NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

New York State Medicaid Billing Guidance for COVID-19 Testing, Specimen Collection, and Therapeutics

Updates are highlighted in yellow

This article replaces the March 8, 2022 guidance titled *New York State Medicaid Billing Guidance for COVID-19 Testing, Specimen Collection and Therapeutics*, located at: https://www.health.ny.gov/health_care/medicaid/covid19/guidance_for_specimen_collection.htm

The services in this guidance document are currently reimbursable by NYS Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC) Plans. The fees below are specific to FFS.* For individuals enrolled in an MMC Plan, providers must check with the individual's MMC Plan for implementation details and billing guidance.

Laboratory Testing and Specimen Collection

Providers are reminded that Coronavirus (COVID-19) tests must be Food and Drug Administration (FDA)-approved or granted Emergency Use Authorization (EUA) through the FDA and in agreement with the level of complexity assigned by Wadsworth Laboratory to be eligible for reimbursement. COVID-19 test coverage for diagnostic and screening, including administration, must be consistent with the recommendations of the Centers for Disease Control and Prevention (CDC).

*The fees and effective dates below are current as of December 2021. Providers should periodically check their respective fee schedules in eMedNY for updates through the eMedNY "Provider Manuals" web page located at: https://www.emedny.org/ProviderManuals/index.aspx. Complexity levels are available on the CDC Clinical Laboratory Improvement Amendments (CLIA) "Test Complexities" web page at: https://www.cdc.gov/clia/test-complexities.html. Tests with EUA can be found on the FDA "Emergency Use Authorizations for Medical Devices" web page at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

Please note: COVID-19 test codes not outlined in this guidance are not covered.

Individuals with signs or symptoms of COVID-19 *should* have diagnostic testing. The CDC also recommends testing for the following individuals listed on the CDC "Overview of Testing for SARS-CoV-2, the virus that causes COVID-19" web page at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html. Providers are reminded that, "all persons being tested, regardless of results, should receive counseling on the continuation of risk reduction behaviors that help prevent the transmission of SARS-CoV-2 (e.g., wearing masks, physical distancing, and avoiding crowds and poorly ventilated spaces)" per CDC guidance. Additional information regarding risk reduction behaviors is available on the CDC COVID-19 "Protect Yourself" web page at: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

Providers who are already receiving payment from another source for COVID-19 testing, specimen collection, or monoclonal antibody infusion are not eligible for reimbursement from Medicaid for those tests, specimen collections, or infusions.

Reminder

Providers are prohibited from charging Medicaid members a co-payment or any cost sharing responsibility for specimen collection or testing to diagnose or screen for COVID-19, or for monoclonal antibody infusions to treat a SARS-CoV-2 infection. Check the emergency indicator box on claims submissions to waive cost sharing for these services.

Home-Based Testing

COVID-19 diagnostic tests with "at-home" sample collection are eligible for reimbursement when the criteria outlined in this guidance are met and the test is processed in a NYS-approved laboratory. Additionally, over-the-counter (OTC) FDA-authorized COVID-19 diagnostic and screening tests that provide "at-home" results are eligible for reimbursement during the public health emergency (PHE). For details on coverage of point-of-care tests with at-home results and no member cost sharing, please refer to the *New York State (NYS) Medicaid Pharmacy Policy and Billing Guidance for At Home COVID-19 Testing* at: https://health.ny.gov/health_care/medicaid/covid19/docs/guidance_home_covid_testing.pdf.

Molecular/Polymerase Chain Reaction (PCR) Tests

- **"87635"** (**effective 3/13/2020**) – Infectious agent detection by nucleic acid [deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)]; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (COVID-19), amplified probe technique.
  FFS fee =$51.31
- **"U0002"** (**effective 3/13/2020**) – 2019-nCoV Coronavirus, SARS-CoV-2/2019- nCov (COVID-19), any technique, multiple types, or subtypes (includes all targets), non-CDC.
  FFS fee = $51.31

High Throughput Tests

These tests utilize highly sophisticated throughput machines which require more intensive technician training (to ensure the role of extremely skilled personnel) and more time intensive processes (to assure quality). A high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day.

It is noted throughout the *CMS-Ruling 2020-1-R* document, located at: https://www.cms.gov/files/document/cms-2020-01-r.pdf, that **"U0003"** should identify tests that would otherwise be identified by CPT code **"87635"** but for being performed with these high throughput technologies. **"U0004"** should identify tests that would otherwise be identified by **"U0002"** but for being performed with these high throughput technologies. Additionally, neither **"U0003"** nor **"U0004"** should be used for tests that detect COVID-19 antibodies.

