

February 12, 2021

COVID-19 TESTING BRIEF

from Avalon Healthcare Solutions

CONTENTS

LAB TESTING UPDATE 2

- ✓ Avalon Laboratory Network Capacity & Turnaround Time Report 2
- ✓ 2021 CPT Code Changes 3
- ✓ Genetic Testing Utilization Offsets PAMA Savings for the Medicare Lab Spend 3

EMERGING VIRAL MUTATIONS..... 5

POLICY UPDATE 6

- ✓ COVID- 19 Testing 6
- ✓ From The White House 6
- ✓ Payers and Providers 6

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Avalon is an expert in lab management with a foundation in science. Clinically-driven lab strategies are transforming lab testing into actionable intelligence for value-driven care. Avalon's core program includes a full delegation of Routine Testing Management, Genetic Testing Management, Independent Laboratory Network Management, and Medical Specialty Rx Management. You can learn more about our impact [here](#) and the latest news [here](#).

AVALON LABORATORY NETWORK CAPACITY & TURNAROUND TIME REPORT

LAB	RT-PCR Y/N	MULTIPLE PLATFORMS	CAPACITY (PER DAY)	TAT (DAYS)
LabCorp	Y	Y	275,000	1-2 days
Quest	Y	Y	215,000	2 days
Premier Medical Lab	Y	Y	100,000	1-2 days
BioReference	Y	Y	70,000	1 day
Eurofins-Diatherix	Y	N	60,000	1-3 days
Aegis	Y	Y	60,000	1-2 days
Mako Medical Lab	Y	Y	50,000	1-2 days
GenetWorx	Y	Y	40,000	2 days
AIT (American Institute of Tox)	Y	Y	20,000	1-2 days
Sonic-CPL	Y	Y	20,000	1-3 days
Genesis DX (DNA Analytical)	Y	Y	16,000	1-2 days
MDL (Medical Diagnostic Lab)	Y	N	12,000	1-2 days
LabTech	Y	Y	10,000	1-2 days
AccuReference	Y	N	10,000	2 days
PathGroup	Y	Y	8,000	2-3 days
Luxor	Y	Y	5,000	1 day
Transplant Genomics	Y	N	5,000	1-2 days
Neogenomics	Y	Y	5,000	1-4 days
Precision Genetics	Y	N	4,000	1-2 days
BAKO	Y	N	2,500	1-2 days
Radeas	Y	Y	2,400	1-2 days
Wake Medical Lab Consultants	Y	Y	1,500	1 day
NephronPharm	Y	Y	1500	2-3 days

2021 CPT CODE CHANGES

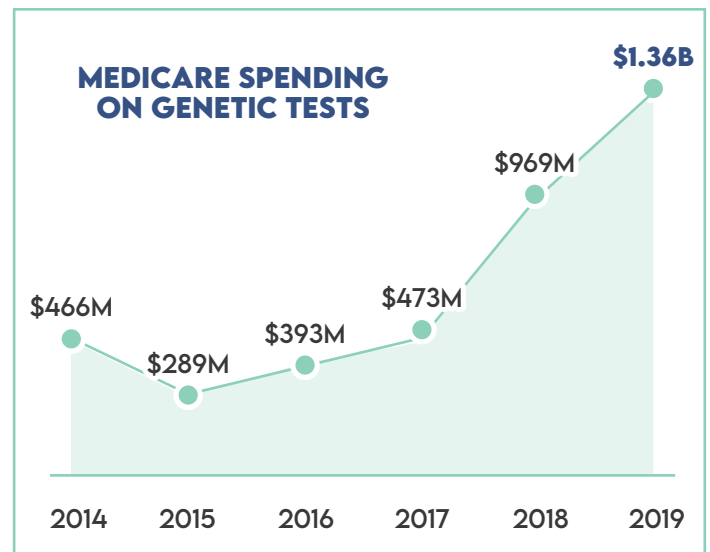
Changes to the CPT code set are considered through an open editorial process managed by the CPT Editorial Panel, an independent body convened by the AMA that collects broad input from the healthcare community and beyond to ensure CPT content reflects the coding

demands of digital health, precision medicine, augmented intelligence, and other aspects of a modern healthcare system. There were 329 changes to the CPT code set for the year 2021. Of those changes, 104 were new laboratory CPT codes with 92 of those new codes describing genetic tests.

