Laboratory and Pathology Payment Policy

Applicability

This Policy applies to the following Fallon Health products:
☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP
☒ NaviCare SCO (Medicaid-only)
☒ Summit Eldercare PACE
☒ Fallon Health Weinberg PACE
☒ Community Care (Commercial/Exchange)

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.

Reimbursement

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

The Plan reimburses:

- 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.
- Routine screening labs (for additional information refer to Preventive Services Payment Policy).
- Clinical laboratory tests, when performed by a technician under physician supervision.
- Laboratory and pathology consultant opinions when deemed medically necessary.
- CPT 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 testing.
- 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
- 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 does not reimburse CPT 36415 (collection of venous blood by venipuncture) separately and/or when billed along with an

E&M office visit (99202-99205; 99211-99215), preventive medicine service (99381-99387; 99391-99397), pathology and laboratory CPT codes 80000-89999, and T1015 (Clinical Visit).

- The Plan does not separately reimburse CPT 36591 (collection of blood specimen from a completely implantable venous access device) and/or CPT 36592 (collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified) when billed along with CPT 96360-96379 (IV hydration/infusion services).
- Saliva drug screening when performed on the same date of service as urine drug screening.
- The Plan does not separately reimburse CPT 36416 (collection of capillary blood specimen e.g., finger, heel, ear stick).
- The Plan does not reimburse consumer-initiated lab testing. Consumer-initiated lab testing refers to the practice whereby a consumer initiates a request for a laboratory test through a website or online platform. Consumer-initiated lab testing is not reimbursed even when a physician affiliated with the lab provides oversight.

COVID-19 diagnostic testing for Community Care members

Fallon Health covers medically necessary COVID-19 diagnostic testing for symptomatic individuals, for those individuals identified as close contacts of persons with COVID-19 by state or local health officials, and for asymptomatic individuals under circumstances defined by guidelines established by the state's Secretary of Health and Human Services, the Department of Public Health, or federal COVID-19 guidance (DOI Bulletin 2021-08).

COVID-19 diagnostic testing must be ordered by a plan provider, in relation to a covered office visit.

COVID-19 diagnostic testing is covered without member cost-sharing (copayments, coinsurance or deductibles), at both in-network and out-of-network providers in accordance with Section 70 of Chapter 260 of the Acts of 2020.

The federal public health emergency due to COVID-19 ended on May 11, 2023 and recent IRS guidance may impact member cost sharing for COVID-19 testing and treatment.

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.

COVID-19 diagnostic testing for MassHealth ACO, NaviCare and Summit ElderCare PACE plan members

In accordance with MassHealth Managed Care Entity Bulletin 66 August 2021, the Plan will reimburse medically necessary, clinically appropriate COVID-19 lab tests ordered by a plan provider. Payable CPT codes are listed in Subchapter 6 of the Independent Clinical Lab Manual and in Subchapter 6 of the Acute Outpatient Hospital Manual.

In order to receive reimbursement, an independent clinical laboratory must be either contracted with the Plan or enrolled in MassHealth on the date of service.

When provided by an out-of-state, independent clinical lab, laboratory services are reimbursable only under the circumstances described in 130 CME 450.109; or if the Plan determines that the independent clinical lab services are not available from any laboratory contracted with the Plan or enrolled in MassHealth on the date of service.

COVID-19 diagnostic testing for Fallon Medicare Plus, Fallon Medicare Plus Central, NaviCare HMO SNP and PACE plan members

Laboratory tests for the diagnosis of COVID-19 that are ordered by a Plan provider are covered with no member cost-sharing.

COVID-19 antibody (serology) testing

Effective June 1, 2020, Fallon Health requires prior authorization for COVID-19 antibody (serology) testing. In guidance issued originally on February 29, 2020 and subsequently updated on March 16, May 4, May 11, 2020, November 15, 2021, September 27, 2022, and January 12,

2023, 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]

Regarding COVID-19 antibody (serology) testing, the FDA continues to recommend the following: Instructions for use and patient test reports for serology tests should include information that helps users and patients understand the test results, including the following:

- Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct (i.e., diagnostic) testing for SARS-CoV-2 is necessary.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Nothing in the FDA guidance is intended to impact or supersede CDC's recommendations regarding which patients should be tested for COVID-19 however and the CDC published Interim Guidelines for COVID-19 Antibody Testing (Updated as of December 16, 2022). The Interim Guidelines for COVID-19 Antibody Testing are archived for historical purposes and are no longer being updated.[2]

Antibody tests have public health value for monitoring and evaluating population levels of immunity, as well as clinical utility for patients.

