Laboratory and Pathology Payment Policy

Policy

The Plan will pay for covered laboratory and pathology services provided at a contracted facility. Supporting documentation may be requested to verify that the services provided follow the Plan guidelines.

Definition

Laboratory and pathology services include the study of tissues, fluids, and other materials obtained from a patient to study the nature and cause of disease.

Reimbursement

Laboratory services are reimbursed based on terms outlined in the provider contract. All claims are subject to payment edits.

The Plan does reimburse:

- Panel codes, when all individual tests in the panel have been performed (genetic testing panels require prior authorization for each individual test).
- Individual codes, when all components in a panel have not been performed.
- Testing for medication levels.
- Drug screens billed with 80305-80307, G0480-G0483, and G0659. Routine screening labs.
- Clinical laboratory tests, when performed by a technician under physician supervision.
- Laboratory and pathology consultant opinions when deemed medically necessary.
- The Plan does reimburse for 36415 (collection of venous blood by venipuncture) when it is the sole service provided.

The Plan does **not** reimburse:

- Laboratory services related to or associated with alternative, holistic, naturopathic, and/or functional health medicine.
- Paternity blood tests.
- Drug testing that is required for reasons unrelated to the care of the member, including but not limited to:
    - Court-ordered
    - Forensic or criminal situations
    - Administrative or social service investigations or proceedings
    - Work place or school compliance screening
    - Residential monitoring purposes
- Urine drug testing that is performed without a clear treatment role and decision making response to either a positive or negative result.
- Qualitative drug screens for single or multiple drug classes 80375 – 80377 or 80300 – 80304.
- Automated lab tests that are billed with modifier 26. These tests have no professional component.
- Laboratory and pathology services submitted with unlisted CPT codes without prior authorization.
- Genetic testing services that are not prior authorized.
- Drugs, devices, treatments, procedures, and laboratory and pathology tests that are experimental, unproven, or investigational.
- Unless stated otherwise in the provider contract, the Plan will not reimburse separately for 36415 (collection of venous blood by venipuncture) and/or when billed along with an E&M office visit (99201-05; 99211-15), preventive medicine service (99381-87; 99391-97), blood laboratory CPT codes 80000-89999, and T1015 (Clinical Visit)
- The Plan will not reimburse separately for 36591 (collection of blood specimen from a completely implantable venous access device) and/or 36592 (collection of blood specimen

using established central or peripheral catheter, venous, not otherwise specified) when billed along with 96360-96379 (IV hydration/infusion services).
- Saliva drug screening when performed on the same date of service as urine drug screening.
- Code 36416 (collection of capillary blood specimen e.g., finger, heel, ear stick).

Coronavirus (COVID-19) Diagnostic Testing

On March 10, 2020, Governor Baker declared a State of Emergency in Massachusetts in response to the 2019 novel coronavirus (COVID-19). Governor Baker ended the State of Emergency in Massachusetts on June 15, 2021. On January 1, 2021, Chapter 260 of the Acts of 2020 was signed into law by Governor Baker. The provisions of Section 70 of Chapter 260 require coverage without cost-sharing for medically necessary COVID-19 testing, at both in-network and out-of-network providers, for commercial plan members. COVID-19 testing is defined as polymerase chain reaction (PCR) and antigen tests approved to diagnose SARS-CoV-2, the virus that causes COVID-19 (Section 70, Chapter 260 of the Acts of 2020). Additionally, Division of Insurance Bulletin 2021-08 outlines the Division's expectations with respect to coverage for COVID-19 testing following the end of the State of Emergency.

Fallon Health covers COVID-19 testing for symptomatic individuals, individuals identified as close contacts by state or local health officials, and asymptomatic individuals upon admission to a Massachusetts healthcare facility.

COVID-19 diagnostic tests must be approved, cleared or authorized by the Food and Drug Administration (FDA) and used in accordance with FDA labeling. Two types of COVID-19 diagnostic tests are covered: molecular and antigen. Molecular COVID-19 diagnostic tests are also known as "PCR tests."

- Fallon Health is waiving member cost-sharing (copayments, coinsurance or deductibles) for covered COVID-19 diagnostic testing.
- To ensure plan members have timely access to medically necessary COVID-19 diagnostic testing, Fallon Health will cover medically necessary COVID-19 diagnostic testing provided by non-contracted (out-of-network) laboratories and healthcare facilities when in-network testing is not available.
- Prior authorization is not required for COVID-19 diagnostic testing, however, documentation in the patient's medical record must support the medical necessity for ordering a the COVID-19 diagnostic test.
- COVID-19 diagnostic testing is covered when ordered by the member's attending health care provider.
    - An attending health care provider is a provider who is licensed under applicable state law, who is acting within the scope of his/her license, and who is responsible for providing care to the member.
    - A provider need not be "directly" responsible for providing care to the member to be considered an attending provider, as long as the provider makes an individualized clinical assessment to determine whether testing is medically appropriate for the member.
    - Clinical decisions about testing made by the member's attending health care provider may include testing of members with signs or symptoms compatible with COVID-19, as well as asymptomatic members with known or suspected recent exposure to COVID-19.
- COVID-19 testing for any purpose not primarily intended for individualized diagnosis or treatment of COVID-19 is not covered.