- **"U0003"** (**effective 4/14/2020**) – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) (COVID-19), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01- R.
  FFS fee = $100.00 (until 12/31/2020), $75.00 (as of 01/01/2021)
- **"U0004"** (**effective 4/14/2020**) – 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.
  FFS fee = $100.00 (until 12/31/2020), $75.00 (as of 01/01/2021)

In accordance with CMS, the fees for high throughput tests were reduced to $75.00 effective 01/01/2021. For dates of service on or after 01/01/2021, "U0005" may be billed as an add on code, when appropriate.

- **"U0005"** (**effective 01/01/2021**) – 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, CDC, or non-CDC, making use of high throughput technologies, completed within two calendar days from date of specimen collection (List separately in addition to either HCPCS code **"U0003"** or **"U0004"**) as described by CMS-2020- 01-R2.
  FFS fee = $25.00

Antigen Tests

- **"87426"** (**effective 06/25/2020**) – Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV-2, SARS-CoV-2 [COVID-19]).
  FFS fee = $45.23
- **"87811"** (**effective 10/06/2020**) – Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (COVID-19).
  FFS fee = $41.38

Multiplex Tests

- **"87428"** (**effective 11/10/2020**) – Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV-2, SARS- CoV-2 [COVID-19]) and influenza virus types a and b.
  FFS fee = $73.49
- **"87636"** (**effective 10/06/2020**) – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) (COVID-19) and influenza virus types a and b, multiplex amplified probe technique.
  FFS fee = $142.63
- **"87637"** (**effective 12/01/2021**) – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types a and b, and respiratory syncytial virus, multiplex amplified probe technique.
  FFS fee = $142.63

Antibody Tests

Please see the following link for information on antibody testing for NYS residents through the FDA "Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication" web page, located at: https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety.

- **"86328"** (**effective 4/10/2020**) – Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) (COVID-19].
  FFS fee = $45.23
- **"86769"** (**effective 4/10/2020**) – Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (COVID-19).
  FFS fee = $42.13

Specimen Collection (**effective 05/22/2020**): During the period of the emergency separate Medicaid reimbursement is available for specimen collection when this is the **only** service being performed. Providers billing for reimbursement of one of the above tests should not bill separately for specimen collection or report. These specimen collection components are included in reimbursement for the test. Providers/Clinics billing for other primary procedures for the same patient on the same day should not bill for specimen collection. For more information, please refer to the table below.

Federally Qualified Health Center (FQHC) and Non-FQHC COVID-19 Specimen Collection

Code	Description	Practitioner/ Clinic (Non-FQHC) Reimbursement	FQHC Reimbursement
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (COVID- 19)	$23.46	**Physician/PA/NP/Midwife**: Bill rate code **"4012"** when **specimen collection only** is provided. Off-site visit rate ($64.97 upstate/$72.73 downstate) will be paid. **Physician/PA/NP/Midwife**: Bill rate code **"4013" when specimen collection and E&M are provided**. Full PPS rate will be paid. **RN/LPN**: bill Procedure Code **"G2023"** (ordered ambulatory) **for specimen collection only**. A fee of $23.46 will be paid. All FQHC services in this chart are eligible for wrap payments

Clinics should bill the codes outlined in this guidance via the ordered ambulatory fee schedule. The COVID-19 test and specimen collection codes are not payable under ambulatory patient groups (APGs).

Skilled Nursing Facilities services are paid at a daily rate; therefore, separate reimbursement is not available.

Certified Home Health Agencies (CHHAs) should perform specimen collection as part of nursing visits when ordered for existing clients who receive nursing services. **CHHA specimen collection for homebound patients who do not receive nursing services** are eligible for reimbursement on or after **11/01/2020**. Please see the table below for details.

Certified Home Health Agency Specimen Collection

Rate Code	Descriptions	CHHA Patient Receiving Nursing Services	CHHA Patient Receiving Personal Care Services	Non-CHHA Homebound Patient	MLTC Patient Homebound Patient
4921	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from a homebound*** individual on behalf of a home health agency, any specimen source(s). Reimburses $25.46. For CHHA use only.	**X** Do not bill for specimen collection or travel. This should be done as part of a nurse visit and is included in the CHHA.	✓ CHHAs providing nursing staff to collect a specimen from their patient who only receives lower-level services may bill rate code **"4921"** and rate code **"4922"** (travel each way) if specimen collection is the only service performed.	✓ CHHAs providing specimen collection to a homebound individual who is not a CHHA patient may bill rate code **"4921"** and rate code **"4922"** (travel each way) if specimen collection is the only service performed.	✓ CHHAs providing specimen collection for homebound patients may bill rate code **"4921"** and rate code **"4922"** (travel each way) if specimen collection is the only service performed.