- Antibody testing should not be used to determine whether someone is currently infected with SARS-CoV-2. Viral tests detect current infection.
- Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person.

Antibody tests are not recommended or authorized by the FDA to assess someone's immunity after COVID-19 vaccination or determine if they need to be vaccinated.

Antibody testing is not a replacement for virologic testing and should not be used to establish the presence or absence of acute SARS-CoV-2 infection.

Indications for antibody testing:

- Antibody tests can be used to aid in the diagnosis of multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A).

Antibody tests with very high sensitivity and specificity are preferred since they are more likely to exhibit high positive (probability that the person testing positive actually has antibodies) and negative predictive values (probability that the person testing negative actually does not have antibodies) when administered at least 3 weeks after the onset of illness.

Antibody tests can be used to monitor and evaluate population levels of immunity (although this is not a covered indication).

Antibody tests should not be used to:

- Diagnose current infection.**
- Determine if someone can return to work or school.
- Group people together in settings such as schools, dormitories, and correctional facilities; or to exempt someone from screening testing.
- Exempt a person who wears personal protective equipment (PPE) at work from following site-specific requirements

[1] U.S. Food and Drug Administration. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised); Issued January 12, 2023. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised.

[2] Centers for Disease Control and Prevention (CDC). Interim Guidellines for COVID-19 Antibody Testing (Updated December 16, 2022). Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html.

**Acute infection from SARS-CoV-2 is determined best by diagnostic testing using a nucleic acid amplification test (NAAT) or antigen test.

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 (serologic) 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.

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.

Serologic assays for COVID-19

- 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]

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 diagnostic testing for Community Care plan members

The federal public health emergency (PHE) for COVID-19 expired at the end of the day on May 11, 2023. As a result, coverage for specimen collection for COVID-19 diagnostic testing for Community Care plan members ended 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.

Independent laboratory specimen collection (HCPCS codes G2023 and G2024) for Medicare lines of business

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[3] Centers for Disease Control and Prevention (CDC). Interim Guidellines for COVID-19 Antibody Testing (Updated December 16, 2022). Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html.

[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/.

Effective for dates of service on or after May 12, 2023, HCPCS codes G2023 and G2024 are no longer payable by Fallon Health for Medicare lines of business. HCPCS codes G2023 and G2024 are temporary codes that were created to support COVID-19 diagnostic testing solely during the COVID–19 PHE. HCPCS codes G2023 and G2024 were terminated on May 11, 2023.

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)

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 Community Care plan members

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 Community Care plan members

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.

The Plan does not cover or reimburse urine drug testing that is performed without a clear treatment role and decision making response to both a positive and negative result.

Presumptive drug testing
Consistent with CMS, as of 1/1/2017, CPT codes 80305, 80306, and 80307 should be used for presumptive drug testing. A maximum of one of these presumptive codes may be billed for each date of service.

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

CPT codes 80305-80307 include specimen validity testing, when performed. If a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed.

Definitive drug testing
Consistent with CMS, as of 1/1/2017, HCPCS codes G0480, G0481, G0482, and G0483 and G0659 should be used for definitive drug testing, also known as confirmatory drug testing. A maximum of one of these definitive/confirmatory codes may be billed for each date of service.

Note: G0659 is not payable for MassHealth ACO members.

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

Definitive/confirmatory drug 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.

HCPCS codes G0480, G0481, G0482, and G0483 and G0659 include specimen validity testing, when performed. If a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed.

Specimen validity testing
HCPCS codes G0480-G0483 and G0659 and CPT codes 80305-80307 include specimen validity testing, when performed. If a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing must not be billed separately.

Source: MLN Matters Proper Coding for Specimen Validity Testing Billed in Combination with Drug Testing SE18001. Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE18001.pdf.