Coronavirus (COVID-19) Antibody Testing

On March 10, 2020, Governor Charlie Baker declared a state of emergency, giving the Administration more flexibility to respond to the Coronavirus outbreak. For the duration of the State of Emergency in Massachusetts due to the outbreak of COVID-19, Fallon Health is covering medically necessary COVID-19 antibody testing. Upon expiration of the State of Emergency, Fallon Health will evaluate the continued need for flexibilities related to COVID-19. Governor Baker ended the State of Emergency in Massachusetts on June 15, 2021.

Effective June 1, 2020, Fallon Health requires prior authorization for COVID-19 antibody testing. In updated guidance issued May 11, 2020, the U.S. Food and Drug Admistration (FDA) recommends that because antibodies are part of the human body's immune response to exposure and not the virus itself, results from antibody testing should not be used to diagnose or exclude COVID-19 infection.[1] Nothing in this guidance is intended to impact or supersede CDC's recommendations regarding which patients should be tested for COVID-19, however, and the CDC has published Interim Guidelines for COVID-19 Antibody Testing (Updated as of September 21, 2021).[2] Data that will inform antibody testing (also referred to as serologic testing) guidance are rapidly evolving. Persons suspected of having COVID-19 who test positive by dirfect viral detection methods (PCR or antigen testing) typically begin to develop measurable antibody 7-14 days after illness onset, and by 3 weeks most persons will test positive for antibody. During this interval, the sensitivity of nucleic acid detection is decreasing, and the sensitivity of serologic testing is increasing. Antibody testing may be useful to support the diagnosis of COVID-19 illness or complications of COVID-19 in the following situations:

- A positive antibody test at least 7 days following acute illness onset in persons who had a previous negative antibody test (e., seroconversion) but did not receive a positive viral test might indicate SARS-CoV-2 infection between the dates of the negative and positive antibody tests.
- A positive antibody test can help support a diagnosis when patients present with complications of COVID-19, such as multisystem inflammatory syndrome or other post-acute sequelae of COVID-19.

Services that are not medically necessary for diagnosis or treatment of illness or injury are not covered services. This includes but is not limited to COVID-19 antibody testing:

- To determine a plan member's ability to return to work or school;
- To determine a plan member's ability to donate blood or plasma; and/or
- As part of epidemiological research, surveillance studies or for other public health reasons.

To ensure plan members have timely access to medically necessary COVID-19 antibody testing, Fallon Health will authorize COVID-19 antibody testing provided by non-contracted (out-of-network) laboratories when in-network testing is not available. The antibody test must be authorized by the FDA under an Emergency Use Authorization).

COVID-19 antibody testing must be ordered by a plan provider who is treating the plan member and who will use the results of the test to manage the member's medical condition. For Medicare Advantage, NaviCare, Summit ElderCare and Fallon Health Weinberg members, COVID-19 antibody tests will be covered when ordered by any healthcare professional authorized to do so under state law.

Serologic methods have important public health and clinical uses for monitoring and responding to the COVID-19 pandemic

- Several serologic assays for COVID-19 have EUA by the FDA, which has independently reviewed their performance.
- Currently, there is no identified advantage whether the assays test for IgG, IgM and IgG, or total antibody[3, 4]

[1] U.S. Food and Drug Administration. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised); Issued May 11, 2020. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

[2] Centers for Disease Control and Prevention (CDC). Interim Guidellines for COVID-19 Antibody Testing (Updated August 1, 2020). Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html.

[3] Centers for Disease Control and Prevention (CDC). Interim Guidellines for COVID-19 Antibody Testing (Updated August 1, 2020). Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

In newly published guidelines on the use of serologic testing in the diagnosis of COVID-19, the Infectious Diseases Society of America (IDSA)[5] identified three potential indications for serologic testing including: 1) evaluation of patients with a high clinical suspicion for COVID-19 when molecular diagnostic testing is negative and at least two weeks have passed since symptom onset; 2) assessment of multisystem inflammatory syndrome in children; and 3) for conducting serosurveillance studies (Fallon Health does not cover surveillance testing).

- The IDSA recommends against using serologic testing to diagnose SARS-CoV-2 infection during the first two weeks (14 days) following symptom onset.
- When COVID-19 infection requires laboratory confirmation for clinical or epidemiological purposes, the IDSA panel recommends testing for IgG or total antibody three to four weeks after symptom onset to detect evidence of past COVID-19 infection.
- The IDSA makes no recommendation either for or against using IgM antibodies to detect evidence of past COVID-19 infection, and recommends against using IgA antibodies to detect evidence of past COVID-19 infection

Given that the CDC has found no identified advantage whether assays test for IgG, IgM and IgG, or total antibody, and based on IDSA recommendations (Hanson et al., 2020), Fallon Health will not reimburse multiple assays for antibodies of different immunoglobulin classes. Serologic testing for COVID-19 (e.g., CPT 86769) should be reported with a unit of one (1).

