October 23, 2015

American
Clinical Laboratory
Association

VIA EMAIL

Glenn McGuirk
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Mail Stop C4-04-04
7500 Security Boulevard
Baltimore, MD 21244

Re: Preliminary Determinations on 2016 CLFS Tests—Drug Testing

Dear Mr. McGuirk:

On behalf of the American Clinical Laboratory Association ("ACLA"), we are pleased to present these comments on the 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations that were released by CMS on September 25. In these comments, we address in detail the issues of pricing for Drugs of Abuse Testing and have attached a chart that provides recommendations on other CY 2016 new and reconsidered preliminary payment recommendations. We are filing a separate statement on issues related to the MAAA testing. As you know, ACLA represents clinical laboratories across the nation, including local, regional, and national laboratories. Many of our members perform testing for drugs of abuse and will be directly affected by the changes made in the Preliminary Determinations.

As you know, these codes have had a complicated history. While the CPT Panel developed new CPT codes for this testing that were to be effective in 2015, CMS rejected those CPT codes and required laboratories to use G-codes that corresponded to the 2014 CPT codes for these services. Laboratories are currently billing for these tests using those codes. Prior to the July Laboratory Open Forum meeting, CMS proposed to implement two G-codes codes for all drugs of abuse testing—one for presumptive and one for definitive—a proposal that raised serious concerns among industry stakeholders.

In response to CMS's proposal, ACLA worked with a broad coalition of industry stakeholders to come up with a new approach that proposed two presumptive codes and four definitive codes, which represented tiers based on the number of tests performed. At its two meetings, the Advisory Committee on Clinical Diagnostic Laboratory Tests recommended that CMS adopt the approach recommended by ACLA and this broad coalition. In the Preliminary Determinations, however, CMS adopted an approach that bears some similarities to what was recommended, but still differs in several material respects. While ACLA is grateful that CMS has chosen to make significant changes in its original proposal, we continue to have concerns about this latest proposal as well.

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The first significant difference between CMS's proposal and what ACLA and the coalition had recommended is in the area of presumptive testing. The coalition had recommended two presumptive codes, one for relatively simple tests, which were frequently considered CLIA-waived, and one for more complex, immunoassay tests. CMS has proposed three presumptive codes, having further subdivided the first category of simple testing into two.

ACLA does not object to the change from two codes to three for presumptive testing. However, we do have serious concerns with regard to the pricing of the GXXX3 code, which is used for presumptive testing performed on immunoassay and other instruments. The coalition had urged CMS to crosswalk this to G0431, which is the code that most closely represents this type of testing; however, CMS has proposed using a different, lower-priced, G-code, G0434, as a crosswalk with a multiplier of three. ACLA believes that such a cross-walk results in a price that is unreasonably low and does not adequately reflect the resources required to perform all of the various types of drug testing that would be included in this group. Therefore, we recommend that CMS adopt the coalition proposal to use G0434 as the base code with a multiplier of 4. [1]

With regard to the definitive testing, both ACLA and CMS establish separate tiers depending on the volume of testing being performed. In determining the number of tests being performed, ACLA and the coalition recommended defining drugs, based on the listing in the AMA's CPT Code Manual. These definitions were the result of extensive effort and deliberation by an expert panel and they represent a clear, unambiguous methodology for counting the drugs being tested.

CMS, however, uses the term "drug class" in its proposal and it is not clear what is meant by that term. The term "drug class," is very ambiguous and subject to various interpretations, a situation that will lead to confusion and inconsistent billing. For example, "drug class" can be defined based on what is detected, the drug's pharmacological activity, the manufacturing source of the drug, its molecular structure or other grouping. The number of drug classes in each tier will vary significantly depending on what criterion is used. Therefore, ACLA urges CMS to use the descriptions set out in CPT to define the various "drug classes" on which the tiers are based. At the recent Advisory Committee meeting, there was discussion that CMS could not simply cross-reference to the descriptions in the CPT Code Manual. If it cannot do this, ACLA believes that CMS should issue a separate list that would define the various drugs covered by these codes, which would mirror the description in the CPT Code Manual. ACLA believes that will avoid any confusion going forward.

In addition, CMS and the coalition also differed on the number of units within each tier, and the price paid for each tier. The coalition had four groups, but it proposed that the first seven tests be paid individually, because there were few economies of scale at that level. After that, the coalition proposed three more tiers: 8-14 CPT codes; 15-21 CPT codes; and 22 or more CPT codes. Each of these codes was priced using the base code of 82542, and multipliers of 8, 10 and

[1] At its most recent meeting, the Advisory Committee proposed adding the descriptor "qualitative" to the presumptive codes; ACLA does not object to that change so long as the descriptors "qualitative or quantitative" continue to be included in the definitive code description.

