College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
1	*Reconsider*	*81334*	***RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8).***	**Crosswalk**	**81259**	**$600.00**	**Crosswalk to 81259 *HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence* as similar resources are used.**
2	**Reconsider**	**81326**	**PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant.**	**Crosswalk**	**81215**	**$375.25**	**Crosswalk to 81215 *BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant* as similar resources are used.**
3	**New--Proprietary Laboratory Analyses**	**0018U**	**Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy A3.**				**No Comment at this Time.**

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
4	New--Proprietary Laboratory Analyses	0019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents.				No Comment at this Time.
5	New--Proprietary Laboratory Analyses	0020U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, with specimen verification including DNA authentication in comparison to buccal DNA, per date of service.				No Comment at this Time.
6	New--Proprietary Laboratory Analyses	0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1,				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score.				
7	New--Proprietary Laboratory Analyses	0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider.				No Comment at this Time
8	New--Proprietary Laboratory Analyses	0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication				No Comment at this Time.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			for or against the use of midostaurin.				
9	New--Proprietary Laboratory Analyses	0024U	Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative.				No Comment at this Time.
10	New--Proprietary Laboratory Analyses	0025U	Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative.				No Comment at this Time.
11	New--Proprietary Laboratory Analyses	0026U	Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative,				No Comment at this Time.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			low probability of malignancy").				
12	New--Proprietary Laboratory Analyses	0027U	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15.				No Comment at this Time.
13	New--Proprietary Laboratory Analyses	0028U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis.				No Comment at this Time.
14	New--Proprietary Laboratory Analyses	0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			rs12777823).				
15	New--Proprietary Laboratory Analyses	0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823).				No Comment at this Time.
16	New--Proprietary Laboratory Analyses	0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7).				No Comment at this Time.
17	New--Proprietary Laboratory Analyses	0032U	COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant.				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
18	New--Proprietary Laboratory Analyses	0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G]).				No Comment at this Time.
19	New--Proprietary Laboratory Analyses	0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine metabolism), gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5).				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
20	New--Proprietary Laboratory Analyses	0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative.				No Comment at this Time.
21	New--Proprietary Laboratory Analyses	0036U	Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses.				No Comment at this Time.
22	New--Proprietary Laboratory Analyses	0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden.				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
23	New--Proprietary Laboratory Analyses	0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative.				No Comment at this Time.
24	New--Proprietary Laboratory Analyses	0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity.				No Comment at this Time.
25	New--Proprietary Laboratory Analyses	0040U	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative.				No Comment at this Time.
26	New--Proprietary Laboratory Analyses	0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM.				No Comment at this Time.
27	New--Proprietary Laboratory Analyses	0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG.				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
28	New--Proprietary Laboratory Analyses	0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM.				No Comment at this Time.
29	New--Proprietary Laboratory Analyses	0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG.				No Comment at this Time.
30	New--Multianalyte Assays with Algorithmic Analyses	0011M	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk				No Comment at this Time.
31	New--Multianalyte Assays with Algorithmic	0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13,				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
	Analyses		CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma				
32	New--Multianalyte Assays with Algorithmic Analyses	0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma				No Comment at this Time.
33	New--Molecular Pathology	8X001	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
34	New--Molecular Pathology	8X002	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)	Crosswalk	81404	$274.83	Crosswalk to 81404 *Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)* as similar resources are used.
35	New--Molecular Pathology	8X003	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
36	New--Molecular Pathology	8X004	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence	Crosswalk	81405	$301.35	Crosswalk to 81405 *Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis)* as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
37	New--Molecular Pathology	8X005	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant	Crosswalk	81403	$185.20	Crosswalk to 81403 *Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons) as similar resources are used.*
38	New--Molecular Pathology	8X006	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
39	New--Molecular Pathology	8X007	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
40	New--Molecular	8X009	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia)	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated*