Specimen Collection for COVID-19 DiagnosticTesting

On March 10, 2020, Governor Charlie Baker declared a state of emergency, giving the Administration more flexibility to respond to the Coronavirus outbreak. For the duration of the State of Emergency in Massachusetts due to the outbreak of COVID-19, Fallon Health is covering specimen collection for COVID-19 diagnostic testing for commercial plan members. Governor Baker ended the State of Emergency in Massachusetts on June 15, 2021. The Families First Coronavirus Response Act (FFCRA) was signed into law on March 18, 2020. Section 6001 of the FFCRA requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for items and services related to the furnishing or administration of COVID-19 diagnostic testing furnished on or after March 18, 2020 through the end of the federal Public Health Emergency (PHE) for COVID-19. In accordance with Section 6001 of the FFCRA, Fallon Health will cover specimen collection for COVID-19 diagnostic testing for commercial plan members through the end of the federal PHE. The federal PHE for COVID-19 expires at the end of the day on May 11, 2023.[6] As a result, coverage for specimen collection for COVID-19 diagnostic testing for commercial plan members will end on May 11, 2023. Claims for specimen collection for COVID-19 diagnostic testing with dates of service on or after May 12, 2023 will deny. This includes independent laboratory specimen collection under HCPCS codes G2023 and G2024, hospital outpatient department specimen collection under HCPCS code C9803, and assessment of symptoms and specimen collection by physicians and nonphysician practitioners under CPT 99211. See below for details.

Independent Laboratory Specimen Collection (HCPCS codes G2023 and G2024)

Emergency waiver authority permits Medicare payment for specimen collection when laboratories send trained technicians to collect a sample from a homebound beneficiary or a non-hospital inpatient for COVID-19 diagnostic testing effective on dates of service on or after March 1, 2020 and continuing for the duration of the federal PHE for COVID-19. CMS created two temporary

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[4] Zhao J, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clin Infect Dis. 2020 Mar 28. https://pubmed.ncbi.nlm.nih.gov/32221519/

[5] Hanson KE, et al. Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19:Serologic Testing. Clin Infect Dis. 2020 Sep 12. https://pubmed.ncbi.nlm.nih.gov/32918466/

[6] Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap: https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html#:~:text=Based%20on%20current%20COVID%2D19,day%20on%20May%2011%2C%202023

HCPCS codes for COVID-19 specimen collection by Independent Laboratories in Interim Final Rule CMS-1744-IFC, effective for dates of service on or after March 1, 2020:

- G2023, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source. *(Use this code for homebound.)*
- G2024, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source.

Effective for dates of service on or after March 1, 2020 and continuing for the duration of the federal PHE for COVID-19, Fallon Health will cover specimen collection for commercial and Medicare lines of business, when a trained laboratory professional collects a specimen for COVID-19 diagnostic testing from a plan member who is homebound (G2023) or who is in a skilled nursing facility (SNF) or on behalf of a home health agency (G2024). Note that G2024 is applicable to members in a non-covered stay in a SNF and not to those members in covered stays whose lab tests would be included in the SNF per diem rate. Independent laboratories can also bill one of the existing HCPCS codes for the travel allowance, as described by HCPCS code P9603 or the flat rate travel allowance as described by HCPCS code P9604.

Beginning March 1, 2020 and continuing for the duration of the federal PHE for COVID-19, the CMS definition of "homebound" was expanded under the Interim Final Rule (CMS-1744-IFC) to allow patients to be considered homebound if it is medically contraindicated for the patient to leave home. During the federal PHE for COVID-19, this would aooly to those patients:
(1) where a physician has determined that it is medically contraindicated for an individual to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19; or
(2) where a physician has determined that it is medically contraindicated for an individual to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

A patient who is exercising "self-quarantine" for his or her own safety, would not be considered "homebound."

The federal PHE for COVID-19 expires at the end of the day on May 11, 2023. Effective for dates of service on or after May 12, 2023, HCPCS codes G2023 and G2024 are no longer payable by Fallon Health for commercial and Medicare lines of business (note: coverage for specimen collection for MassHealth members ended on March 31, 2022). HCPCS codes G2023 and G2024 are temporary codes that were created to support COVID-19 diagnostic testing solely during the COVID–19 PHE.

For documentation additional information on flexibilities authorized by CMS during the COVID-19 PHE, see Laboratories: CMS Flexibilities to Fight COVID-19, available at: https://www.cms.gov/coronavirus-waivers.

