COVID-19 HEALTH CARE PROVIDER UPDATE:
COVID-19 VACCINE UPDATES
MONOCLONAL ANTIBODY THERAPY
SEPTEMBER 10, 2021

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Mary Foote, MD, MPH

New York City Department of Health and Mental Hygiene

Our understanding of COVID-19 is evolving rapidly.
This presentation is based on our knowledge as of September 9, 2021, 5 PM.
OUTLINE

- GENERAL UPDATES
- VACCINE UPDATES
- MONOCLONAL ANTIBODY THERAPY
- QUESTIONS AND ANSWERS
GENERAL UPDATES

Mary Foote, MD, MPH
Health Systems Planning and Strategies Lead, COVID-19 Response
NYC Department of Health and Mental Hygiene
COVID-19, NYC, 3/1/2020-9/4/2021

Figures:
Daily COVID-19 cases, hospitalizations, and deaths

Recent Average Daily COVID-19 Test Percent Positivity, by NYC Zip Code

7-day percent positive

0.7% 9.7%

## SARS-CoV-2 Variants Observed in NYC

- Delta (B.1.617.2) is the most common variant in the city

<table>
<thead>
<tr>
<th>Variant</th>
<th>WHO Name</th>
<th>Classification</th>
<th>Last 4 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.617.2</td>
<td>Delta</td>
<td>Variant of Concern</td>
<td>98% of tested cases</td>
</tr>
<tr>
<td>B.1.1.7</td>
<td>Alpha</td>
<td>Variant of Concern</td>
<td>0% of tested cases</td>
</tr>
<tr>
<td>B.1.351</td>
<td>Beta</td>
<td>Variant of Concern</td>
<td>0% of tested cases</td>
</tr>
<tr>
<td>B.1.427</td>
<td>Epsilon</td>
<td>Variant of Concern</td>
<td>0% of tested cases</td>
</tr>
<tr>
<td>B.1.429</td>
<td>Epsilon</td>
<td>Variant of Concern</td>
<td>0% of tested cases</td>
</tr>
</tbody>
</table>

Data shown are as of 8/21/21

COVID-19 VACCINE UPDATES

Jane R. Zucker, MD, MSc, FIDSA
Branch Director, Vaccine Section
Assistant Commissioner, Bureau of Immunization
NYC Department of Health and Mental Hygiene
COVID-19 VACCINE ADMINISTRATION, NYC

- Over 10.9 million doses administered
- Of all NYC residents:
  - 67% received ≥ 1 dose
  - 60% fully vaccinated
- Of NYC residents aged ≥ 18 years:
  - 79% received ≥ 1 dose
  - 71% fully vaccinated

Data are reported by providers to the Citywide Immunization Registry and may be delayed. [https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page](https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page); updated 9/9/2021
# COVID-19 Vaccination Coverage in NYC by Race/Ethnicity

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>At least 1 dose</th>
<th>Fully vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian/Native Hawaiian or other Pacific Islander</td>
<td>80%</td>
<td>75%</td>
</tr>
<tr>
<td>Black</td>
<td>41%</td>
<td>36%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>56%</td>
<td>48%</td>
</tr>
<tr>
<td>Native American/Alaska Native</td>
<td>83%</td>
<td>74%</td>
</tr>
<tr>
<td>White</td>
<td>51%</td>
<td>48%</td>
</tr>
</tbody>
</table>

Vaccination Requirements in NYC

• As of August 17, people 12 and older are required to show proof they have received at least one dose of a COVID-19 vaccine for:
  • Indoor dining
  • Indoor fitness
  • Indoor entertainment

• Proof of vaccination
  • CDC vaccination card (or photo or photocopy)
  • NYC vaccination record or other official record from inside or outside the U.S. (or photo or photocopy; call 311 for assistance obtaining NYC records)
  • NYC COVID Safe App (upload photo of CDC vaccination card or other official record)
  • New York State Excelsior Pass (or Excelsior Pass Plus)
Pfizer-BioNTech COVID-19 Vaccine Approval