TESTING CATEGORY	NEW	REVISED	DELETED	ADD-ON
Therapeutic Drug Assays	10			
Tier 1 Molecular Pathology Procedures	17	1		
Tier 2 Molecular Pathology Procedures		5		
Multianalyte Assays with Algorithmic Analyses (MAAA)			1	
Chemistry	2	2		
Proprietary Laboratory Analyses (PLA)	75		2	7
	104	8	3	7

GENETIC TESTING UTILIZATION OFFSETS PAMA SAVINGS FOR THE MEDICARE LAB SPEND

The Office of the Inspector General (OIG) published a report in December 2020 detailing the trend in laboratory testing expenses for the Medicare program during the 2018-2019 period. The OIG revealed that the cost of lab services increased by about 1.2% during the year 2019. Of the top 25 tests, 17 tests reduced in cost from the prior period for a savings of \$175 million. These tests were impacted by the previous changes determined by the PAMA market-based pricing instituted in 2014. However, the remaining eight tests (from the top 25) were already at the PAMA median price in the category of genetic testing. Medicare spent \$1.36 billion for genetic testing in 2019. Since there was not an increase in price, the resulting increase in spend was attributed to an increase in utilization.



Source: OIG analysis of 2014-2019 spending on lab tests in Medicare Part B, 2020.

This graph from the OIG report, depicts the trend in genetic testing costs and demonstrates a year over year increase of 40% in the spend for genetic testing by the Medicare program. According to the 2020 Medicare Trust Report, some of the increase in genetic test spending for 2018 and 2019 is due to unnecessary genetic cancer tests.

Another industry publication, Laboratory Economics, published the chart on the following page demonstrating the fastest growing laboratory tests by Medicare payments in 2019 (Laboratory Economics, Oct 2020).

FASTEST-GROWING LAB & PATHOLOGY TESTS BY MEDICARE PAYMENTS FOR 2019

CPT	SHORT DESCRIPTION	2019 PAYMENT	2018 PAYMENT*	1-YEAR # CHG
81407	Molecular Pathology Procedure, Level 8	\$ 17,739,535	\$ 5,906,375	200%
0037U	Targeted Genomic Sequence Analysis (FoundationOne CDx)	78,338,284	32,728,869	139%
81162	BRCA 1&2 Gene Analysis	118,521,577	49,860,043	138%
81408	Molecular Pathology Procedure, Level 9	283,982,476	120,688,407	135%
81599	Unlisted Multianalyte Assay with Algorithmic Analysis	28,088,766	12,309,679	128%
87801	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Multiple Organisms	20,763,398	9,427,984	120%
87481	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Candida	16,472,786	7,873,818	109%
87798	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Not Otherwise Specified	98,683,358	49,150,431	101%
81406	Molecular Pathology Procedure, Level 7	42,214,830	21,850,413	93%
81317	PMS2 Gene Analysis	53,573,782	31,588,686	70%
81298	MSH6 Gene Analysis	42,449,143	26,307,256	61%
81201	APC Gene Analysis	47,249,802	29,785,160	59%
81295	MSH2 Gene Analysis	25,205,062	15,900,312	59%
81479	Unlisted Molecular Pathology Procedure	197,406,615	132,638,865	49%
81528	Genetic Test Analysis, Colorectal Cancer (Cologuard)	240,682,190	167,191,703	44%
81321	PTEN Gene Analysis	10,747,241	7,638,677	41%
87799	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Not Otherwise Specified; Quantification	14,308,447	11,281,832	27%
81405	Molecular Pathology Procedure, Level 6	10,965,971	8,747,436	25%
81292	MLH1 Gene Analysis	10,203,749	8,280,887	23%
87661	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Trichomonas Vaginalis	6,866,958	5,649,910	22%
87502	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Influenza Virus	10,098,055	8,323,937	21%
81404	Molecular Pathology Procedure, Level 5	12,755,555	10,844,908	18%
81545	Thyroid Gene Expression Analysis (Afirma Gene Expression Classifier)	25,357,454	22,337,668	14%
88350	Immunofluorescence, Per Specimen; each Additional Single Antibody Stain Procedure	10,180,708	8,981,309	13%
81521	Breast Cancer Microarray Gene Expression (MammaPrint)	11,750,771	10,581,631	11%
	Total, Top 25 Test	\$1,434,606,513	\$815,876,195	76%
	Genetic Testing**	1,647,079,631	1,129,787,494	46%
	Anatomic Pathology	1,616,182,495	1,588,353,052	2%
	Drug Testing	886,944,077	914,863,739	-3%
	Routine Clinical Lab Tests	3,649,014,636	3,911,136,287	-7%
	Pap & HPV Testing	57,915,782	63,455,538	-9%
	Grand Total, All Medicare Part B Carrier Test Payment	\$7,857,136,621	\$7,607,596,110	3%

*Test codes must have had a minimum of \$5 million in Medicare Part B Carrier spending in 2018 to be included in list.

**Includes all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures, Proprietary Laboratory Analyses codes and G0452 (molecular pathology interpretation).