Specimen Collection for MassHealth ACO, NaviCare and Summit ElderCare plan members (HCPCS codes G2023 and G2024)*

In accordance with MassHealth Managed Care Entity (MCE) Bulletin 29 and MassHealth All Provider (AP) Bulletin 294, effective for dates of service on or after March 12, 2020, Fallon Health will reimburse G2023 or G2024 for COVID-19 specimen collection for MassHealth ACO, NaviCare and Summit ElderCare members when billed by a physician, acute outpatient hospital, community health center, family planning agency or clinical laboratory. COVID-19 specimen collection is payable when billed separately and when billed with other services, including office, outpatient and clinic visits (e.g., an E& M or T1015), and/or laboratory testing of COVID-19 specimens.

For MassHealth ACO members only*

In accordance with MassHealth MCE Bulletin 40 and MassHealth All Provider Bulletin 296, effective for dates of service on or after May 22, 2020, eligible providers may attach modifier CG to HCPCS code G2023 or G2024 for specimen collection and receive additional reimbursement, provided they do not also bill an office, outpatient or clinic visit (e.g., an E& M or T1015) relating to the COVID-19 testing. This modifier can be applied, when in addition to collecting the specimen, the provider:

1. Has a qualified health care professional present at the specimen collection site available to order medically necessary COVID-19 tests, and
2. Ensures that the test results and any follow-up counseling are provided to the member, either directly or through the member's ordering provider.

* Sunset of reimbursement for COVID-19 specimen collection by MassHealth

Through Managed Care Entity Bulletins 29 and 40, and All Provider Bulletin 294 and 296, MassHealth implemented numerous flexibilities to allow providers to separately bill and receive payment for COVID-19 specimen collection. These flexibilities applied to dates of service beginning March 12, 2020, for the duration of the state of emergency declared by Executive Order No. 591. The state of emergency terminated at 12:01 a.m. on June 15, 2021. Accordingly, Managed Care Entity Bulletin 29 and All Provider Bulletin 294 expired at that time.

Through Managed Care Entity Bulletin 70 and its predecessor bulletins and All Provider Bulletin 325 and its predecessor bulletins, MassHealth implemented numerous flexibilities to allow providers to separately bill and receive payment for COVID-19 specimen collection and certain other services following the expiration of the state of emergency. By the terms of All Provider Bulletin 325 and Managed Care Entity Bulletin 70, these flexibilities were scheduled to expire on December 31, 2021. Through All Provider Bulletin 334 and Managed Care Entity Bulletin 78, MassHealth is extended the COVID-19 specimen collection–related flexibilities described in All Provider Bulletin 325 and Managed Care Entity Bulletin 70 through March 31, 2022.

In accordance with MassHealth Managed Care Entity Bulletin 70 and All Provider Bulletin 325, Fallon Health will not reimburse COVID-19 specimen collection effective for dates of service on or after April 1, 2022.

Hospital Outpatient Department Symptom Assessment and Specimen Collection (HCPCS code C9803) for Medicare Advantage, NaviCare, Summit ElderCare, Fallon Health Weinberg PACE and commercial plan members

Emergency waiver authority permits Medicare payment for specimen collection for COVID-19 diagnostic testing during the federal PHE for COVID-19. CMS created temporary HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), any specimen source) in Interim Final Rule CMS-5531-IFC for COVID-19 symptom assessment and specimen collection by hospital outpatient departments, effective for dates of service on or after March 1, 2020. HCPCS code C9803 is conditionally packaged under the OPPS when billed with a separately payable primary service in the same encounter. The OPPS will only make separate payment to a hospital when HCPCS code C9803 is billed without another primary covered hospital outpatient service. The OPPS also will make separate payment for CPT code C9803 when it is billed with a COVID-19 diagnostic laboratory test with a status indicator of ''A'' on Addendum B of the OPPS.

Effective effective for dates of service on or after March 1, 2020 and continuing for the duration of the federal PHE for COVID-19, Fallon Health will reimburse hospital outpatient departments for COVID-19 symptom assessment and specimen collection using HCPCS code C9803, for Medicare Advantage, NaviCare, Summit ElderCare and commercial plan members when specimen collection (C9803) is billed separately or with a COVID-19 diagnostic laboratory test. Specimen collection will not be separately reimbursed when reported by the same provider on the same day as a separately payable primary service including but not limited to an evaluation and management (E & M) service, emergency, urgent care or clinic visit for the same member. This includes face-to-face, telehealth, or telephonic services.

The federal PHE for COVID-19 expires at the end of the day on May 11, 2023. Effective for dates of service on or after May 12, 2023, HCPCS codes C9803 is no longer payable by Fallon Health. HCPCS code C9803 is a temporary code that was created to support COVID-19 diagnostic testing solely during the COVID–19 PHE.

For documentation and additional information on flexibilities authorized by CMS during the COVID-19 PHE, see Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs: CMS Flexibilities to Fight COVID-19, available at: https://www.cms.gov/coronavirus-waivers.