• Fully approved by U.S. Food and Drug Administration (FDA) and recommended by ACIP for individuals ≥ 16 years, as of August 31, 2021
  • Marketed as Comirnaty®
  • Continues to be available under emergency use authorization (EUA) for:
    • Individuals 12 to 15 years of age
    • Administration of a third dose in certain immunocompromised individuals
    • Vaccine available under EUA is the same vaccine/vial as the approved vaccine

• COVID-19 vaccination providers are responsible for adhering to all requirements outlined in CDC COVID-19 Vaccination Program Provider Agreement
  • Off-label use not recommended

https://www.fda.gov/media/151710/download
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-30.html
Third mRNA Vaccine Dose for Immunocompromised People

• People with some immunocompromising conditions have a reduced immune response to COVID-19 vaccination
  • A third dose of an mRNA vaccine can increase immune response
  • Safety profile of third dose among immunocompromised people is acceptable

• Third dose of Pfizer or Moderna COVID-19 vaccine is authorized and recommended for people with moderate to severe immunosuppression
  • EUA amended by U.S. FDA and recommended by ACIP, as of August 13, 2021

• Third dose vs. booster dose:
  • Third doses - given to increase immune response in people who may not have mounted an optimal response to initial vaccination
  • Booster doses - given to increase antibody levels that may have declined over time

Updated fact sheet for health care providers:
Pfizer - https://www.fda.gov/media/144413/download; Moderna - https://www.fda.gov/media/144637/download
CDC General Best Practices https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html
IDSA Policy Statement https://academic.oup.com/cid/article/58/3/e44/336537
Percent of subjects with antibody response after two mRNA COVID-19 vaccine doses by immunocompromising condition and study (n=63)

Studies that compared response after 1st and 2nd dose demonstrated less robust response after dose 1
Antibody measurement and threshold levels vary by study protocol

Evidence to Recommendations Framework: Additional doses of mRNA COVID-19 vaccines as part of a primary series for immunocompromised

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/02-COVID-Dooling-508.pdf
## Antibody Response Following Additional Dose

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient Population</th>
<th>2nd Dose</th>
<th>3rd Dose Seronegative after 2nd dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sample Size</td>
<td>Seronegative N (%)</td>
</tr>
<tr>
<td>Kamar et al.</td>
<td>Recipients of solid-organ transplant</td>
<td>99</td>
<td>59 (60)</td>
</tr>
<tr>
<td>Werbel et al.</td>
<td>Recipients of solid-organ transplant</td>
<td>30</td>
<td>24 (80)</td>
</tr>
<tr>
<td>Longlune et al.</td>
<td>Patients on hemodialysis</td>
<td>82</td>
<td>13 (16)</td>
</tr>
<tr>
<td>Epsi et al.</td>
<td>Patients on hemodialysis</td>
<td>106</td>
<td>66 (62)</td>
</tr>
<tr>
<td>Ducloix et al.</td>
<td>Patients on hemodialysis</td>
<td>45</td>
<td>5 (11)</td>
</tr>
</tbody>
</table>

Among those who had **no detectable antibody** response to an initial mRNA vaccine series, 33-50% developed an antibody response to an additional dose.

Evidence to Recommendations Framework: Additional doses of mRNA COVID-19 vaccines as part of a primary series for immunocompromised
[https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/02-COVID-Dooling-508.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-13/02-COVID-Dooling-508.pdf)
Third mRNA Vaccine Dose for Immunocompromised People

• Examples of moderate to severe immunosuppression include:
  • Active treatment for solid tumor or hematologic malignancies
  • Receipt of solid-organ transplant and taking immunosuppressive therapy
  • Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy)
  • Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
  • Advanced or untreated HIV infection
  • Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

For more information see:
CDC General Best Practices https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html
IDSA Policy Statement https://academic.oup.com/cid/article/58/3/e44/336537
Third mRNA Vaccine Dose for Immunocompromised People

• Inform immunocompromised individuals of potential for a reduced immune response to vaccination, even after a third dose

• Administer third dose at least 28 days after second dose
  • No maximum time period for when a third dose can be given after the second dose

• Use same mRNA vaccine product as the primary two-dose series
  • However, an alternate mRNA vaccine (Pfizer or Moderna) may be used if the original vaccine product is not available

• At this time, additional doses are not authorized for immunocompromised individuals who receive Johnson & Johnson/Janssen COVID-19 vaccine
  • Studies are ongoing and additional information likely available soon

