



Potential CMS-relevant content for practitioners' education

Inter-Society Coordinating Committee

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Requirements for Medicare Payment

1. Item or service must be legal
2. Congress must have given permission to pay for the item or service (benefit category)
[1861(s)(1)]
3. Item or service must be “reasonable and necessary” (coverage) [1862(a)(1)(A), 1861(s)(3)]
4. Coding & payment instructions needed

Clinical Laboratory Fee Schedule:

- CLFS Pricing of new codes:
 - Crosswalk – Use price of an existing code that is conducted using the same or a similar methodology
 - Gapfilling – For codes that are truly novel and dissimilar to other codes already being paid under the clinical lab fee schedule

Molecular Pathology (MoPATH):

- Prior to 2013, MoPATH tests paid under “stacking” codes:
 - CPT codes that describe each of the various steps required to perform a given test
 - Different “stacks” of codes are billed depending on the components of the furnished test
- For 2012, CPT created specific codes for MoPATH tests:
 - CMS did not price codes for 2012 and instructed continued use of the stacking codes
 - Significant debate whether MoPATH codes ordinarily require physician work and paid under the PFS, or are clinical diagnostic laboratory tests be paid on the CLFS
 - Use 2013 PFS rule to request public comment on whether to price under the PFS or CLFS and pricing methodology

MoPATH Continued:

- Tier 1 and Tier 2
- Over 100 Tier 1 codes in 2014 CPT
 - “Analyte-specific”
- 9 Tier 2 levels
 - Over 600 different gene analyses
 - Coding does not specify within level
 - Currently evaluated by local contractors for coverage and payment decisions

Local vs National Decisions

- Nearly all coverage decisions about genomic tests have been made at the local level (Medicare Administrative Contractors)
 - Exception: Warfarin sensitivity
- Nearly all payment decisions about genetic tests have been made at the local level
 - MACs used gapfilling to submit prices to CMS. CMS calculated a median

CMS does not direct which test must be used

- KRAS (81275)
- Multiple labs perform this test
- Reimbursement is \$198.97 no matter which company's test a provider selects.

Medicare does not set prices for other payers

- Historically private payers and Medicaid have used Medicare pricing
- Not all MoPath tests fit the statutory requirements for coverage
- For any test not listed on 2014 CLFS, consult local MAC

HR4302: Protecting Access to Medicare Act of 2014

- Revamps CLFS
- Incentives for FDA approval
- Faster process for some tests from availability until Medicare reimbursement
- Creation of committee for reviewing tests
- Details of implementation to occur through NPRM; opportunity for public comment

CLFS advisory panel

- Input on payment rates and coverage decisions for all tests on CLFS
- Participation in annual meeting
- CMS soliciting recommendations for participants