Symptom Assessment and Specimen Collection by Physicians and Qualified Nonphysician Practitioners for Medicare Advantage, NaviCare, Summit ElderCare and Fallon Health Weinberg and commercial plan members

Emergency waiver authority permits Medicare payment for specimen collection for COVID-19 diagnostic testing during the federal PHE for COVID-19. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an office/ outpatient E/M visit (CPT codes 99202– 99205, 99211–99215). CMS authorized the use of CPT 99211 to be billed for COVID-19 symptom assessment and specimen collection by physicians and qualified nonphysician practitioners in Interim Final Rule CMS-5531-IFC effective March 1, 2020 and continuing for the duration of the federal PHE for COVID-19. CPT 99211 can be used to bill for COVID-19 symptom assessment and specimen collection for both new and established patients. Please note that a physician or qualified nonphysician practitioner cannot bill for services provided by clinical staff unless those staff meet all the requirements to furnish services “incident to” services, as described in 42 CFR 410.26 and further described in section 60 of Chapter 15 Covered Medical and other Health Services in the Medicare Benefit Policy Manual. CMS also adopted an interim policy to permit the direct supervision requirement to be met through virtual presence of the supervising physician or practitioner using interactive audio and video technology for the duration of the public health emergency (CMS-1744-IFC). For the duration of the public health emergency, Medicare will permit the use of CPT 99211 for assessment and specimen collection for new patients as well as established patients.

Effective for dates of service on or after March 1, 2020 and continuing for the duration of the federal PHE for COVID-19, Fallon Health will reimburse physicians and qualified nonphysician practitioners for symptom assessment and specimen collection for COVID-19 diagnostic testing for Medicare and commercial plan members using CPT code 99211.

When billing CPT 99211 for symptom assessment and specimen collection for COVID-19 diagnostic testing for Medicare and commercial members, please assign one of the following ICD-10-CM diagnosis codes to CPT 99211 to ensure member cost-sharing is waived:

- Diagnosis code Z20.828, Contact with and (suspected) exposure to other viral communicable diseases, or
- Diagnosis code Z03.818, Encounter for observation for suspected exposure to other biological agents ruled out.

The federal PHE for COVID-19 expires at the end of the day on May 11, 2023. Effective for dates of service on or after May 12, 2023, CPT code 99211 is no longer reimbursed by Fallon Health COVID-19 symptom assessment and specimen collection. After the PHE, the usual requirements for billing level 1 Evaluation and Management visits (CPT code 99211) apply.

For documentation and additional information on flexibilities authorized by CMS during the COVID-19 PHE, see Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19, available at: https://www.cms.gov/coronavirus-waivers.

Urine Drug Testing

Urine drug testing should not routinely include a panel of all drugs prone to abuse. Tests should be focused on detecting the specific drugs of concern, and frequency of testing should be at the lowest level to detect presence of drugs bearing in mind the reasons for which the drug is being screened.

Presumptive

Consistent with the CMS rule, as of 1/1/2017, codes 80305 – 80307 should be used for presumptive testing. A maximum of one of these presumptive codes may be billed for each date of service.

The Plan will not reimburse presumptive drug screening greater than (20) units within a calendar year beginning January 1st of each year per member, as it exceeds clinical guidelines.

Confirmatory

Consistent with the CMS rule, as of 1/1/2017, codes G0480 – G0483 and G0659 should be used for confirmatory testing. A maximum of one of these confirmatory codes may be billed for each date of service.

The Plan will not reimburse confirmatory drug screening greater than (20) units within a calendar year beginning January 1st of each year per member, as it exceeds clinical guidelines.

Confirmatory testing will only be reimbursed when a drug has returned positive or the result is negative and the negative finding is inconsistent with the patient's medical history, and only when confirmation is requested by the ordering practitioner.

- Single drug class testing on the same date of service as a drug screening panel test performed by multiple drug classes by high complexity test method (e.g. immunoassay, enzyme assay, per patient encounter). These include but are not limited to testing exclusively for barbiturates, opiates, ethanol, or benzodiazepine classes.
- Quantitative assays should not be routinely reported for drug classes being tested as part of the drug screen service.

In regards to panel testing, if any tests included in the panel do not meet criteria the entire panel may be denied. Custom panels routinely requested that are unspecific to the member's clinical condition will not be reimbursed.

Advanced Diagnostic Laboratory Tests (ADLTs) under the Medicare Clinical Lab Fee Schedule

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) established a new subcategory of clinical diagnostic laboratory tests known as advanced diagnostic laboratory tests (ADLTs) with separate reporting and payment requirements. To be an ADLT under CMS regulations, the test must be covered under Medicare Part B, offered and furnished only by a "single laboratory," and not sold for use by any other laboratory except that "single laboratory" or a "successor owner." In addition, the test must meet one of the following criteria (A or B):

Criterion (A): The test:

1. Is an analysis of multiple biomarkers of DNA, RNA, or proteins;
2. When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or respond to a particular therapy or therapies;
3. Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
4. May include other assays.

Criterion (B): The test is cleared or approved by the FDA. Laboratories requesting ADLT status under Criterion (B) are required to submit documentation of premarket approval or premarket notification from the FDA.

