CMS Laboratory Open Door Meeting: CLFS Reimbursement Policy Recommendations CY 2015

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The Coalition represents the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists and patient advocacy groups – all linked by a common mission: to develop and commercialize state-of-the-art diagnostics that improve patient health.

The Coalition is committed to working collaboratively and in an open and transparent manner with CMS

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Category 1 MAAA Recommendation

Recommendation:

- C21 supports CMS's policy to set Medicare payment by gapfill when the Medicare contractor determines the code is payable.
- Consistent with AMA CPT's policy that each code describes a unique test developed and furnished by a single laboratory or manufacturer, the payment amount established for a code should be specifically and uniquely applicable to the specific test for which the code is assigned as identified in CPT Appendix O.

Rationale:

- Local contractor determination. The complexity of MAAAs require a deep inquiry into the components of and benefits derived from the test to evaluate Medicare coverage. That inquiry requires extended dialogue between the laboratory/manufacturer and the entity making the coverage determination. Because such extensive interaction is necessary, the local contractor is best positioned to conduct the inquiry and make the coverage determination, as well as the payment amount decision.
- Gapfill. Because there are no or few analogues in the existing CLFS, gapfill remains the only option for determining the payment amount. Consistent with the policies underlying PAMA, contractors should review commercial payer rates, among other data points, to determine Medicare payment.

Genomic Sequencing Procedures Recommendation

Recommendation:

- CMS should set payment by gapfill when the Medicare contractor determines the code is payable.
- Contractors should be allowed to develop and use unique test identifiers.

Rationale:

- Local contractor determination. Since GSP codes are largely non-specific and without sufficient granularity to accurately differentiate amongst the wide variety of GSP tests, extended dialogue between the laboratory/manufacturer and the entity making the coverage determination is necessary to ensure that an appropriate coverage decision is made. Because such extensive interaction is necessary, the local contractor is best positioned to conduct the inquiry and make the coverage determination.
- Gapfill. The GSP code category was created as a distinct code category because these codes are unlike anything else on the CLFS. Because there are no analogues in the existing CLFS, gapfill remains the best option for determining the payment amount. Consistent with the policies underlying PAMA, contractors should review commercial payer rates, among other data points, to determine Medicare payment.
- Unique test identifiers. Allowing contractors to establish and use unique test identifiers is consistent with CMS's transparency interests: Unique test identifiers allows CMS and its contractors to more accurately identify the tests submitted for payment.

CY 2015 CLFS Codes

Category	2015 Code	Descriptor	C21 Recommendation
MAAA Category 1*	815XX	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score Oncotype DX® Breast Cancer Assay (Genomic Health, Inc.)	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis, panel must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	Gapfill by covering contractor

*Administrative MAAA codes not listed

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CY 2015 CLFS Codes

Category	2015 Code	Descriptor	C21 Recommendation
Genomic Sequencing Procedures	814XX	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/ deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Hereditary colon cancer syndromes, (eg, Lynch syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2	Gapfill by covering contractor

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CY 2015 CLFS Codes

Category	2015 Code	Descriptor	C21 Recommendation
Genomic Sequencing Procedures	814XX	Hereditary colon cancer syndromes, (eg, Lynch syndrome, familial adenomatosis polyposis); duplication/deletion gene analysis panel, must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes. Including, BCSIL, C10orf2, COQ2, COX 10, DGUOK, MPV17, OPA1, PDSS2 POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMAT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed	Gapfill by covering contractor

CY 2015 CLFS Codes

Category	2015 Code	Descriptor	C21 Recommendation
Genomic Sequencing Procedures	814XX	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants, and copy number variants or rearrangements, if performed	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxis and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON], genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KCM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2	Gapfill by covering contractor
Genomic Sequencing Procedures	814XX	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KCM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2	Gapfill by covering contractor