Updated fact sheet for health care providers:
Pfizer - https://www.fda.gov/media/144413/download; Moderna - https://www.fda.gov/media/144637/download
Vaccines for People who are Pregnant, Nursing, or Trying to Become Pregnant

• CDC, American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine strongly recommend COVID-19 vaccination for all people who are pregnant, nursing, trying to get pregnant now, or might become pregnant in the future

• Evidence of safety and effectiveness of COVID-19 vaccination during pregnancy:
  • Data from v-safe pregnancy registry found no increased risk for miscarriage among people who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy
  • Three safety monitoring systems found no safety concerns for people vaccinated late in pregnancy or for their babies
  • Accumulating data show high vaccine effectiveness among pregnant people

• Benefits of COVID-19 vaccination outweigh any known or potential risks

Vaccines for People who are Pregnant, Nursing, or Trying to Become Pregnant

• Low COVID-19 vaccination uptake among people who are pregnant (only 25% of pregnant people received ≥ 1 dose during pregnancy as of 9/4/21\(^1\)), increased circulation of the delta variant and increased risk of severe illness and pregnancy complications from COVID-19 make vaccination for this population urgent

• Misinformation: claims of infertility based on misconception that antibodies made in response to COVID-19 infection or vaccination will attack syncytin-1 proteins in the placenta

Possibility of COVID-19 Illness after Vaccination

• Breakthrough infections are expected
  • COVID-19 vaccines prevent most infections but are not 100% effective

• Compared to unvaccinated people, fully vaccinated people with breakthrough COVID-19:
  • Have less severe symptoms
  • Are less likely to be hospitalized or die
  • May be less likely to develop “long COVID”

• People with vaccine breakthrough infections can be contagious
  • CDC recommends that fully vaccinated people continue taking steps to prevent transmission, including wearing a mask in public indoor settings if they are in an area of substantial or high transmission, such as NYC

COVID-19 Vaccination Works

• COVID-19 vaccines are protecting New Yorkers against infection and illness

• Between January 17 - August 17, 2021, unvaccinated people in NYC made up:
  • 96% of all COVID-19 cases
  • 97% of COVID-19 hospitalizations
  • 97% of COVID-19 deaths

• With the recent increase in COVID-19 cases in NYC, breakthrough infections in vaccinated people have also increased
  • Unvaccinated people still have 3 times higher rate of becoming a case and are almost 10 times more likely to be hospitalized with COVID-19 than vaccinated people

Data on Post-Vaccination Outcomes (August 23)
Breakthrough Infections FAQ
COVID-19 Hospitalization Rates and Percent of Adults Fully Vaccinated against COVID-19, by ZIP Code

Hospitalization data for past 28 days as of 9/7/21  
Vaccination data cumulative through 9/1/21
Co-Administration of COVID-19 and Other Vaccines

• Vaccines may be administered regardless of timing between COVID-19 and non-COVID-19 vaccines (including live vaccines)
  • Includes administration of COVID-19 and non-COVID-19 vaccines on same or different days

• Applies to all ages

• Many people have fallen behind on routine vaccination during the pandemic; use the opportunity to administer other needed immunizations
  • For adolescents, consider need for school-required immunizations and to administer missed immunizations such as human papilloma virus (HPV) vaccine
  • When deciding whether to co-administer COVID-19 and other vaccines, considerations may include reactogenicity of other vaccines (e.g., reactogenic adjuvanted vaccines such as Shingrix)

• Co-administer influenza and COVID-19 vaccines whenever possible

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration
Benefits of Vaccination for People with History of COVID-19

People who have had COVID-19 should get vaccinated

- Vaccination is associated with a decreased risk of reinfection\(^1\)
- Vaccination can boost the immune response in people with prior infection for potentially more durable and longer-lasting protection
- Vaccination may also offer better protection against COVID-19 variants
- People who have recovered from COVID-19 may be vaccinated as soon as they meet criteria to discontinue isolation

Serologic Testing is Not Recommended for Vaccination Decisions

Serologic testing should **not** be used to determine if a person should receive COVID-19 vaccination

• Even if antibodies are detected, it is not known whether they correlate with immunity to or protection from COVID-19