In order for a test to be an ADLT, the test must be covered under Medicare Part B. Evidence of Medicare Part B coverage must include the date the test was first covered and at least one of the following items:

- Payment for the test by a MAC based on a reasonable and necessary determination for the test (for example, a copy of the remittance notice from the MAC);
- Coverage determination under the Molecular Diagnostic Services (MolDX) program;
- A local coverage determination (LCD) for the test;
- A national coverage determination (NCD) for the test;
- Other documentation that demonstrates Medicare Part B coverage.

CMS Application process:
Laboratories must submit an application to CMS to request ADLT status for a laboratory test. ADLT status determinations for laboratory tests is conducted by CMS on a quarterly basis. Through the application process, CMS will approve a test as either an existing ADLT or a new ADLT.

- An existing ADLT is a laboratory test for which ADLT status has been granted by CMS and payment for the test has been made under the Medicare CLFS prior to January 1, 2018.
- A new ADLT is a laboratory test for which ADLT status has been granted by CMS and for which payment has not been made under the Medicare CLFS prior to January 1, 2018. The payment methodology is different before, during, and after the new ADLT initial period.

CMS Payment Methodology for New ADLTs
New ADLTs will be paid at a rate equal to their actual list charge during a New ADLT Initial Period of three calendar quarters. The New ADLT Initial Period begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made for the test or the date ADLT status is granted by CMS. There is no “New ADLT Initial Period” for existing ADLTs.

After the New ADLT initial period, payment amounts for new ADLTs will be determined using the weighted median of private payor rates determined for the test, based on data reported by laboratories during the New ADLT Initial Period. Once a new ADLT is assigned its own unique HCPCS code, meaning one that describes only a single test, the HCPCS code and payment amount will be included on the Medicare Clinical Lab Fee Schedule.

The *List of CMS Approved ADLTs* and additional information regarding these tests is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations#ADLT_tests.

ADLT claims submission process:
When billing for ADLTs for Medicare members, providers must use the unique CPT/HCPCS code assigned to the test. If the ADLT does not have a unique CPT/HCPCS code on the date of service, the provider must report the appropriate unlisted code and the DEX Z-code assigned to the test by the MolDX program. The test specific DEX Z-Code is submitted in Loop 2400, SV101-7 (5010A1-837P) or SV202-7 (5010A1-837I) claim line detail field.

At this time (October 1, 2022), there is one ADLT that has not been assigned a unique CPT/HCPCS code on the *List of CMS Approved ADLTs*. This test is Signatera by Natera, Inc. Signatera is a Next Generation Sequencing-based test for minimal residual disease (MRD) testing for solid tumor cancers.

At this time, there are six versions of Signatera by Natera, Inc. and all are billed with CPT code 81479. The New ADLT Initial Period for Signatera was from 7/1/2021 to 3/31/2022.

1. Signatera Recurrence Monitoring Whole Exome Design and Plasma Test is billed with DEX Z-Code Identifier ZB8DC.
2. Signatera Recurrence Monitoring Single Plasma Test is billed with DEX Z-code Identifier ZB8DD
3. Signatera Whole Exome and Plasma Series Bundle for Molecular Residual Disease is billed with DEX Z-Code Identifier Z0085

4. Signatera Recurrence Monitoring Plasma Test, Bundle is billed with DEX Z-Code Identifier Z0086
5. Signatera Recurrence Monitoring Bespoke Assay Design (from CGP) + Plasma Test is billed with DEX Z-Code Identifier Z0014
6. Signatera Bespoke Assay Design (from CGP) + Plasma Series Bundle for Molecular Residual Disease is billed with DEX Z-Code Identifier Z0015

Medicare Administrative Contractor instructions for billing for MRD testing by Next Generation Sequencing that measures multiple analytes are to use CPT code 81479 with 1 unit of service and with the assigned DEX Z-code (**Palmetto GBA Billing and Coding: MOLDX: Minimal Residual Disease Testing for Solid Tumor Cancers A58376**, Effective Date 12/26/2021).

ADLT reimbursement:
Reimbursement for covered ADLTs for Medicare members will be made at the payment amount assigned to the test by CMS on the date of service. In general, the date of service for clinical diagnostic laboratory tests is the date of specimen collection.

Reminder: Fallon Health requires prior authorization for genetic testing. The ordering physician must obtain prior authorization (approval in advance) for genetic testing from Fallon Health before testing is performed.

Molecular Pathology, Microdissection (88380, 88381)

Molecular pathology procedures are medical laboratory procedures involving the analyses of nucleic acid (i.e., DNA, RNA) to detect variants in genes that may be indicative of germline (inherited) or somatic (acquired) conditions, or to test for histocompatibility antigens (e.g., HLA). Code selection is typically based on the specific gene(s) that is being analyed. The molecular pathology coes include all analytical services performed in the test (e.g., cell lysis, nucleic acid stabilization, extraction, digestion, amplification and detection. Additional procedures that are required prior to cell lysis, for example, microdissection (CPT 88380, 88381) may be reported separately and utilization must be clearly supported based on the application and clinical utility. Such claims may be subject to pre- or post-payment medical review.