Rate Code	Descriptions	CHHA Patient Receiving Nursing Services	CHHA Patient Receiving Personal Care Services	NON-CHHA Homebound Patient	MLTC Patient Homebound Patient
4922	Travel for COVID-19 specimen collection. Reimburses $9.35 each way. For CHHA use only. When seeing multiple patients in the same location**, only bill one trip charge for the first Medicaid member visit	N/A	N/A	N/A	N/A

**The same location is defined as a vehicle is not necessary to travel between visits.
***Patients are considered "homebound" if they meet these two criteria. Patients either need supportive devices such as crutches, canes, wheelchairs, and walkers; special transportation; or help from someone else to leave their home because of illness or injury OR have a condition that makes leaving the home medically inadvisable. There must exist a normal inability to leave home; and leaving home must require a considerable and taxing effort.

If specimen collection occurs during a home visit where other scheduled services are being provided, a specimen collection fee and travel expense cannot be billed. Payment is included in the CHHA's per diem payment. CHHAs may bill for members who only receive lower-level services when a nurse is sent to collect the specimen (see chart above). This includes homebound patients enrolled in Managed Long-Term Care (LTC). COVID specimen collection should not be billed to Medicaid when a home health visit is covered by Medicare [either episodic or Low Utilization Payment Adjustment (LUPA)/fee-for-service payment].

Reporting Test Results

Providers are required to report SARS-CoV-2 diagnostic or serology testing results, including those using SARS-CoV-2 point-of-care tests, to the Commissioner of Health through the Electronic Clinical Laboratory Reporting System (ECLRS) within 24 hours. Required reporting includes all positive, negative, and indeterminate results, as well as test type, specimen source, and several demographic details of the individual tested. Results must be reported to ECLRS through HL7 or manual entry. Contact the ECLRS Help Desk by telephone at (866) 325-7743 or by email at eclrs@health.ny.gov, with any technical questions. For additional testing guidance from the CDC and Wadsworth Center please refer to the following links:

- NYS DOH "COVID-19 Testing" web page at: https://coronavirus.health.ny.gov/covid-19-testing
- CDC COVID-19 "Laboratories" web page at: https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html
- NYS DOH Wadsworth Center "Clinical Laboratory Evaluation Program" web page at: https://www.wadsworth.org/regulatory/clep
- NYS DOH Wadsworth Center "Physician Office Laboratory Evaluation Program" web page at: https://www.wadsworth.org/regulatory/polep

COVID-19 Therapeutics

Administration Codes, Payment Allowances and Effective Dates for COVID-19 Therapeutics

Code	Labeler Name	Procedure Name	Payment Allowances	Effective Date
Q0239	Eli Lilly	Injection, bamlanivimab, 700 mg	$0.00	11/10/2020 – 4/16/2021* EUA REVOKED
M0239	Eli Lilly	Intravenous infusion, bamlanivimab, includes infusion and post administration monitoring	$309.60	11/10/2020 – 4/16/2021* EUA REVOKED
Q0240	Regeneron	Injection, casirivimab and imdevimab, 600 mg	$0.00	7/30/2021 - 1/24/2022**
M0240	Regeneron	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses	$309.60	7/30/2021 - 1/24/2022**
Q0243	Regeneron	Injection, casirivimab and imdevimab, 2400 mg	$0.00	11/21/2020 - 1/24/2022**
Q0244	Regeneron	Injection, casirivimab and imdevimab, 1200 mg	$0.00	06/03/2021 - 1/24/2022**
M0243	Regeneron	Intravenous infusion, casirivimab and imdevimab, includes infusion and post administration monitoring	$309.60	11/21/2020 - 1/24/2022**
Q0245	Eli Lilly	Injection, bamlanivimab and etesevimab, 2100 mg	$0.00	2/09/2021 - 1/24/2022**
M0245	Eli Lilly	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring	$309.60	2/09/2021 - 1/24/2022**
Q0247	GSK	Injection, sotrovimab, 500 mg	@ Acquisition Cost per Invoice	5/26/2021 – 3/25/2022***
M0247	GSK	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring	$309.60	5/26/2021 - 3/25/2022***
Q0220	AstraZeneca	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, 300 mg	$0.00	12/8/2021
M0220	AstraZeneca	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only,includes injection and post administration monitoring	$105.35	12/8/2021
J0248	Gilead	Injection, remdesivir, 1 mg	@ Acquisition Cost per Invoice	1/21/2022 FDA-approved for outpatient use
96365	N/A	Infusion into a vein for therapy, prevention, or diagnosis, 1 hour or less	$35.00	N/A
Q0222	Eli Lilly	injection, bebtelovimab, 175 mg	$0.00	2/11/2022

Code	Labeler Name	Procedure Name	Payment Allowances	Effective Date
M0222	Eli Lilly	Intravenous injection, bebtelovimab, includes injection and post administration monitoring	$245.35	2/11/2022

The above infusion codes are reimbursable when provided in a hospital outpatient department or physician´s office. Providers should bill the codes outlined in this guidance via the ordered ambulatory and/or physician fee schedule. The payment allowances for the above infusion administration codes include all costs for any saline, any other fluid, and/or any other drug used for the infusion and any post-infusion patient monitoring.