Claim Edit for Definitive Drug Testing Billed on the Same Date of Service as Presumptive Drug Testing
MassHealth does not pay for definitive and presumptive testing/screening on the same date of service (DOS), as noted in MassHealth Transmittal Letter LAB-50 (Updated) March 2020 and MassHealth Transmittal Letter PHY-152 (July 2017).

Consistent with MassHealth, Fallon Health implemented a claim edit that will deny definitive drug testing (G0480, G0481, G0482 and G0483) billed on the same date of service as presumptive

drug testing (CPT 80305, 80306 and 80307) effective for dates of service on or after July 1, 2023. The claim edit applies to claims for MassHealth ACO members only.

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.

<u>CMS Application process</u>

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.

<u>CMS Payment Methodology for New ADLTs</u>

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/payment/fee-schedules/clinical-laboratory-fee-schedule/adlt-information.

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.

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 (CPT 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.

Laboratory NCDs

The Center for Medicare & Medicaid Services (CMS) has developed 23 NCDs for clinical diagnostic laboratory services. These NCDs are in Sections 190.12 - 190.34 of the NCD Manual. The NCDs are applicable to services billed under Part B regardless of the entity providing the services. The NCDs are binding on Medicare Advantage plans when processing claims for clinical diagnostic laboratory services on an outpatient basis. Whereas most NCDs describe covered indications and limitations in narrative form, laboratory NCDs list specific ICD-10 codes that fall into 3 categories:

- Covered ICD-10 codes
- Non-covered ICD-10 codes
- Codes That Do Not Support Medical Necessity.

(*Source:* Medicare Claims Processing Manual, Chapter 16, Section 120.2 - Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services)

Effective for dates of service on and after 12/01/2024, Fallon Health is implementing laboratory NCD edits so that claims subject to one of the 23 NCDs are processed in accordance with the NCD. These edits will apply to claims for Fallon Medicare Plus/Plus Central, NaviCare, Summit ElderCare PACE, Fallon Health Weinberg PACE and Community Care members.

On a quarterly basis, CMS updates the NCD edit module as necessary for ministerial coding changes and to implement the NCD decisions described above. Fallon Health's laboratory NCD edits will be updated accordingly.

Alphabetical list of current NCDs:
190.25 Alpha-fetoprotein
190.15 Blood Counts
190.20 Blood Glucose Testing
190.26 Carcinoembryonic Antigen
190.19 Collagen Crosslinks, Any Method
190.24 Digoxin Therapeutic Drug Assay
190.34 Fecal Occult Blood Test
190.32 Gamma Glutamyl Transferase
190.21 Glycated Hemoglobin/Glycated Protein
190.33 Hepatitis Panel/Acute Hepatitis Panel
190.27 Human Chorionic Gonadotropin
190.14 Human Immunodeficiency Virus (HIV) Testing (Diagnosis)
190.13 Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)
190.23 Lipid Testing
190.16 Partial Thromboplastin Time (PTT)
190.31 Prostate Specific Antigen
190.17 Prothrombin Time (PT)
190.18 Serum Iron Studies
190.22 Thyroid Testing
190.28 Tumor Antigen by Immunoassay (CA 125)
190.29 Tumor Antigen by Immunoassay (CA 15-3/CA 27.29)
190.30 Tumor Antigen by Immunoassay (CA 19-9)
190.12 Urine Culture, Bacterial

Before Submitting Claims

- Refer to the ICD-10 code lists for the applicable NCD: https://www.cms.gov/medicare/coverage/determination-process/basics/lab-ncds-icd-10.

The diagnosis code may be listed as primary or secondary, up to the fourth diagnosis code position. Diagnosis pointers field should be used for diagnosis code to indicate the related services performed. In cases where there are more than four diagnoses, we ask that providers prioritize the most relevant diagnoses to the procedures being billed.

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.

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.
January 2025 – Under Reimbursement, Laboratory services the plan does not reimburse, added lab tests ordered by a plan member through a website or online platform; updated COVID-19 Diagnostic Testing to reflect current coverage and reimbursement; removed outdated information about Signatera by Natera, Inc. under Advanced Diagnostic Laboratory Tests (ADLTs); added new section under Reimbursement for Laboratory NCDs.

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.