

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

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 diagnostic testing. Upon expiration of the State of Emergency, Fallon Health will evaluate the continued need for flexibilities related to COVID-19.

- At this time, two types of COVID-19 diagnostic testing 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. Molecular tests are nucleic acid amplification tests and may also be known as PCR tests.
- 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 must support 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.

Code	Description	Coverage	Coverage Effective Date
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	Use for the CDC’s 2019 Novel Coronavirus diagnostic test kit.	2/4/2020
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	Use for validated, in-house-developed COVID-19 diagnostic tests.	2/4/2020
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	When deciding which code to assign for COVID-19 testing, use 87635 for tests performed using the amplified probe technique, and U0002 for tests performed using other methodologies not described by CPT code 87635.	3/13/2020
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory	Use for tests that would otherwise be identified by	4/14/2020

	syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R.	CPT code 87635 but for being performed with these high throughput technologies (CMS-Ruling 2020-1-R).	
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R.	Use for tests that would otherwise be identified by U0002 but for being performed with these high throughput technologies (CMS-Ruling 2020-1-R).	4/14/2020

Coronavirus (COVID-19) Antibody Testing

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.

Effective June 1, 2020, Fallon Health will require prior authorization for COVID-19 antibody testing. In updated guidance issued May 11, 2020, the U.S. Food and Drug Administration (FDA) recommends that because antibodies are part of the human body's immune response to exposure and not the virus itself, antibody testing should not be used to diagnose or exclude COVID-19 infection.¹

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 (EUA). To date, the FDA has authorized one EUA for an antibody test that is intended for use by clinical laboratories.

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. For the duration of the State of Emergency, Fallon Health is waiving member cost-sharing (copayments, coinsurance or deductibles) for medically necessary COVID-19 testing.

Code	Description	Coverage	Coverage Effective Date
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Use for COVID-19 antibody testing using single-step method.	4/10/2020

¹ U.S. Food and Drug Administration. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised); Issued May 11, 2020.

86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Use for COVID-19 antibody testing using multiple-step method.	4/10/2020
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Specimen Collection for COVID-19 Diagnostic Testing

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. Upon expiration of the State of Emergency, Fallon Health will evaluate the continued need for flexibilities related to COVID-19.

Independent Laboratory Specimen Collection (HCPCS codes G2023 and G2024)

CMS created two new HCPCS codes for specimen collection by Independent Laboratories in the 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.

These codes are covered for all lines of business when a trained laboratory professional collects the 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.

The CMS definition of “homebound” was also expanded under the Interim Final Rule (CMS-1744-IFC) to include:

- (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.”

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 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.

Hospital Outpatient Department Specimen Collection (HCPCS code C9803) for Medicare Advantage, NaviCare, Summit ElderCare and commercial plan members

The services described by 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) are services that are integral and ancillary to other primary services, such as emergency room or clinic visits (this includes face-to-face, telehealth or

telephonic services), Effective effective for dates of service on or after March 1, 2020 Fallon Health will reimburse hospital outpatient departments for COVID-19 specimen collection (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 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.

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

Typically, specimen collection is part of (bundled with) an office/outpatient E & M service (CPT 99212-99215). Effective for dates of service on or after March 1, 2020, physicians and nonphysician practitioners (NPPs) will be reimbursed for assessment of symptoms and specimen collection for COVID-19 diagnostic testing for Medicare Advantage and NaviCare plan members using CPT code 99211. Please note that a physician or NPP 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 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.

For Medicare Advantage, NaviCare and members presenting for assessment of symptoms and specimen collection for suspected COVID-19, Please assign one of the following ICD-10-CM diagnosis codes to CPT 99211:

- 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.

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.

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.

Billing/coding guidelines

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:

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

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.

- 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.

Molecular testing:

McKesson Z-Code™ identifiers are unique 5 digit alpha-numeric codes assigned to specific Molecular tests based on the uniqueness of the specific test. 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 Z-Code™ with a molecular testing claim.

Place of service

This policy applies to services rendered in all settings.

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.

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.