- Scraping tumor off an unstained slide, if performed, is included in the payment for a molecular pathology procedure (e.g., CPT codes 81105-81408). A provider/supplier may not report microdissection (CPT codes 88380 or 88381) for this process.
- CPT codes 88380 and 88381 describe microdissection procedures and include sample preparation of microscopically identified target cells. Microdissection of “normal tissue” to compare to target tumor tissue is not separately reportable as an additional unit of service. Comparison to “normal tissue” is a necessary component of the test since an interpretation of the tumor tissue cannot be rendered without it.

No payment is made for CPT 88380 or 88381 to hospitals reimbursed under the Medicare hospital outpatient prospective payment system. Under this reimbursement methodology, payment for CPT 88380 and 88381 is packaged into the payment for other services (SI = N).

HCPCS codes G0306, G0307

HCPCS codes G0306 and G0307 were established by Medicare in 2004 to permit continued billing of complete CBC (with or without differential) without a platelet count. HCPCS G0306 and G0307 are covered for Medicare plan members only (Medicare Advantage, NaviCare and PACE). Note HCPCS G0306 and G0307 are not payable on the same date of service as CPT 85025 or 85027.

Referral/notification/prior authorization requirements

The ordering physician is required to obtain prior authorization for:

- Unlisted CPT and HCPCS codes.
- The applicable laboratory codes found on the *List of Procedures Requiring Preauthorization*, which is located in the *Managing Patient Care* section of the *Provider Manual*, under *PCP Referral and Plan Preauthorization Process.*

- Genetic testing – as described in the *Genetic Testing Medical Policy* located in the *Provider Manual* in the *Medical Policy* section.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as approved by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be approved by the interdisciplinary team.

Billing/coding guidelines

- Services should be submitted using industry standard forms or HIPAA-standard electronic formats.
- The referring or ordering physician's name must be submitted in the appropriate place on the claim form (i.e., Box 17 on CMS form).
- Use panel codes only when all individual tests included in the panel have been performed. If other tests are performed, together with those specified in the panel, bill separately in addition to the panel code.
- For laboratory or pathology services that have a professional and technical component, the appropriate TC or 26 modifier is required to be listed first.
- Use modifier 91 to indicate that laboratory test(s) were repeated to obtain subsequent (multiple) test results. This modifier may only be used for laboratory test(s) performed more than once on the same day on the same patient.
- Do not use modifier 91 when laboratory tests are repeated due to specimen mishandling, insufficient sampling, or re-confirmation. This modifier may not be used when other codes(s) describe a series of test results (e.g., glucose tolerance tests, evocative/suppression testing).
- Use modifier QW for all CLIA-waived lab tests performed in a physician's office.
- Requests for laboratory services must be in writing and include the following information:
    - Date of the request.
    - The name or any other means of identifying the member to be tested.
    - The legible name and address of the authorized prescriber.
    - The name of the specific laboratory tests to be performed.
    - For standing orders, the frequency for performing each laboratory test.
    - For standing orders, the duration and maximum number of times each laboratory test is to be performed.
    - A statement by the authorized prescriber that the testing is required as part of the member's medical or drug treatment plan.

Pathology services associated with routine screening colonoscopies
In accordance with the clarification issued by the Department of Labor regarding compliance with the Affordable Care Act, Fallon Health will remove cost-sharing from pathology services associated with routine screening colonoscopies effective January 1, 2016. In order to allow these claims to process properly, the Pathologist should bill this service under CPT code 88305. In addition, a corresponding ICD-10 code from the following list must accompany the billing of 88305. Failure to submit a claim with the proper CPT and ICD-10 combination may result in cost-sharing for the member. This change only applies to routine screening colonoscopies. Cost-sharing may still apply to any other pathology performed related to other colonoscopies.

ICD-10 code	Description

C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
D12.0	Benign neoplasm of cecum
D12.1	Benign neoplasm of appendix
D12.2	Benign neoplasm of ascending colon
D12.3	Benign neoplasm of transverse colon
D12.4	Benign neoplasm of descending colon
D12.5	Benign neoplasm of sigmoid colon
D12.6	Benign neoplasm of colon, unspecified
D12.7	Benign neoplasm of rectosigmoid junction
D12.8	Benign neoplasm of rectum
D12.9	Benign neoplasm of anus and anal canal
K62.0	Anal polyp
K62.1	Rectal polyp
K63.5	Polyp of colon
Z12.11	Encounter for screening for malignant neoplasm of colon

Molecular testing
DEX Z-Code™ Identifiers are unique 5 digit alpha-numeric codes assigned to molecular diagnostic tests and laboratory developed tests by the MolDX® Program administered by Palmetto GBA. Effective January 1, 2017 for Independent Laboratory claims and April 1, 2017 for Hospital-based lab claims, the Provider is required to submit the applicable DEX Z-Code™ Identifier with claims for molecular diagnostic tests and laboratory developed tests. For additional information on DEX Z-Code™ Identifiers: https://www.dexzcodes.com/.

