Genomic Medicine 5:
CMS Payment for Genomic Tests

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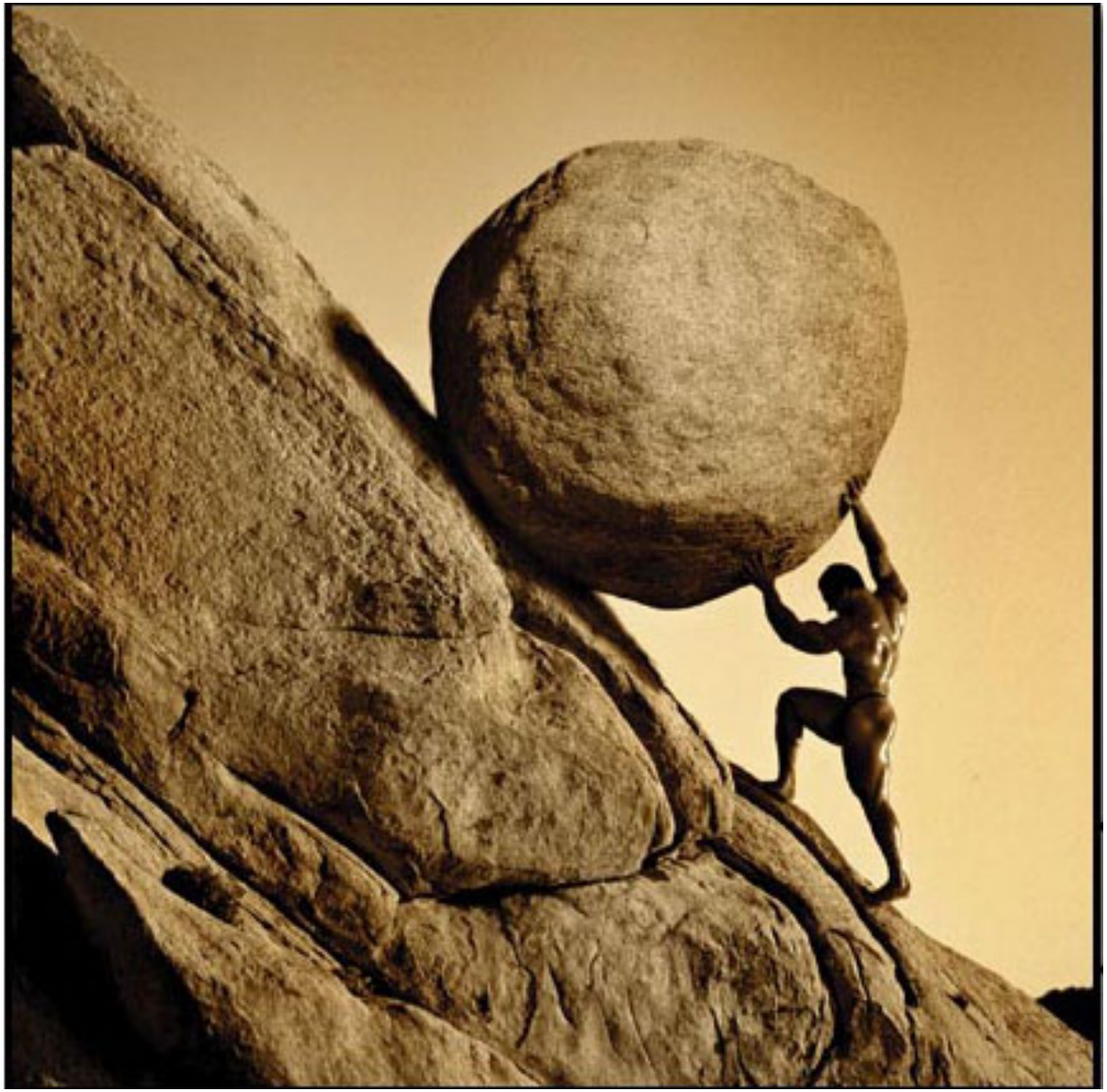
Medicare Payment Process



Medicare Payment Process

“While I can explain the meaning of life, I don’t dare try to explain Medicare reimbursement.”

3

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)

3. Item or service must be “reasonable and necessary” (coverage)

4. Coding & payment instructions needed

Legality

- Typically, only for items and services subject to FDA approval.
- More complicated with diagnostics.
- If FDA has determined that a diagnostic test needs FDA approval, CMS will not pay for that test until approval given

Benefit Category

Congress defined both specific and broad benefit categories

- 1861(s)(3) of the Act: "diagnostic X-ray tests…diagnostic laboratory tests, and other diagnostic tests"
- Longstanding interpretation of 1862(a)(1)(A) that Congress prohibited payment for prevention and screening.
- Screening refers to the application of a medical procedure or test to people who as yet have no symptoms of a particular disease, for the purpose of determining their likelihood of having the disease
- Congress has required payment for specific preventive/screening services; e.g., cervical, PSA, mammography.
- 1862(ddd)(1): "…additional preventive services mean services…that are
  A. reasonable and necessary for the prevention or early detection of illness or disability;
  B. recommended with a grade of A or B by the USPSTF…"

Coverage(1)

- 1862(a)(1)(A) "…no payment may be made…for items or services which…are not **reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