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
	Pathology		gene analysis, evaluation to detect abnormal (eg, expanded) alleles				*variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
41	New--Molecular Pathology	8X010	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
42	New--Molecular Pathology	8X011	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources.
43	New--Molecular Pathology	8X012	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat*) as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
44	New--Molecular Pathology	8X008	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
45	New--Molecular Pathology	81X78	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Crosswalk	81408	$2000.00	Crosswalk to 81408 *Molecular pathology procedure, Level 9 (eg, analysis of >50 exons in a single gene by DNA sequence analysis)* as similar resources are used.
46	New--Molecular Pathology	81X79	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of	Crosswalk	81213	$553.00	Crosswalk to *81213 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants* as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			large gene rearrangements)				
47	New--Molecular Pathology	81X81	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Crosswalk	81408 x0.5	$2000. x0.5 =$1,000.	Crosswalk to 81408 *Molecular pathology procedure, Level 9 (eg, analysis of >50 exons in a single gene by DNA sequence analysis)* times (0.5) as similar resources are used.
48	New--Molecular Pathology	81X82	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Crosswalk	81213 x0.5	$553. x0.5 =$276.50	Crosswalk to *81213 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants* times (0.5) as similar resources are used.
49	New--Molecular Pathology	81X83	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion	Crosswalk	81213 x0.5	$553. x0.5 =$276.50	Crosswalk to *81213 BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants* times (0.5) as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			analysis (ie, detection of large gene rearrangements)				
50	New--Molecular Pathology	81X09	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	Crosswalk	81210	$175.40	Crosswalk to 81210 *BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)* as similar resources are used.
51	New--Molecular Pathology	8X013	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
52	New--Molecular Pathology	8X014	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence	Crosswalk	81407	$846.27	Crosswalk to 81407 *Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of >50 exons, sequence analysis of multiple genes on one platform)* as similar resources are used.
53	New--Molecular	8X015	CACNA1A (calcium voltage-gated channel	Crosswalk	81403	$185.20	Crosswalk to 81403 *Molecular pathology procedure, Level 4 (eg, analysis of single exon by*

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
	Pathology		subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant				*DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)* as similar resources are used.
54	New--Molecular Pathology	8X016	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
55	New--Molecular Pathology	8X017	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
56	New--Molecular Pathology	8X018	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis;	Crosswalk	81404	$274.83	Crosswalk to 81404 *Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or*

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			full gene sequence				***duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)*** **as similar resources are used.**
57	**New--Molecular Pathology**	**8X019**	**CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)**	**Crosswalk**	**81403**	**$185.20**	**Crosswalk to 81403** ***Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)*** **as similar resources are used.**
58	**New--Molecular Pathology**	**8X020**	**DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles**	**Crosswalk**	**81401**	**$137.00**	**Crosswalk to 81401** ***Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)*** **as similar resources are used.**

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
59	New--Molecular Pathology	8X021	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)	Crosswalk	81404	$274.83	Crosswalk to 81404 *Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)* as similar resources are used.
60	New--Molecular Pathology	81X07	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	Crosswalk	81175	$707.02	Crosswalk to 81175 *ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence* as similar resources are used.
61	New--Molecular Pathology	81X08	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	Crosswalk	81210	$175.40	Crosswalk to 81210 *BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)* as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
62	New--Molecular Pathology	8X022	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)*.
63	New--Molecular Pathology	8X023	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)	Crosswalk	81404	$274.83	Crosswalk to 81404 *Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)* as similar resources are used.
64	New--Molecular Pathology	8X024	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence	Crosswalk	81404	$274.83	Crosswalk to 81404 *Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)* as similar resources are used.
65	New--Molecular	8X025	FXN (frataxin) (eg, Friedreich ataxia) gene	Crosswalk	81403	$185.20	Crosswalk to 81403 *Molecular pathology procedure, Level 4 (eg, analysis of single exon by*

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
	Pathology		analysis; known familial variant(s)				***DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)*** as similar resources are used.
66	New--Molecular Pathology	8X026	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 ***Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)*** as similar resources are used.
67	New--Molecular Pathology	8X027	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)	Crosswalk	81404	$274.83	Crosswalk to 81404 ***Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)*** as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
68	New--Molecular Pathology	81X11	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	Crosswalk	81210	$175.40	Crosswalk to 81210 *BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)* as similar resources are used.
69	New--Molecular Pathology	8X000	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	Crosswalk	81225	$291.36	Crosswalk to 81225 *CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)* as similar resources are used.
70	New--Molecular Pathology	8X028	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
71	New--Molecular	8X010	PLCG2 (phospholipase C gamma 2) (eg, chronic	Crosswalk	81225	$291.36	Crosswalk to 81225 *CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug*

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
	Pathology		lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)				***metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)*** **as similar resources are used.**
72	New--Molecular Pathology	8X035	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 ***Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)*** **as similar resources are used.**
73	New--Molecular Pathology	8X032	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis, includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	Crosswalk	81401	$137.00	Crosswalk to 81401 ***Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)*** **as similar resources are used.**
74	New--Molecular Pathology	8X033	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	Crosswalk	81317	$707.02	Crosswalk to 81317 PMS2 ***(postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis*** **as similar resources are used.**