Note: Providers should bill CPT code **"96365"** to be reimbursed for the infusion/injection when administering J0248 (remdesivir).

*EUA REVOKED by FDA for bamlanivimab (Eli Lilly - Q0239) **effective 4/16/2021** (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab)
EUA REVISED/No Longer Authorized by FDA for casirivimab and imdevimab, (Regeneron - Q0243, Q0244), and bamlanivimab and etesevimab,(Eli Lilly – Q0245) **effective 1/24/2022 (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron)
***EUA Revised/No Longer Authorized by FDA for sotrovimab (GSK – Q0247) **effective 3/25/2022** (FDA updates Sotrovimab emergency use authorization | FDA)

Claims will only be reimbursed for injections or infusions provided on dates of service within the effective dates noted in the table above.

Administration Codes, Payment Allowances and Effective Dates for COVID-19 Therapeutics Provided in a Home Setting

Code	Labeler Name	Procedure Name	Payment Allowances	Effective Date
M0241	Regeneron	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence – Subsequent repeat doses	$525.00	7/30/21 - 1/24/2022**
M0244	Regeneron	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence – 1st dose	$525.00	5/6/2021 - 1/24/2022**
M0246	Eli Lilly	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence	$525.00	5/6/2021 - 1/24/2022**
M0248	GSK	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring in the home or residence	$525.00	5/26/2021 – 3/25/2022***

Code	Labeler Name	Procedure Name	Payment Allowances	Effective Date
M0221	AstraZeneca	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, includes injection and post administration monitoring in the home or residence	$175.35	12/8/2021
M0223	Eli Lilly	Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence	$385.35	2/11/2022

Providers should bill the codes outlined in the table above via the physician fee schedule. The payment allowances for the above infusion administration codes include all costs for any saline, any other fluid, and/or any other drug used for the infusion and any post-infusion patient monitoring.

*EUA REVOKED by FDA for bamlanivimab (Eli Lilly - Q0239) **effective 4/16/2021** (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab).
EUA REVISED/No Longer Authorized by FDA for casirivimab and imdevimab, (Regeneron - Q0243, Q0244), and bamlanivimab and etesevimab,(Eli Lilly – Q0245) **effective 1/24/2022 (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron)
***EUA Revised/No Longer Authorized by FDA for sotrovimab (GSK – Q0247) **effective 3/25/2022** (FDA updates Sotrovimab emergency use authorization | FDA)

Claims will only be reimbursed for injections or infusions provided on dates of service within the effective dates noted in the above table.

Additional information on the COVID-19 Monoclonal Antibodies and their administration can be found at the following links:

- CMS "COVID-19 Vaccines and Monoclonal Antibodies" web page at: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies
- PHE "HHS Announces State/territory-coordinated Distribution System for Monoclonal Antibody Therapeutics" web page at: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/Update-13Sept21.aspx
- NYS DOH "COVID-19 Monoclonal Antibody (mAb) Therapeutics: Information for Providers" web page at: https://coronavirus.health.ny.gov/monoclonal-antibody-therapeutics

Questions and Additional Information:

- FFS claim questions should be directed to the eMedNY Call Center at (800) 343-9000.
- FFS coverage and policy questions should be directed to the Office of Health Insurance Programs (OHIP) Division of Program Development and Management (DPDM) by telephone at (518) 473-2160 or by email at FFSMedicaidPolicy@health.ny.gov.
- FFS Pharmacy coverage and policy questions should be directed to the Medicaid Pharmacy Policy Unit by telephone at (518) 486-3209 or by email at PPNO@health.ny.gov.
- MMC general coverage questions should be directed to the OHIP Division of Health Plan Contracting and Oversight (DHPCO) by email at covques@health.ny.gov or by telephone at (518) 473-1134.
- MMC reimbursement, billing, and/or documentation requirement questions should be directed to enrollee MMC Plans.
- MMC Plan contact information can be found in the eMedNY *New York State Medicaid Program Information for All Providers Managed Care Information* document at: https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_All_Providers_Managed_Care_Information.pdf.