Source: Laboratory Economics from Medicare Part B National Summary Data Files, 2018 & 2019

You will note that some of the largest groups in testing are contained within the Molecular Pathology Procedure codes (CPT codes 81400-81408). As was discussed during our recent webinar, these codes are non-specific and may describe a myriad of gene-based tests and can be problematic for a claims system to identify the actual test performed, the clinical utility of the test and how to apply reimbursement. The PLA codes referenced in the earlier section for 2021 CPT code changes are another challenge in that they can be classed as Advanced Diagnostic Laboratory Tests (ADLTs) and therefore are afforded temporary pricing status by CMS that may approximate the charge value of the new test. Fees as much as \$7,100 have been assigned to these tests.

*Clinical Laboratory News** highlighted some of the challenges in the management of genetic testing. First, there is a lack of specificity in CPT codes. As was previously described, the Tier 2 CPT codes are non-specific and may describe an increasing number of gene-based testing. As an example, the Tier 2 CPT code 81405 describes over 100 gene-based tests. While a traditional prior authorization program can identify the testing requested and align to medical policy, an extended genetic test management program will preemptively assess new technologies, incorporate useful testing to policy and offer alternative coding solutions with predetermined reimbursement.

The second challenge identified was a lack of genetic expertise within the plans. Avalon has accomplished contractual and collaborative relationships with genetic counseling firms as a means of extending that genetic knowledge to health plans, providers and to patients.

Another challenge is that health plans are in need of comprehensive medical policies for genetic tests. The Avalon program includes the curation and maintenance of new genetic policies including our clinical team staying abreast of changes in the science and evaluating emerging lab technologies. This is a solution for yet another problem for the plans; the ability to assess and compare genetic tests.

A health plan expert also identified the need to cross the lines between the plan and providers and cultivate collaborations that can further the utility of genetic testing. Through a comprehensive approach to laboratory benefit management, Avalon identifies issues and brings the appropriate parties together to foster best-in-class solutions.

Finally, there remains the issue of the abuse of unnecessary testing by some laboratories resulting in excessive utilization and cost to both the health plans and their members. A comprehensive lab benefit management program manages this problem in both a prospective and retrospective effort.

*Anderson, Daniel and Astion, Michael. "More Than a CPT Code." *Clinical Laboratory News*, April 1, 2019.

EMERGING VIRAL MUTATIONS

For an overview of COVID-19 emerging viral mutations as of January 2021, please watch [this webinar](#) featuring a presentation from Avalon's Medical Policy Specialist Jerm Day-Storms, PhD, MA, MWC. For the latest updates please see:



[FDA Letter to Clinicians](#) outlining tests affected by variants.



The CDC's SARS-CoV-2 Emerging Variants [webpage](#).

COVID-19 TESTING

- The Department of Defense will pay \$231.8M to Ellume, an Australian company that was part of the [NIH RADx program](#), in exchange for [8.5 million at-home COVID-19 tests](#). The contract will help fund construction of [Ellume's first manufacturing plant in the U.S.](#) that will produce more than 500,000 tests per day.
- On January 21, 2021, President Biden issued an Executive Order (EO) establishing the [COVID-19 Pandemic Testing Board](#), that includes instructions to the Secretaries of HHS, Treasury and Labor to offer COVID-19 testing free of charge to the uninsured and clarify the coverage obligations of group health plans. On the same day, President Biden issued a [national testing strategy](#) that includes plans for more drive-thru testing sites, investments in at-home and rapid antigen tests, supplies, lab capacity and genomic sequencing to keep better track of hot spots and new variants. Read more [here](#).

FROM THE WHITE HOUSE

- On January 28, 2021, President Biden issued an [Executive Order](#) directing HHS to establish a special enrollment period for HealthCare.gov. HHS quickly [announced](#) a new special enrollment period will begin on February 15, and committed to spending [\\$50 million on outreach and education](#). President Biden also directed federal agencies to [reexamine several other policies](#), including policies that undermine protections for people with preexisting conditions and waiver policies under Medicaid. The Biden administration is [expected to address the Medicaid waivers soon](#) because there is pending litigation before the U.S. Supreme Court regarding Arkansas and New Hampshire's Medicaid work requirements.
- According to a [memo from the White House Chief of Staff](#), all new regulations that are not yet implemented will be reviewed by federal agency leaders to decide if they will be reopened for public comment or other action.

PAYERS AND PROVIDERS

- Hospitals are [pushing back against new UnitedHealthcare policies](#) that threaten payments for lab tests and specialty drugs in outpatient settings.
- HCA, one of the largest hospital systems in the U.S., launched a [COVID-19 Research Consortium](#) to study how to combat the pandemic [with several others](#), including HHS' Agency for Healthcare Research and Quality, Johns Hopkins, Columbia, Duke, and Harvard Pilgrim.
- Andy Slavitt, former CMS Administrator and now a senior White House adviser, said health care providers, [should not hold back vaccine doses](#) in fear that more [will not be forthcoming](#). President Biden will [expand weekly COVID-19 vaccine supply](#) to 10.5M this week and begin to allocate doses to over 40,000 pharmacy locations nationwide starting February 11, 2021.

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