Ordering/Referring Provider NPI
Effective December 1, 2020, all claims for items and services that are a result of an order or referral must include the applicable qualifier, ordering/referring provider's name, and valid NPI.

On a CMS-1500 claim form (02-12) or electronic equivalent:

- Report the name of the referring or ordering provider in Item 17 and the appropriate qualifier to the left of the dotted line on the CMS-1500 (Version 02/12) claim form: DN (referring provider) or DK (ordering provider); report the name of the referring or ordering provider in 2310A Referring Provider Loop, segment NM1 Referring Provider Name (Segment NM101 (Qualifier), Segment NM103-NM105 (Name)).
- No information should appear in Item 17a. Item 17a was formerly used to report the Unique Physician Identification Number (UPIN), which is no longer used -- leave this item blank.
- Report the National Provider Identifier (NPI) of the referring/ordering provider in Item 17b or the 837P 2310A Referring Provider Loop, segment NM109 [NPI].

Qualifier	Provider Role
DN	Referring Provider
DK	Ordering Provider

Place of service

This policy applies to services rendered in all settings.

Excluded products

This policy does not apply to Fallon Health Weinberg MLTC as laboratory and pathology services are not covered under this plan.

Policy history

Origination date: 01/31/2001

Previous revision date(s): 04/16/2003, 03/31/2004, 03/30/2005, 03/15/2006, 01/31/2007, 05/09/2007, 09/30/2008, 01/01/2009
05/01/2012 - Added that genetic tests that are not prior authorized will not be reimbursed.
09/01/2012 - Added discussion about drug testing.
03/01/2013 - Added that The Plan will not reimburse qualitative drug screens for single (80101) or multiple (80100) drug classes and that it will reimburse drug screens billed with G0431 or G0434.
03/01/2014 - Added statement that automated labs billed with modifier 26 will not be reimbursed, reimbursement limits for urine drug testing, and documentation standards for laboratory requests.
11/01/2014 - Updated to reflect that policy applies to services rendered in all settings, updated the limit per 365 days for drug confirmation (CPT code 80102) to 20, and moved to new template.
07/01/2015 - Updated the reimbursement, referral/notification/prior authorization requirements, and billing/coding guideline sections.
01/01/2016 - Updated reimbursement section.
05/01/2016 - Updated reimbursement and billing/coding sections to reflect removal of cost-share from pathology services associated with routine screening colonoscopies and to replace deleted laboratory codes.
09/01/2016 - Added codes to the billing/coding guidelines section.
03/01/2017 - Updated the reimbursement section.
05/01/2017 - Added new code G0659 and molecular testing code requirement.

Connection date and details:	November 2017 – Updated the reimbursement section. January 2018 - Added limit of 20 presumptive urine drug screens per year, changed methodology of confirmatory drug screening limit from 365 days to calendar year beginning each January July 2018 – Added Saliva testing on the same date as urine screening to non-reimbursable services. July 2019 – Removed termed drug screening codes, add code T1015 to non-reimbursed with codes (36415), updated coverage of code 36416. April 30, 2020 – Updated with COVID-19 diagnostic testing and specimen collection fee for COVID-19 diagnostic testing. June 1, 2020 – Updated information related to COVID-19 antibody testing and specimen collection. June 26, 2020 – Updated information related to specimen collection. August 31, 2020 – Added CDC guidance related to antibody testing; added instructions for using CG modifier. October 2020 – Clarified that serologic testing for COVID-19 (e.g., CPT 86769) should be reported with a unit of one (1); Added requirement for ordering/referring provider's name, qualifier, and valid NPI. January 2022 – Reimbursement section updated to include information on Advanced Diagnostic Laboratory Tests. October 2022 – Added documentation related to sunset of reimbursement for COVID-19 specimen collection for MassHealth ACO members effective March 31, 2022; updated subsection on reimbursement for ADLTs; added subsection on billing for microdissection (CPT 88380, 88381). January 2023 – Reimbursement section updated to include coverage information for G0306, G0307. April 2023 – Updated reimbursement for COVID-19 specimen collection for Medicare and commercial plan members for dates of service on or after the end of the federal Public Health Emergency for COVID-19.

The criteria listed above apply to Fallon Health Plan and its subsidiaries. This payment policy has been developed to provide information regarding general billing, coding, and documentation guidelines for The Plan. Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply and this policy is not a guarantee of payment. The Plan reserves the right to apply this payment policy to all of The Plan companies and subsidiaries. The Plan routinely verifies that charges billed are in accordance with the guidelines stated in this payment policy and are appropriately documented in the medical records. Payments are subject to post-payment audits and retraction of overpayments.