• If someone misinterprets a positive antibody test, they may take fewer precautions, increasing their risk of being infected with and transmitting SARS-CoV-2

• Not all antibody tests have been evaluated and authorized by the FDA, and no antibody tests have been validated to determine response to vaccination or approved for this purpose

Importance of Vaccinating Adolescents

• Cases of COVID-19 are increasing among children; delta variant appears to be playing a role
  • Children represented nearly 27% of cases reported in the U.S. 8/26-9/2/2021

• COVID-19 can be milder in children than in adults; however, children can develop severe infections, illness requiring hospitalization, and complications including multisystem inflammatory syndrome in children and long COVID

• Vaccination also helps
  • Prevent or reduce the spread of COVID-19 to others
  • Decrease emergence of other SARS-CoV-2 variants
  • Protect the community

American Academy of Pediatrics and Children’s Hospital Association
Vaccination of Minors (NY State Policies)

• Consent must be provided by parent/guardian for children ages 12 to 17 to be vaccinated
  • Consent can be provided in person, over the phone, or, for City-run sites and some additional providers, in writing
  • Proof they are the child’s parent/guardian is not needed

• Children ages 12 to 15 must have a parent/guardian/designated adult accompany them to a vaccination site
  • EXCEPTION for school-based health centers

• Proof of age is required
  • If child does not have an ID or other document with date of birth, parent/guardian can accompany child to vaccination site to attest to their age
Anticipated Developments in COVID-19 Vaccines

• Moderna has applied for full FDA approval of their product for persons ≥ 18 years
  • Approval may occur by the end of 2021
• Moderna has applied to FDA to extend EUA to adolescents ages 12 to 17 years
• Pfizer and Moderna are conducting studies in children < 12 years old
• Pfizer and Moderna have submitted data to support booster doses
  • FDA Advisory Committee meeting on booster doses scheduled for Sept. 17
Anticipated Developments in COVID-19 Vaccines

• Booster doses
  • FDA has not yet authorized booster doses
  • Evaluation of need/recommendation for booster doses by FDA and ACIP in process

• Information needed to make a determination on booster doses:
  • Is vaccine effectiveness (VE) waning over time?
  • Is VE reduced for the delta variant?
  • Does the need vary by sub-population?
  • Are booster doses safe and immunogenic?
Summary of vaccine effectiveness estimates since introduction of the Delta variant

- Vaccines remain effective in preventing hospitalization and severe disease but might be less effective in preventing infection or milder symptomatic illness.
- Reasons for lower effectiveness likely include both waning over time and Delta variant.

Take Every Opportunity to Vaccinate

• Use every opportunity to vaccinate every eligible person against COVID-19

• Ask about vaccination status at every encounter
  • Document vaccination in the medical record
  • Offer vaccination, or refer to another facility for vaccination

• Per CDC, New York State and NYC guidance:
  • Vaccinate even if this means you will not be able to use an entire multi-dose vial

Updated Pfizer fact sheet for health care providers: https://www.fda.gov/media/144413/download
Commissioner’s Advisory: Offer Vaccination Information to all Unvaccinated Patients at Every Visit

• Issued Sept. 9, 2021
• Accompanied by new program to compensate providers for conducting outreach to certain unvaccinated patients
• For more information about this advisory and compensation:
  • See frequently asked questions and COVID-19 Vaccine Outreach and Counseling Program Toolkit
  • Join provider webinar dedicated to these topics Friday, Sept. 17, 1 p.m.

Give Your Strong Recommendation

• Your strong recommendation is critical to your patients choosing to get vaccinated
• Start conversations with patients and parents to address concerns
• Remind everyone that COVID-19 vaccines are available to everyone at no cost and regardless of immigration status
• Resources on communicating with patients: nyc.gov/VaccineTalks
COVID-19 Vaccine Resources in NYC

• COVID-19 vaccines are available throughout NYC, including at pharmacies, Federally Qualified Health Centers, hospitals, mobile sites, vaccination events, school health centers and can also be administered at home.

• Visit nyc.gov/vaccinefinder (searchable by vaccine brand, walk-in, ADA accessible) or call 877-VAX-4NYC (877-829-4692) to find a vaccination site.