12 respectively. CMS has proposed the following tiers, based on drug classes as noted above: 1-7 drug classes; 8-14 drug classes; 15-34 drug classes; and 35 or more.

As noted above, ACLA believes the definitions set out in CPT should be used to determine the number of "drug classes" being tested. By doing so, the number of drugs that will be tested will likely be significantly lower than proposed by CMS as there are only 35 total drug classes in the CPT code set, some of them would not be ordered together, and others are very rarely ordered. It will thus be rare that a patient would be tested for more than 22 drugs at one time; therefore, the total number of drugs in each tier will be significantly reduced, which explains why the coalition's top tier has a lower threshold than CMS's.

Furthermore, the prices that CMS has proposed for its tiers are between 43 and 60 percent below the amounts that the coalition proposed and are significantly below appropriate levels that would cover the costs of performing this testing. Both the coalition and CMS used the same CPT code, CPT 82542, as the basis of its cross-walking recommendations; however, the difference in price results from two factors. First, the coalition had separately priced the first seven codes, due to the reduced efficiencies at that level, whereas CMS had paid for these tests as a bundle, at a deeply discounted rate. Second, both the coalition and CMS discounted the incremental tests after these initial tests, but CMS multiplied the base code by .10, while the coalition multiplied it by .25.

At the Advisory Meeting, CMS noted there would be significant programming and implementation issues with paying for each of the first seven tests individually. ACLA believes that a method that pays for the first seven tests individually is much preferred. However, if this is not possible, it is willing to accept a new tier that would consist of up to seven tests. However, we do not think the multiplier of 2.5 used by CMS for this purpose is appropriate. As was noted at the Advisory Committee meeting by one of the panel members, there are not significant efficiencies at this number of tests. Moreover, it is relatively common for physicians to order between four and five confirmatory tests. Therefore, a multiplier at 2.5 will not adequately reimburse laboratories for this testing. ACLA therefore proposes that CMS adopt a multiplier of 4.5 for this first tier, with a base CPT code of 82542.

With regard to the upper three tiers, CMS uses a multiplier of .10, while the coalition had proposed a multiplier of .25. Even though there are economies of scale that can be achieved as testing volumes increase, ACLA does not believe the 90% discount on additional tests, as proposed by CMS, can be justified, and such a deep cut is not sustainable. Therefore, ACLA agrees with the coalition position that a multiplier of .25 is appropriate.

Finally, although CMS states that it bases its proposal on an earlier cross-walking proposal that was made by various stakeholders, that proposal was significantly different than the current situation and therefore is not a relevant basis on which to make pricing decisions. That recommendation was made based on the methodology in the CPT Code Manual, which CMS has chosen not to adopt, and (1) only applied to the costs of testing within a single drug class, and (2) paid full crosswalk rates for any drugs tested in different drug classes. The costs of testing within a single drug class and the economies of scale that can be achieved are significantly

different than those present under the current proposal, which looks at testing across all drug classes. Therefore, it is not reasonable to use that proposal in the current situation.

Therefore, with regard to the definitive codes, ACLA recommends the following:

- Adopt the following four tiers and multipliers:

Code	Number of tests per tier	Pricing
GYYY1	Up to 7	Preferred - CPT 82542 * 1 per drug class Alternative - CPT 82542 * 4.5
GYYY2	8-14	CPT 82542 * 8
GYYY3	15-21	CPT 82542 * 10
GYYY4	22+	CPT 82542 * 12

- Include in a transmittal or other document a listing of the codes, based on those in the CPT Code Manual, so there is no confusion about how these tests are to be counted.

Thank you for your consideration. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

JoAnne Glisson
Senior Vice President

cc: Marc Hartstein

Attachment

ACLA 2016 CMS CLFS Recommendations
as of 9.28.15

	A	B	C	D	E	F
2	**2016 CPT/ HCPCS**	**2016 CPT Description**	**ACLA Rationale** **(Includes original rationales for July 2015 in black and ACLA recommendations on the preliminary payment determinations in red.)**	**ACLA recommend-ation crosswalk to code listed or gap-fill JULY 2015**	**CMS proposed CLFS 9.28.15**	**Proposed NLA (using CMS 2015 fee schedule as of Jan. 2015)**
3	**Organ or Disease Oriented Panels**					
4	80081	OBSTETRIC PANEL with HIV	The current obstetric panel is not listed in the CLFS, however, the new panel code is listed on the Annual Laboratory Public Meeting list for Calendar Year 2016 Updates. The sum of the performed procedures, and existing CPT components, should be used for pricing. We recommend a crosswalk of 80055 plus the HIV test 87389. **CMS acknowledged all OB panel components, but neglected to include CPT 86901 in the proposed cross-walk. CPT 86901, with current NLA of $4.06, represents the separate blood typing procedure for Rh factor. This code should be included in the final crosswalk for the payment determination.**	Original ACLA proposal was to sum of components of 80055 + 87389	**sum of 85025, 87340, 87389, 86762, 86592, 86850, 86900 add CPT 86901 to the component list**	**10.58** **14.06** **32.77** **19.58** **5.81** **5.20** **4.06** **subtotal = $92.06** **add $4.06 for CPT 86901 for new total $96.12**
5	80055	OBSTETRIC PANEL (original)	**NEW TO CLFS 9/28/15 (Crosswalk to 80081 MINUS 87389: HIV-1 antigen(s) with HIV-1 and HIV-2 antibodies, single result)**	ACLA did not make a proposal at the July meeting due to 80055 not being a part of the current CLFS. However, we support CMS's proposal to create a cross-walk based on all components of the current OB panel, CPT 80055.	**80081 MINUS 87389: HIV code HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result.**	**$96.12 minus $32.77 = $63.35**