- R&N
  - Adequate evidence to conclude that the item or service improves health outcomes
    - emphasis of outcomes experienced by patients
    - generalizable to the Medicare population
  - Adequate evidence = appropriate study design that allows CMS to determine health outcomes for the intended Medicare population
  - For diagnostic tests = clinical utility

Coverage(2)

- Coverage determinations
  - National
  - Local
- Restrictions
  - Specific populations
  - Specific providers/facilities
- NCD: Warfarin sensitivity

Coding/Payment(1)

- CMS does not pay bills. Hires contractors who manage claims on a regional basis.
- Payments are based on fee schedules
- Priced codes are necessary for payment
- Not paying for priced codes requires significant editing in the claims processing system
- Generally, lab tests are paid using the
  - Physician Fee Schedule (PFS); or
  - Clinical Laboratory Fee Schedule (CLFS)

Physician Fee Schedule:

- Used to pay for physician and practitioner services that have a statutory benefit category:
  - Physicians, nurse practitioners, physician assistants, clinical nurse specialists, etc…
  - PhD geneticists may do interpretation of molecular tests but do not have a separate benefit category in Medicare statute
- For diagnostic tests, PFS will generally be used when there is a separately paid physician interpretation (e.g. diagnostic x-ray tests and physician pathology services)

Clinical Laboratory Fee Schedule:

- CLFS payment is in accordance with section 1833(h) of the Act
- Payment is lower of the amount established in one of our contractor regions, the national price if established, or the billed amount
- Contractor pricing is typical:
  - 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. Requires data on actual costs
- Once established, CMS does not change prices
- No deductibles or coinsurance apply to CLFS services

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
- For 2013, MoPath codes are priced under the CLFS and contractors are currently developing prices using the gapfill method

Stacking Code Examples

Code	Payment	Totals	
		CFTR	MLH
83891	$ 5.64	1	1
83898	$ 23.58	90	54
83909	$ 23.58	60	36
83912	$ 5.64	1	1
Total Cost		$3,548.30	$2,133.48

83891: isolation or extraction of highly purified nucleic acid, each nucleic acid type

83898: Amplification, target, each nucleic acid sequence

83909: Separation and identification by high-resolution technique (eg capillary electrophoresis), each nucleic acid preparation

83912: Interpretation and report

ASPA (aspartoacylase) (eg, Canavan disease) gene analysis; common variants (eg, E285A, Y231X))

Code	Payment	Lab 1	Lab 2	Lab 3
83890	$ 5.64	1		
83891	$ 5.64		1	1
83892	$ 5.64	1	2	1
83894	$ 5.64		1	
83896	$ 5.64	5		
83900	$ 47.18	1		1
83901	$ 23.58		1	2
83909	$ 23.58	1		
83912	$ 5.64	1	1	1
83914	$ 23.58	5		4
		$ 233.78	$ 51.78	$ 205.58

83890: Molecular diagnostics; molecular isolation or extraction, each nucleic acid type (DNA or RNA)

83891: isolation or extraction of highly purified nucleic acid, each nucleic acid type

83892: Enzymatic digestion, each enzyme treatment

83894: separation by gel electrophoresis, each nucleic acid preparation

83896: Nucleic acid probe, each

83900: Amplification, target, multiple2 nucleic acid sequences

83901: Amplification, target, multiple2 (List separately in addition to code for primary procedure)

83909: Separation and identification by high-resolution technique (eg capillary electrophoresis), each nucleic acid preparation

83912: Interpretation and report

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CPT Coding

- Tier 1: 105 specific tests; e.g., BRCA, KRAS, CFTR
- Tier 2: Based on resources used in test
  - Level 1: 27 genes
  - Level 2: 51 genes
  - Level 3: 9 genes
  - Level 4: 21 genes
  - Level 5: 42 genes
  - Level 6: 50 genes
  - Level 7: 62 genes
  - Level 8: 15 genes
  - Level 9: 10 genes
  - Unlisted procedure

= 287 genes

Billing Using New CPT Codes

Hypertrophic cardiomyopathy panel

ACTC, CAV3, GLA, LAMP2, MTTG, MTTI, MTTK, MTTQ, MYBPC3, MYH7, MYL2, MYL3, PRKAG2, TNNC1, TNNI3, TNNT2, TPM1, TTR

81401	1
81404	2
81405	7
81406	2
81407	2
81409	4

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Stacking Code Examples

	CFTR	MLH
Stacking Codes	$3,548.30	$2,133.48
Gap fill	$800 - $1343	$650 - $1360
Some contractors define as screening and are not paying.		

ASPA (aspartoacylase) (eg, Canavan disease) gene analysis; common variants (eg, E285A, Y231X))

	Lab 1	Lab 2	Lab 3
Stacking Codes	$ 233.78	$ 51.78	$ 205.58
Gapfill	$93 - $123		
Some contractors define as screening and are not paying.			

Current Status

- Contractors and CMS will complete pricing of current CPT defined MoPath tests including determining coverage status.

- There are no national coverage determinations ongoing at this time.

Obstacles/Opportunities

- Statutory limitations on coverage (screening) and payment (CLFS).
- Extensive number of tests and “unusual” CPT grouping.
- Lack of evidence of clinical utility.
- Lack of information on costs of testing.