• Anyone 12 or older is eligible for in-home vaccination:
  • Sign up at nyc.gov/homevaccine or by calling 877-VAX-4NYC.

• Dedicated line for providers and staff to make vaccine appointments:
  • 877-VAX-4NYC; press 2 at the second prompt.

• Providers can refer a patient to the Vaccine Appointment Hotline by filling out a short request form (patients will receive call within 48 hours).
UPDATE ON MONOCLONAL ANTIBODIES FOR THERAPY FOR COVID-19 IN NYC

Mary Foote, MD, MPH
Health Systems Planning and Strategies Lead, COVID-19 Response
NYC Department of Health and Mental Hygiene
Summary of COVID-19 Therapeutics

- **Exposed / Asymptomatic Infected**
  - Healthy, no infection
  - Not hospitalized, no limitations
    - Casirivimab + Imdevimab (RGN)
  - Not hospitalized, with limitations
    - Monoclonal Antibodies
      - Bamlanivimab + Etesevimab (Lilly)
      - Casirivimab + Imdevimab (RGN)
      - Sotrovimab (GSK/Vir)

- **Early Symptomatic**
  - Not hospitalized, no act. medical problems
  - Hospitalized, not on oxygen
    - Remdesivir
  - Hospitalized, on oxygen
    - Tocilizumab

- **Hospital Admission**
  - Hospitalized, high flow oxygen/non-invasive ventilation
  - Hospitalized, mechanical ventilation/ECMO
    - Dexamethasone
    - Baricitinib (with Remdesivir)

Source: Assistant Secretary of Preparedness and Response:
Rationale for Use of Monoclonal Antibody (mAb) Therapeutics

• Delayed production of neutralizing antibodies correlated with fatal COVID-19\(^1\)

• Monoclonal antibody (mAb) therapeutics:\(^2\)
  • As treatment
    • Keep symptoms from getting worse and shorten duration
    • Lower risk of hospitalization and death by 70-85%
  • As post-exposure prophylaxis (PEP)
    • Lower risk of symptomatic infection
  • Reduce stress on the health care system

• Recommended for use by:
  • National Institutes of Health (NIH)
  • Infectious Disease Society of America (IDSA)

2. NYC DOHMH https://on.nyc.gov/3mZSWpr
mAb Products and Use

- REGEN-COV (Regeneron) – Casirivimab 600 mg + imdevimab 600 mg
  - July 20, 2021: Updated EUA for use as PEP
  - Can now be given by IV infusion or subcutaneous injection – infusion preferred for treatment
- Bamlanivimab and Etesevimab (Eli Lilly)
- Sotrovimab (GlaxoSmithKline)
  - Commercially available, not distributed by U.S. Government

Clinical considerations
- Given via a one-time IV infusion or subcutaneous injection (REGEN-COV)
  - 15 to 60-minute infusion time + 60-minute observation
  - For treatment: must be given within 10 days of symptoms onset
  - Can be administered in outpatient or hospital settings

FDA factsheet for REGEN-COV EUA Fact Sheet
EXPANDED: mAb Treatment Eligibility

• mAbs authorized for the treatment of patients who:
  • Have mild to moderate COVID-19 symptoms
  • Have a positive direct SARS-CoV-2 viral test
    • Nucleic acid amplification (NAA) or antigen test
  • Are 12 years of age or older
  • Weigh at least 88 pounds (40 kg)
  • Are at risk for progressing to severe COVID-19 or hospitalization due to medical condition or other factors (e.g., race or ethnicity or people facing longstanding systemic health and social inequities, and people with disabilities)
Examples of Medical Conditions and Factors Associated with Increased Risk for Severe COVID-19

- Advanced age 65
- Obesity or being overweight (e.g., BMI ≥25 for adults or children with BMI ≥85th percentile of patients of same age and gender based on [CDC growth charts](https://www.cdc.gov/growthcharts/),)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or currently receiving immnosuppressive treatment
- Cardiovascular disease or hypertension
- Chronic lung diseases (e.g., COPD, moderate-to-severe asthma, interstitial lung disease, and pulmonary hypertension)
- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes, severe congenital anomalies)
- Dependence on medical-related technologies (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))
- Asthma, reactive airway, or other chronic respiratory disease (e.g., cystic fibrosis) that requires daily medication.