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6	86850	(Antibody screen, RBC, each serum technique)	**NEW TO CLFS 9/28/15 (crosswalk to similar code 86902 and add to CLFS)**		**86902**	**$5.20**
7	**G Codes**					
8	G0472	Hepatitis C antibody screening for individual at high risk and other covered indication(s)	86803, Hepatitis C antibody is the AMA CPT for diagnostic procedures. G0472 should be cross-walked to this code as the same laboratory procedure is performed.	crosswalk to 86803	**86803**	**$19.42**
9	**Molecular Pathology, GSP, MAAA, ADLT**					
11	81162	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis	ACLA suggests a crosswalk to the sum of BRCA1, BRCA2 full sequence analysis, (CPT 81211) and uncommon dup/del variants (CPT 81213).*****CMS 9.28.15 10% decrease for each test crosswalked. ACLA continues to support the crosswalk with the full amount of the listed price on the CLFS.**	crosswalk to 81211 + 81213	**0.90 TIMES 81211 PLUS 0.90 TIMES 81213**	~~$2,178.04~~ ~~$581.26~~ ~~$2759.30~~ **$2483.37**
12	81170	ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain	ACLA has reviewed AMP data and we agree that a crosswalk to EGFR is appropriate due to the very similar analysis and work performed. CPT 81235 is the best crosswalk. Please also see AMP rationale. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81235	**81235**	**$329.18**

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13	81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence	ACLA has reviewed AMP data and we agree that a crosswalk to EGFR is appropriate due to the very similar analysis and work performed. CPT 81235 is the best crosswalk. Please also see AMP rationale. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81235	**81235**	**$329.18**
14	81219	CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9	ACLA has reviewed AMP's rationale and agrees that CALR is most similar to the FLT3 mutations assay, therefore recommending a cross-walk to 81245. Please also see AMPs detailed rationale to be submitted to CMS. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81245	**81245**	**$165.51**
15	81272	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis; targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)	ACLA has reviewed AMP data and we agree that KIT should also be crosswalked to EGFR as the most similar procedure currently performed. Please also see AMP's more detailed rationale for this crosswalk. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81235	**81235**	**$329.18**
16	81273	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)	ACLA suggests crosswalk to JAK2 V617F variant, CPT 81270. This is a very similar procedure utilizing similar resources. Both are single variant gene analysis assays. Therefore, a crosswalk to 81270 is recommended. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81270	**81270**	**$124.75**

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17	81276	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)	ACLA suggests a crosswalk to the existing KRAS gene analysis procedure, CPT 81275 (*KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene*) (eg, carcinoma) gene analysis, variants in codons 12 and 13). The new CPT was assigned for the same KRAS procedure that is currently coded as a Tier 2 (81403) in 2015. ACLA has also discussed and agrees with AMP's rationale for the crosswalk. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81275	**81275**	**$196.99**
18	81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)	NRAS assays are similar to KRAS, CPT 81275. However, additional resources are required, therefore, ACLA agrees with the AMP crosswalk to cover all procedures and resources. Please also see AMP's detailed recommendation. **ACLA supports CMS' proposed payment recommendation.**	crosswalk to 81275 times 1.5	**81275 times 1.5**	$196.99 + 50% **$295.48**
19	81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis; targeted sequence analysis (eg, exons 12, 18)	ACLA has reviewed AMP's recommendations and agrees the best crosswalk for PDGFRA would be KRAS, CPT 81235. Please also see AMP's detailed recommendation.*****CMS 9.28.15 crosswalk to 81245 FLT3. ACLA continues to support its original reccommendation to crosswalk to 81235.**	crosswalk to 81235	**81245**	**$165.51**
20						

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21	81412	Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	
22	81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	
23	81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer);duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	

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24	81434	Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	
25	81437	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	
26	81438	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	

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27	81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1	Gapfill ACLA supports CMS' proposal to gapfill this code. There are no similar tests on the CLFS that this code could be crosswalked for the purpose of payment. Therefore, CMS must gapfil this code.		**gapfill**	