to participate effectively in this process, laboratories should:
  - Reach out to key payer targets to provide positive or negative feedback on current rates.
  - Submit data to payers to support accurate rate-setting.
  - Actively monitor payment rates for MoPath codes and respond accordingly.

Take action now to support the fight for sustainable molecular diagnostic reimbursement in 2013 and beyond.
How to Analyze Fully Loaded Costs for a Molecular Pathology Test
Cost Data is Highly Valued in Rate-Setting

- Cost data is the most *objective* rate-setting input that payers can use, in comparison to charges, payments from other payers, etc.
- CMS has specifically requested cost information to help them evaluate the proposed MAC gap-fill rates:

> “Please provide specific **cost**, test methodology, and any other information that will help CMS and its contractors review the price for a particular service code.”

Source: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html)
Analyzing Costs for a Molecular Pathology Test

- Cost information provided to payers can be organized into the following sections:
  - General information on each test of interest
  - Staff salaries & benefits
  - Fixed & variable equipment costs
  - Overhead cost
  - R&D cost

- Data should be provided to payers on a per test/code basis.
- Make sure to capture the “fully loaded” costs of running each type of test:
  - This includes costs such as overhead, R&D and other indirect costs that are necessary for running your lab.
- It is up to each lab to decide what information they wish to provide, or if they would like to provide any additional data.
## Cost Data Inputs For Each Test

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| **General Information**       | • Specify the molecular pathology test of interest  
                                 • Provide the annual testing volume  
                                 • Provide the average number of tests performed per run |
| **Staff Salaries & Benefits** | • Specify the total number of lab staff involved in running each type of test (e.g., lab director, supervisor, tech)  
                                 • Provide the average salary amount for each staff type (if preferred, national average data may be used instead) |
| **Fixed Equipment Costs**     | • Identify the capital equipment used in performing the test  
                                 • Identify the acquisition cost and average useful life |
| **Variable Equipment Costs**  | • Specify the per run cost of any disposable equipment required (e.g., reagents, disposable plastic ware, etc.) |
| **Overhead Costs**            | • Provide the annual total cost of overhead such as rent, utilities, etc.  
                                 • Estimate the percentage of overhead allocated to each test |
| **R&D Costs**                 | • Estimate the percentage of total costs attributed to R&D |
Calculating “Amortized” Costs

Fixed Equipment Costs

1. Identify each piece of capital equipment used to perform the test
2. Determine the annual depreciation cost for each piece of capital equipment by dividing the acquisition cost by the average useful life
3. Estimate the percentage of costs allocated to the test of interest
   • Calculation: (volume of test of interest)/(volume of all tests performed using this equipment)
Calculating “Amortized” Costs

**Fixed Equipment Costs**

Identify each piece of capital equipment used to perform the test

Determine the annual depreciation cost for each piece of capital equipment by dividing the acquisition cost by the average useful life

Estimate the percentage of costs allocated to the test of interest
  • Calculation: \((\text{volume of test of interest})/(\text{volume of all tests performed using this equipment})\)

**Overhead Costs**

Identify all overhead line items
  • e.g., rent, utilities, administrative fees, etc.

Determine the annual cost of each overhead line item

Estimate the percentage of annual costs allocated to the test of interest
  • Calculation: \((\text{volume of test of interest})/(\text{volume of all tests performed in the lab})\)
Calculating “Amortized” Costs

**Fixed Equipment Costs**
- Identify each piece of capital equipment used to perform the test
- Determine the annual depreciation cost for each piece of capital equipment by dividing the acquisition cost by the average useful life
- Estimate the percentage of costs allocated to the test of interest
  - Calculation: \( \frac{\text{volume of test of interest}}{\text{volume of all tests performed using this equipment}} \)

**Overhead Costs**
- Identify all overhead line items
  - e.g., rent, utilities, administrative fees, etc.
- Determine the annual cost of each overhead line item
- Estimate the percentage of annual costs allocated to the test of interest
  - Calculation: \( \frac{\text{volume of test of interest}}{\text{volume of all tests performed in the lab}} \)

**Staffing Costs**
- Identify the number and type of FTEs who run and manage the testing process
  - i.e. lab director, technician, geneticist
- Estimate FTEs as fractions if staff have responsibilities unrelated to the test
  - Calculation: \( \text{staff} \times \% \text{ of time} \)
- Multiply the number and type of FTEs by the average salary & benefits for that FTE type
Support ACMG’s Rate-Setting Advocacy Efforts

- ACMG wants to support the industry’s rate-setting efforts by providing CMS with fully loaded cost data for specific MoPath codes of interest
  - Cost data will be collected from any willing labs through an online survey until **June 28, 2013**
  - Cost data collected will be consolidated and analyzed for submission to CMS by the July 8 deadline
- The survey allows labs to submit information for each test/code of interest (e.g., cystic fibrosis, chromosomal microarray analysis)
- Labs can use this survey as a substitute for or in addition to their own submissions to CMS

Please visit [https://www.surveymonkey.com/s/ACMG_cost_survey](https://www.surveymonkey.com/s/ACMG_cost_survey) to fill out our survey before June 28, 2013
Frequently Asked Questions (FAQs)
Q: Why is there such significant variation in the proposed MAC gap-fill rates?

Answer: Unfortunately, there is no standardized process for gap-filling. While it is apparent that some of the MACs collaborated in developing their fee schedules, it is unclear what methodologies were utilized to arrive at those rates. While some may have developed their own methodologies, others appear to have followed the lead of one particular MAC, Palmetto.

Regardless of the variation, however, many of these rates are clearly inadequate, and underscore the need for proactive lab participation in advocating for more appropriate payments.
Q: Is July 8, 2013, the final deadline for rate-setting advocacy efforts?

Answer: July 8 is the deadline for submitting written comments to CMS on the proposed MAC gap-fill rates. However, rate-setting advocacy efforts can and should continue beyond July 8.

It is imperative that labs continue to engage CMS and their local MACs until accurate payment rates are established for molecular diagnostic procedures.
Q: Can my lab really make a difference in influencing the outcome of rate-setting?

Answer: Absolutely. This is a critical time for the industry, and every lab needs to make themselves heard in order to secure the future of molecular diagnostics.

For many labs, the current proposed rates do not even cover the costs of testing, and it is important for CMS to hear this message directly from each lab in order to drive the positive changes needed.
Thank you for participating in this webinar series.

We strongly encourage you to take action immediately to support the fight for sustainable molecular diagnostic reimbursement.