FDA factsheets for [bamlanivimab/etesevimab](https://www.fda.gov/), [casirivimab/imdevimab](https://www.fda.gov/) (administered together), and [sotrovimab](https://www.fda.gov/) for additional information
NEW: mAb Post-Exposure Prophylaxis (PEP)

• EUA for REGEN-COV (casirivimab and imdevimab) permits use as PEP in patients who are:
  • 12 years of age and older, weighing at least 40kg/88lbs
  • At high risk for progressing to severe COVID-19
  • Not fully vaccinated OR not expected to mount adequate immune response (e.g., immunocompromised); AND
    • Were exposed to individual with COVID-19 OR
    • Are at high risk of exposure because of COVID-19 in individuals in the same institutional setting (such as nursing homes or correctional facilities)
• PEP authorization based on a phase 3, randomized, double-blind, placebo-controlled trial (N=1505)
  • Asymptomatic contacts receiving PEP within 96 hours of a household member testing positive had an 81.4% reduced risk of symptomatic COVID-19 compared to placebo group
  • Length of symptoms was reduced (3.2 to 1.2 weeks) and risk of developing asymptomatic or symptomatic infection was reduced by 66.4% in the treatment group\(^1\)

COVID-19 Vaccination and mAb Therapy

• AFTER mAb
  • Defer COVID-19 vaccination for 90 days after receiving mAb treatment or convalescent plasma

• If FULLY OR PARTIALLY VACCINATED
  • Any eligible patient who develops lab-confirmed COVID-19 after vaccination can still receive mAb treatment
  • Can be used as PEP in patients who are not expected to mount an adequate immune response following vaccination (i.e., immunocompromised patients)
mAbs and SARS-CoV-2 Variants

Revised guidance:

• In vitro studies suggest bamlanivimab and etesivimab combined are not active against gamma (P.1) and beta (B.1.251) variants

• Delta variant (B.1.617.2), over 97% of sequenced cases in NYC, is resistant to bamlanivimab, but full activity when combined with etesivimab

• REGEN-COV and sotrovimab are likely to retain activity against known circulating variant of concern, including delta

SARS-CoV-2 Neutralization Data for Bamlanivimab and Etesevimab Together (1:2 Molar Ratio)

Spread of Variants in NYC

These charts show the percent and number of tested cases each week that have the four most common variants in New York City: B.1.1.7, B.1.526, P.1 and B.1.617.2.

Percent of tested COVID-19 cases with virus variants (for week ending on listed date)

Recent data are incomplete.

Delta
8/21
99%

Referring Patients for mAb Treatment

• Greater New York Hospital Association (GNYHA) list of hospitals and networks providing mAbs
  • https://hitesite.org/monoclonalantibody -- will be continuously updated

• NYC Health+Hospitals
  • Visit ExpressCare.nyc and click “Talk to a Doctor Now” or call 212-COVID19 (212-268-4319)
  • Provides treatment regardless of ability to pay

• Become a treatment site
  • Learn how to prepare via the HHS monoclonal antibody outpatient administration playbook
  • Information on direct ordering of mAbs and direct order form

• CMS has increased reimbursement rates for mAb treatment (effective May 6, 2021)
  • $450 reimbursement for mAb administration in most health care settings
  • $750 reimbursement when administered in the beneficiary's home
Updates on COVID-19 Monoclonal Antibody (mAb) Treatment in the Outpatient Setting

Overview

- All providers should know how and when to refer patients for monoclonal antibody (mAb) treatment.
- mAb treatment, when given early after symptom onset, can decrease the risk of hospitalization and death due to COVID-19 by as much as 70% to 85%.
- Eligibility criteria for mAb treatment have been expanded to include additional medical conditions and factors that may place patients at high risk for progression to severe COVID-19.
- Continue to refer eligible symptomatic patients for mAb treatment, regardless of vaccination status.
- Sotrovimab is a new mAb product that has been granted emergency use authorization (EUA) by the Food and Drug Administration (FDA).
- The EUA for REGEN-COV (casirivimab + imdevimab) has been updated to reduce the dose and allow for subcutaneous administration.
- The EUA for REGEN-COV has also been expanded to include use as post-exposure prophylaxis for people exposed to someone with COVID-19 and at high risk for severe illness.
- Health care providers should use only REGEN-COV or sotrovimab for the treatment of COVID-19 until further notice due to increasing prevalence of SARS-CoV-2 variants resistant to bamlanivimab and etesevimab.

What is monoclonal antibody treatment?

Monoclonal antibodies are made in a lab and work similarly to antibodies your immune system makes to fight infection. Monoclonal antibody treatment helps your body fight COVID-19 while your immune system begins to make its own antibodies. In clinical studies, monoclonal antibody treatments were shown to be safe and effective.

Who is eligible for monoclonal antibody treatment?

Treatment is authorized for people who meet all the following:
- Tested positive for COVID-19
- Have had mild to moderate COVID-19 symptoms for 10 days or less
- Are age 12 or older and weigh at least 88 pounds
- Are at high risk for severe COVID-19 illness, including older adults and people with certain underlying health conditions, such as obesity, diabetes, chronic kidney disease or a weakened immune system

What are the side effects?

Side effects may include:
- A reaction at the site of the IV, including pain, swelling, or bruising
- Nausea, vomiting, or diarrhea
- Itching, rash, or hives
- Allergic reactions and other serious side effects are rare. If you experience fever, trouble breathing, rapid or slow heart rate, tingling, weakness, cough, or other concerning symptoms, contact your health care provider right away. Call 911 or go to an emergency department if your symptoms become severe or worsen.

Where can I get monoclonal antibody treatment?

Call your provider right away if you test positive for COVID-19 to see if you are eligible for treatment and for help finding a treatment site. You can also talk to an NYC Health + Hospitals doctor by visiting expresscare.nyc and clicking “Talk to a Doctor Now,” or calling 212-COVID19 (212-268-4319). For a list of monoclonal antibody treatment locations, visit nyc.gov/monoclonalantibody.

How much does monoclonal antibody treatment cost?

Treatment is covered by Medicaid and Medicare plans at no cost. If you have private insurance, check with the treating facility and your health plan about costs. NYC Health + Hospitals provides treatment and care regardless of immigration status or ability to pay.
Conclusion

• mAbs are an essential tool to prevent progression to severe COVID-19

• Important to ensure access for communities most impacted by COVID-19

• Consider PEP therapy to reduce the risk of infection in high-risk exposed patients

• The earlier treatment is given, the better it prevents disease progression, hospitalization and death
  • Talk to your at risk patients about the importance of getting tested as soon as symptoms develop
Additional COVID-19 Resources

COVID-19 Vaccines

• NYC Health Department - COVID-19 Vaccine:
  • Providers:
    • Vaccine information: nyc.gov/health/covidvaccineprovider
    • Vaccine communication resources: nyc.gov/VaccineTalks
    • Provider hotline to schedule vaccine appointments: 877-VAX-4NYC (877-8229-4692); press 2 at second prompt
  • Public: nyc.gov/covidvaccine
• Citywide Immunization Registry Reporting Assistance
  • https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic
• Vaccine Provider Assistance: nycimmunize@health.nyc.gov

General COVID-19 Resources

• Provider page: https://www1.nyc.gov/site/doh/covid/covid-19-providers.page
• Data page: https://www1.nyc.gov/site/doh/covid/covid-19-data.page
• Dear Colleague COVID-19 newsletters (sign up for City Health Information subscription at: nyc.gov/health/register)
• NYC Health Alert Network (sign up at https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page)
• Provider Access Line: 866-692-3641
CONTINUING MEDICAL EDUCATION

CME Accreditation Statement for Joint Providership
NYC Health + Hospitals is accredited by The Medical Society of the State of New York (MSSNY) to provide continuing medical education for physicians. This activity has been planned and implemented in accordance with the Accreditation Requirements and Policies of the MSSNY through the joint providership of NYC Health + Hospitals and the NYC Department of Health and Mental Hygiene. NYC Health + Hospitals designates this continuing medical education activity for a maximum of 1 AMA PRA Category 1 Credit™. Physicians should claim only credit commensurate with the extent of their participation in the activity.