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
75	New--Molecular Pathology	8X034	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	Crosswalk	81403	$185.20	Crosswalk to 81403 *Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)* as similar resources are used.
76	New--Molecular Pathology	8X036	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Crosswalk	81401	$137.00	Crosswalk to 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)* as similar resources are used.
77	New--Molecular Pathology	80X00	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma	Crosswalk	81121	$295.79	81121 *IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)* as similar

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			multiforme) gene analysis, targeted sequence analysis (eg, promoter region)				resources are used.
78	New--Molecular Pathology	813X0	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)	Crosswalk	81230	$174.81	Crosswalk to *81230 CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)* as similar resources are used.
79	New--Genomic Sequencing Procedures and Other Molecular Multianalyte Assays	81X43	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic	Crosswalk	81412	$2448.56	Crosswalk to *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* as similar resources are used.

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)				
80	New--Multianalyte Assays with Algorithmic Analyses	816X0	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy				No Comment at this Time.
81	New--Chemistry	80X01	Dihydrotestosterone (DHT)	Crosswalk	82634	$36.14	Code 80X01 has been established for CPT 2019 to specifically capture *Dihydrotestosterone* testing used for medical purposes from existing CPT code 80327 *Anabolic steroids; 1 or 2*. CPT

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
							code 80327 is not included on the CMS 2018 Clinical Laboratory Fee Schedule as the CMS does not recognize 80327 for reporting purposes. We recommend a crosswalk to CPT code 82634 *Deoxycortisol, 11-* as it is also a type of steroid and similar resources are used.
82	New--Multianalyte Assays with Algorithmic Analyses	815X0	Infectious disease, chronic Hepatitis C Virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver				No Comment at this Time.
83	New--Chemistry	8372X	Lipoprotein, direct measurement; small dense LDL cholesterol	Crosswalk	83704	$38.95	CPT code 8372x has been established to report direct measurement of small dense Low-density lipoprotein cholesterol. Crosswalk to *83704 quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance*

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
							spectroscopy), includes lipoprotein particle subclass(es), when performed **as similar resources are used.**
84	**New--Proprietary Laboratory Analyses**	**0045U**	**Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score**				**No Comment at this Time.**
85	**New--Proprietary Laboratory Analyses**	**0046U**	***FLT3*** **(fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative**				**No Comment at this Time.**
86	**New--Proprietary Laboratory Analyses**	**0047U**	**Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12**				**No Comment at this Time.**

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score				
87	New--Proprietary Laboratory Analyses	0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)				No Comment at this Time.
88	New--Proprietary Laboratory Analyses	0049U	*NPM1* (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
89	New--Proprietary Laboratory Analyses	0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements				No Comment at this Time.
90	New--Proprietary Laboratory Analyses	0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service				No Comment at this Time.
91	New--Proprietary Laboratory Analyses	0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
92	New--Proprietary Laboratory Analyses	0053U	Oncology (prostate cancer), FISH analysis of 4 genes (*ASAP1, HDAC9, CHD1* and *PTEN*), needle biopsy specimen, algorithm reported as probability of higher tumor grade				No Comment at this Time.
93	New--Proprietary Laboratory Analyses	0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service				No Comment at this Time.
94	New--Proprietary Laboratory Analyses	0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			single nucleotide polymorphism targets and two control targets), plasma				
95	New--Proprietary Laboratory Analyses	0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)				No Comment at this Time.
96	New--Proprietary Laboratory Analyses	0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
97	New--Proprietary Laboratory Analyses	0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative				No Comment at this Time.
98	New--Proprietary Laboratory Analyses	0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative				No Comment at this Time.
99	New--Proprietary Laboratory Analyses	0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood				No Comment at this Time.
100	New--Proprietary Laboratory Analyses	0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin				No Comment at this Time.

College of American Pathologists
2019 Clinical Laboratory Fee Schedule Recommendations
CMS Annual Public Meeting
June 25, 2018 Baltimore, MD

CMS Item #	CMS Code Type	2019 Code #	Code Descriptor (HCPCS Long Code Descriptor)	Gap fill or Crosswalk?	If crosswalk, then to what existing code?	CMS 2018 CLFS Rate	Rationale
			[ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis				