# COVID-19
# HEALTH CARE PROVIDER UPDATE:

## COVID-19 EPIDEMIOLOGY IN NYC, VACCINES FOR ADOLESCENTS, AND MONOCLONAL ANTIBODY TREATMENT

## JUNE 4, 2021

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*Our understanding of COVID-19 is evolving rapidly.*
*This presentation is based on our knowledge as of June 3, 2021, 5 PM.*

# OUTLINE

- RECENT EPIDEMIOLOGY OF COVID-19 IN NYC
- VACCINE UPDATES
- MONOCLONAL ANTIBODY TREATMENT
- QUESTIONS AND ANSWERS

# Recent Epidemiology of COVID-19 in NYC

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# Vaccination of Adolescents and Other COVID-19 Vaccine Updates

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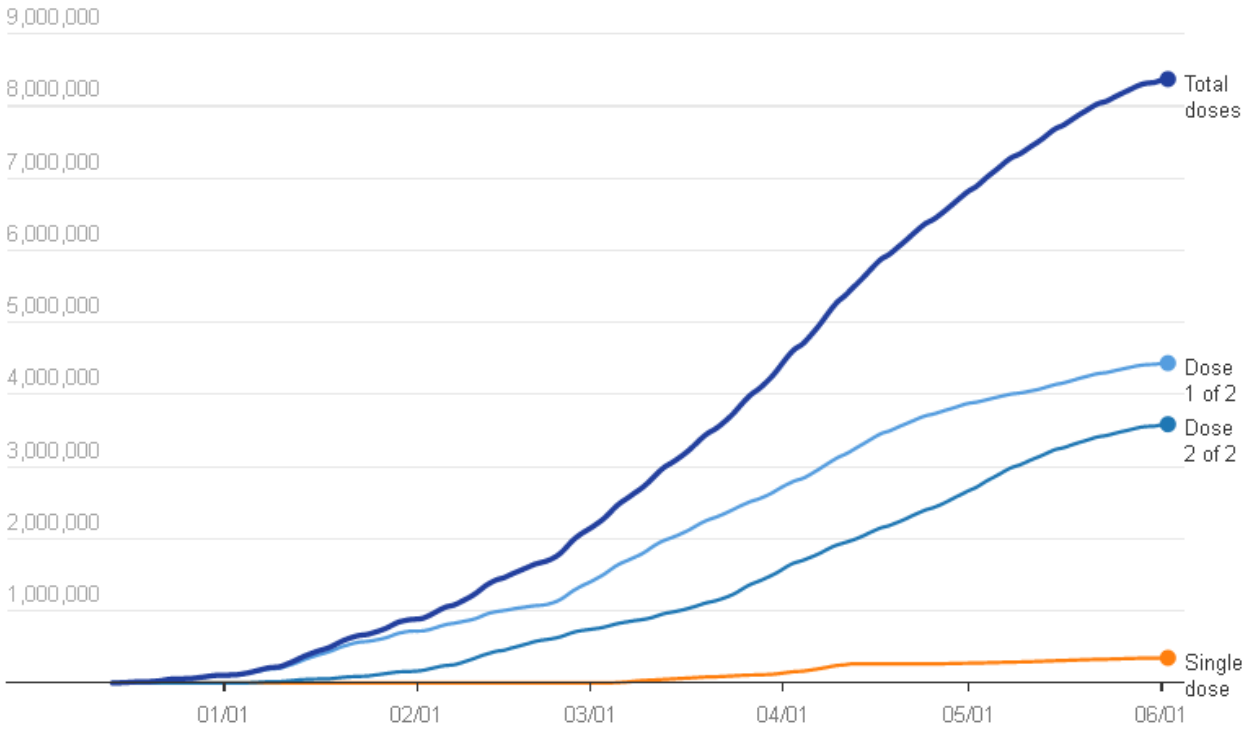
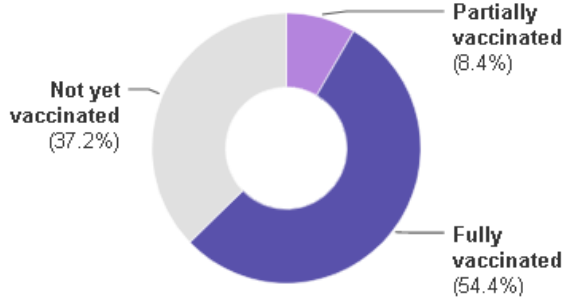
# COVID-19 VACCINE ADMINISTRATION, NYC

- Over 8.3 million doses administered
- Of NYC residents aged ≥ 18 years:
  - 63% received ≥ 1 dose
  - 54% fully vaccinated

**DOSES ADMINISTERED**




**PERCENT OF ADULT RESIDENTS 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; updated 6/3/2021

# Pfizer-BioNTech COVID-19 Vaccine for Adolescents

## Background: COVID-19 among adolescents

- Adolescents, especially those who are Black or Latino, are at risk for severe COVID-19
- Among U.S. adolescents 12-17 years old:
  - >1.5 million cases of COVID-19*
  - >13,000 hospitalizations due to COVID-19*
  - >800 cases of multisystem inflammatory syndrome in children (MIS-C)*
- Among NYC adolescents 13-17 years old:
  - >30,000 cases of COVID-19**
  - >500 hospitalizations due to COVID-19**
- Adolescents can spread COVID-19 infection to others within households and communities

*Cases and hospitalizations were from March 1, 2020 – April 30, 2021. Cases of MIS-C were as of May 3, 2021
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/04-COVID-Oliver-508.pdf
** As of June 2, 2021. NYC Health Department COVID-19 Data page: https://github.com/nychealth/coronavirus-data/blob/master/totals/by-age.csv

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# Pfizer-BioNTech COVID-19 Vaccine Authorized & Recommended for Ages 12-15 Years in U.S.

- May 10, 2021: Food and Drug Administration (FDA) expanded emergency use authorization (EUA) to include adolescents aged 12-15 years
- May 12, 2021: Advisory Committee on Immunization Practices (ACIP) recommended the vaccine in this age group

Wallace M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021. MMWR 2021;70:749–752. DOI: http://dx.doi.org/10.15585/mmwr.mm7020e1

# Pfizer-BioNTech COVID-19 Vaccine Clinical Trial Findings for Participants Aged 12-15 Years

- 2,260 adolescents in this age group randomly assigned to vaccine or placebo in 1:1 ratio
- Efficacy of two doses in preventing symptomatic, laboratory-confirmed COVID-19: 100%
- Side effects:
  - Mild to moderate; similar to those seen in people aged 16-25 years
  - Pain at injection site (79%-86%), fatigue (60%-66%), headache (55%-65%), chills (28%-42%), joint pain (10%-16%), muscle pain (24%-32%), fever (10%-20%)
  - More common after second dose (except pain at injection site)
- 0.4% of participants in vaccine group reported ≥ 1 serious adverse event vs. 0.2% in placebo group
  - No serious adverse events were considered related to vaccine by FDA

Frenck RW, et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. N Engl J Med. 2021 May 27. doi: 10.1056/NEJMoa2107456

Wallace M, et al. The ACIP's Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021. MMWR 2021;70:749–752. DOI: http://dx.doi.org/10.15585/mmwr.mm7020e1

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# Administration and Clinical Considerations

- Same dose (30 µg, 0.3 mL) and schedule as for older age groups: 2 doses, separated by ≥ 21 days
- Same contraindications and precautions as for other age groups

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

# Consent for Vaccination of Minors in NY State

- Parent/guardian must provide consent for their child to be vaccinated in person or by phone
  - Not necessary to provide proof they are the child's parent/guardian
- Some providers, including all City-run sites, accept proof of consent in writing; however, in-person or phone consent is preferred
- All minors ages 12 to 15 years must be accompanied to the vaccination site by a parent, guardian, or adult caregiver designated by parent/guardian
- 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

# Co-Administration of COVID-19 and Other Vaccines

- Vaccines may now 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 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)

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration

# Updated Recommendations for Use of Johnson & Johnson/Janssen COVID-19 Vaccine

- April 27, 2021: ACIP reaffirmed interim recommendation for use in all people ≥ 18 years
- EUA now contains a warning about thrombosis with thrombocytopenia syndrome (TTS)
- As of May 7, 2021, 28 cases of TTS reported among recipients of Johnson & Johnson/Janssen COVID-19 vaccine
  - Predominantly among females (female, 22; male, 6)
  - Median age 40 years (range, 18-59 years)

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf

# Updated Recommendations for Use of the Johnson & Johnson/Janssen COVID-19 Vaccine

- Benefits of vaccine, including efficacy in preventing serious illness, hospitalization, and death due to COVID-19, outweigh rare but potential risk of TTS
- Educate all potential vaccine recipients, especially women <50 years, about risk for TTS from and availability of alternative (mRNA) COVID-19 vaccines
- Provide vaccine recipients with updated patient fact sheet and instruct to seek care immediately if they develop:
  - Shortness of breath
  - Chest pain
  - Leg swelling
  - Persistent abdominal pain
  - Severe or persistent headache or blurred vision
  - Easy bruising or petechiae beyond the site of the injection

MacNeil JR, et al. Updated Recommendations from the ACIP for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. MMWR 2021;70:651-656
DOI: http://dx.doi.org/10.15585/mmwr.mm7017e4
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations

# Revised Clinical Considerations for Use of Johnson & Johnson/Janssen COVID-19 Vaccine

- Offer mRNA vaccine for people with history of an immune-mediated syndrome with thrombosis and thrombocytopenia (e.g. heparin-induced thrombocytopenia) if ≤ 90 days since illness resolved
    - > 90 days, use any FDA-authorized COVID-19 vaccine
- Risk factors for or a personal history of thrombosis not associated with thrombocytopenia are unlikely to increase risk for TTS after Johnson & Johnson/Janssen COVID-19 vaccine
    - Includes pregnancy and use of hormonal contraceptives
    - Can receive any authorized COVID-19 vaccine

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations

# Revised Clinical Considerations for Use of Johnson & Johnson/Janssen COVID-19 Vaccine

- Taking aspirin or an anticoagulant before any COVID-19 vaccine is not recommended, unless part of routine medications
- Patients with suspected TTS after Johnson & Johnson/Janssen COVID-19 vaccination should **not** be treated with heparin unless platelet factor 4-ELISA ("HIT" ELISA) assay is negative

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations

# Myocarditis and Pericarditis after mRNA COVID-19 Vaccines

- Rare reports of myocarditis and pericarditis after receipt of Moderna and Pfizer-BioNTech COVID-19 vaccines are being investigated
  - Cases identified during routine review of COVID-19 vaccine safety monitoring data
  - To date, rates of myocarditis/pericarditis appear similar to baseline rates
- Cases have occurred
  - Mostly in male adolescents and young adults age ≥ 16 years
  - Typically, several days after mRNA COVID-19 vaccination
  - More frequently after the second vaccine dose than after the first dose
- Most cases have been mild and have responded to medical treatment and rest

ACIP Vaccine Safety Technical Work Group report 5/17/2021: https://www.cdc.gov/vaccines/acip/work-groups-vast/technical-report-2021-05-17.html

CDC's Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

# Myocarditis and Pericarditis after mRNA COVID-19 Vaccines: Key Messages for NYC Providers

- Consider myocarditis and pericarditis when evaluating chest pain, dyspnea, or palpitations
  - Ask about a history of COVID-19 vaccination
- Review CDC guidance for providers:
  - Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults
- Report cases of myocarditis, pericarditis and other serious events after vaccination to VAERS
- CDC continues to recommend COVID-19 vaccination for people ≥ 12 years
  - CDC information for patients: Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

# Non-FDA-Authorized COVID-19 Vaccines Received Outside the U.S.

| Patient's Vaccination Status | Recommendation for COVID-19 Vaccination in U.S. |
|---|---|
| Fully vaccinated with COVID-19 vaccine authorized by World Health Organization | No further COVID-19 vaccination needed |
| Partially vaccinated with COVID-19 vaccine authorized by World Health Organization | Start new COVID-19 series with FDA-authorized vaccine* |
| Fully or partially vaccinated with COVID-19 vaccine not authorized by World Health Organization | Start new COVID-19 series with FDA-authorized vaccine* |

*Start FDA-authorized COVID-19 vaccine series ≥ 28 days after the last dose of the non-FDA authorized COVID-19 vaccine
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#people-vaccinated-outside-us

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# New York State Excelsior Pass

- Digital record of COVID-19 vaccination
  - Stored in smartphone
  - Can be used by businesses/venues to confirm vaccination
  - Adults may hold pass for accompanying minors
  - Does not provide vaccination dates
- Vaccine recipient's information must match the information submitted in the NYC Citywide Immunization Registry (CIR) vaccination record
  - Especially for name, date of birth, phone number and zip code
  - Need the county where vaccine provider is registered
- Confirm correct vaccine recipient information at each step:
  - Collection from recipient
  - Entry of data into CIR

New York State Excelsior Pass: https://covid19vaccine.health.ny.gov/excelsior-pass

# Anticipated Developments in COVID-19 Vaccines

- Pfizer-BioNTech and Moderna have applied for full FDA approval of their products (in persons ≥ 16 years and ≥ 18 years, respectively)
  - Approval of both products may occur by the end of 2021
- Moderna has applied to FDA to extend EUA to adolescents ages 12-17 years
- Pfizer-BioNTech and Moderna are conducting studies in children < 12 years old
- Pfizer-BioNTech and Moderna booster doses being tested for potential need
  - Variant protection, durability
- Pfizer-BioNTech is conducting studies in pregnant people
  - Follow up of newborns for 6 months

# Take Every Opportunity to Vaccinate

- Use **every** opportunity to vaccinate every eligible person against COVID-19
- Updated CDC, New York State and New York City guidance: vaccinate even if this means you will not be able to use an entire multi-dose vial
  - New, more flexible policy will allow for broader administration
- Other recent changes that make providing COVID-19 vaccines easier:
  - Storage of Pfizer-BioNTech vaccine
    - Undiluted frozen vials may be transported and stored at temperatures commonly found in pharmaceutical freezers for up to two weeks (2/25/21)
    - Thawed, undiluted vaccine may be refrigerated for up to 30 days (5/19/21)
  - Pfizer-BioNTech vaccine now available in 450 and 1170 dose orders
  - Moderna vaccine now available in 14 dose vials

https://coronavirus.health.ny.gov/system/files/documents/2021/05/guidance_for_facilities_receiving_vaccine_5.21.21.pdf
https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf
Updated Pfizer-BioNTech fact sheet for health care providers: https://www.fda.gov/media/144413/download

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# NYC Youth Vaccination Week: June 3-8

- Participate in this week of action by promoting vaccination for adolescents through a strong recommendation and information-sharing
- City conducting series of virtual and in-person events:
  - **Youth Vax Block Parties and Vaccinations**: food, music, activities and vaccinations with Pfizer-BioNTech in all five boroughs
  - **Virtual Events:** workshops will provide information to parents, youth, and educators about the COVID-19 vaccine
  - **Mobile vaccine units:** units providing youth vaccinations will be parked across the city (including beaches & iconic sites)
- List of events: https://www1.nyc.gov/site/coronavirus/vaccines/vaccine-events.page

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# COVID-19 Vaccine Resources in NYC

- COVID-19 vaccines are available at many NYC locations, including pharmacies, Federally Qualified Health Centers and hospitals
- Patients can find a vaccination site at nyc.gov/vaccinefinder
  - Searchable by vaccine brand, walk-in or ADA accessible
  - They can also call 877-VAX-4NYC (877-829-4692) for assistance making an appointment at a City-run site
- Dedicated line for providers and staff to help patients make vaccine appointments:
  - 877-VAX-4NYC (877-829-4692); press 2 at the second prompt
- Providers can refer a patient to the Vaccine Appointment Hotline by filling out a short request form:
  - Patients referred through this form will receive a call within 48 hours

# Give Your Strong Recommendation

- Your strong recommendation is critical to your patients choosing to get vaccinated
- Start conversations with parents and patients to address concerns
- Remind parents of benefits of vaccination, including:
  - Protecting their children's health
  - Preventing transmission from their children to others
  - Enabling children to resume activities stopped due to the pandemic
- Remind everyone that COVID-19 vaccines:
  - Are available to everyone at no cost
  - Will be given to all people living in the U.S., regardless of immigration status
- Resources on communicating with patients: nyc.gov/VaccineTalks

# Update on Monoclonal Antibodies for Treatment of COVID-19 in NYC

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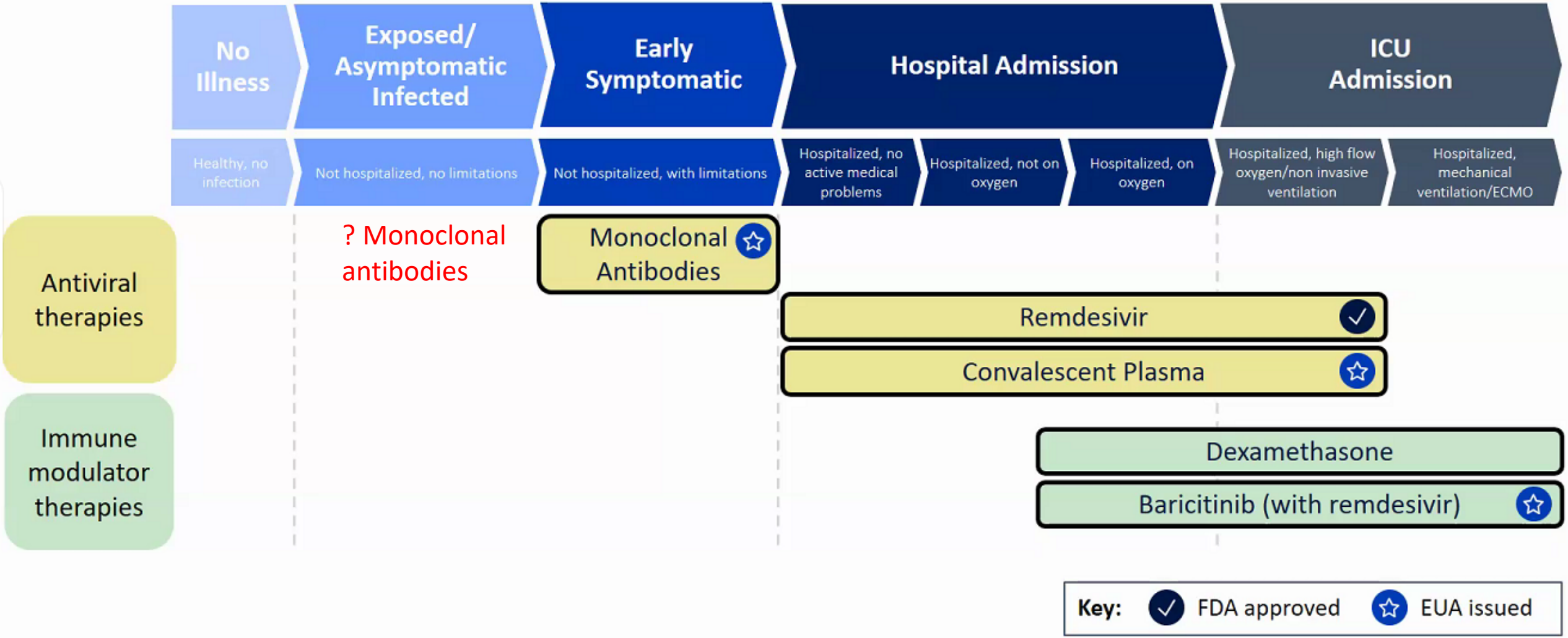
COVID-19 ICS Emergency Response
NYC Department of Health and Mental Hygiene

# Interventions depend on stage of COVID-19 illness

*Objective: optimize therapeutic use to prevent or shorten hospitalizations*




Source: https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/; Coronavirus disease 2019 (COVID-19): Management in hospitalized adults - UpToDate

# Monoclonal Antibody (mAb) Therapeutics

- **Approved Products**
  - Eli Lilly
    - Bamlanivimab 700 mg + etesivimab 1,400 mg – cocktail administers as single dose
  - Regeneron
    - Casirivimab 1,200 mg + imdevimab 1,200 mg – cocktail administers as single dose

- **No Longer Approved**
  - Bamlanivimab alone unlikely to be active against most B.1.526 and other variants
    - **No longer authorized → EUA revoked by FDA**
  - Etesevimab can now be ordered alone to complement on-site supplies of bamlanivimab; however, bamlanivimab monotherapy discontinued nationwide

- **Clinical Considerations**
  - Given via a one-time intravenous (IV) infusion
    - 16-60 min infusion time + 60 min observation
  - Must be given within 10 days of symptoms onset

# Emergency Use Authorization Eligibility

- **mAbs are 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 high risk for progressing to severe COVID-19 or hospitalization

# Updated EUA Eligibility Criteria

| Adults who meet at least one of the following: | Pediatrics (Age 12-17) who meet at least one of the following: |
|---|---|
| • Age 65 or older<br>• Obesity or being overweight with a BMI ≥25<br>• Pregnancy<br>• Chronic kidney disease<br>• Type I or II diabetes<br>• Immunosuppressive disease or currently receiving immunosuppressive treatment<br>• Cardiovascular disease or hypertension<br>• Chronic lung diseases (e.g., COPD, moderate-to-severe asthma, interstitial lung disease, and pulmonary hypertension) | • Obesity or being overweight with BMI ≥85th percentile of patients of same age and gender based on CDC growth charts,<br>• Sickle cell disease<br>• Congenital or acquired heart disease<br>• Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes, severe congenital anomalies)<br>• Dependence on medical-related technologies (e.g., trracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))<br>• Asthma, reactive airway, or other chronic respiratory disease (e.g., cystic fibrosis) that requires daily medication. |

Effective 5/14/21; see updated FDA factsheets for bamlanivimab/etesevimab (administered together) and casirivimab/imdevimab for additional information

# COVID-19 Vaccination and mAb Treatment

- Patients are advised to defer COVID-19 vaccination for 90 days after receiving mAb treatment
- Any eligible patient who develops lab-confirmed COVID-19 after vaccination can receive mAb treatment

# NYC COVID-19 Cases Caused by Variants

Data pulled 6/01/21 from GISAID; variants available in GISAID for NYC residents, cumulative*

| | |
|---|---|
| Variants of concern that are being monitored by CDC | |
| B.1.1.7 | 4,883 |
| B.1.351 | 39 |
| B.1.429 | 254 |
| B.1.427 | 144 |
| P.1 | 315 |
| Other variants of interest being monitored by CDC | |
| B.1.526/B.1.526.2 | 7,303 |
| B.1.526.1 | 1,490 |
| B.1.525 | 56 |
| B.1.617 | 0 |
| B.1.617.1 | 3 |
| B.1.617.2 | 80 |
| B.1.617.3 | 0 |
| P.2 | 12 |
| Number of genome sequences from specimens from NYC residents in GISAID, cumulative* | 20,935 |

* GISAID is a global science repository for open-access to genomic data of SARS-CoV2. Cumulative refers to January 2021 – present. All sequences noted as "available in GISAID" have passed critical quality control checks and are publicly available.

https://www1.nyc.gov/site/doh/covid/covid-19-main.page
https://www1.nyc.gov/site/doh/covid/covid-19-data-archive.page

For national data go to:
https://covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html#variant-proportions

## Trends based on a sample of specimens submitted to Pandemic Response Lab, as of 5/23

| Specimen collection date, week | Total specimens sequenced by PRL | B.1.1.7 (N, %) | B.1.351 (N, %) | B.1.429 (N, %) | B.1.427 (N, %) | P.1 (N, %) | B.1.526 (N, %)* | | B.1.526.1 (N,%) | B.1.525 (N, %) | B.1.617 (N, %) | B.1.617.1 (N, %) | B.1.617.2 (N, %) | B.1.617.3 (N, %) | P.2 (N, %) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | S:E484K+ (N, %) | S:E484K- (N, %) | | | | | | | |
| April 12 - 18 | 1404 | 532 (37.9%) | 5 (0.4%) | 11 (0.8%) | 6 (0.4%) | 47 (3.4%) | 366 (26.1%) | 196 (14.0%) | 97 (6.9%) | 9 (0.6%) | 1 (0.1%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| April 19-25 | 955 | 402 (41.5%) | 1 (0.1%) | 3 (0.3%) | 9 (0.8%) | 34 (3.6%) | 229 (24%) | 121 (12.7%) | 52 (5.4%) | 5 (0.5%) | 0 (0%) | 1 (0.1%) | 3 (0.3%) | 0 (0%) | 0 (0%) |
| April 26 - May 2 | 699 | 303 (43.3%) | 1 (0.1%) | 2 (0.3%) | 1 (0.1%) | 41 (5.9%) | 130 (18.5%) | 87 (12.4%) | 55 (7.9%) | 1 (0.1%) | 0 (0%) | 0 (0%) | 16 (2.3%) | 0 (0%) | 0 (0%) |
| May 3 - 9 | 414 | 196 (47.3%) | 5 (1.2%) | 2 (0.5%) | 2 (0.5%) | 24 (5.8%) | 56 (13.5%) | 39 (9.4%) | 17 (4.1%) | 5 (1.2%) | 0 (0%) | 0 (0%) | 17 (4.1%) | 0 (0%) | 2 (0.5%) |
| May 10 - 16 | 361 | 147 (40.7%) | 0 (0%) | 1 (0.3%) | 2 (0.6%) | 18 (5%) | 47 (13%) | 54 (15%) | 26 (7.2%) | 4 (1.1%) | 0 (0%) | 0 (0%) | 15 (4.2%) | 0 (0%) | 0 (0%) |

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# SARS-CoV-2 Variants & Monoclonal Antibodies

**Preliminary data on efficacy:**

- Both mAb products active against B.1.1.7 ("UK" variant)
- Shipments of bamlanivimab/etesivimab and etesivimab to complement existing bamlanivimab has been paused in 8 states (AZ, CA, FL, IL, IN, MA, OR, WA) due to P.1 and B.1.351 prevalence
  - CDC has identified increased combined frequency above 10% of circulating P.1 and B.1.351 variants in these states
  - Results from in vitro studies suggest:
    - Bamlanivimab/etesivimab administered together are not active against either the P.1 or B.1.351 variants
    - Casirivimab/imdevimab is likely to retain activity against the P.1 or B.1.351 variants

See Section 15 of FDA fact sheets for info on variants of concern: bamlanivimab with etesevimab and casirivimab with imdevimab

# SARS-CoV-2 Variants & Monoclonal Antibodies

**Preliminary data on efficacy:**

- Although B.1.1.7 variant is still the dominant strain in NYC, we must monitor other variants that could affect efficacy of one or more mAbs and lead to potential pause in use
- Manufacturers now required to study and routinely report on variant resistance (per FDA)
- Updated EUA data shows reduced efficacy of bamlanivimab/etesivimab on B.1.526 (with E484K mutation)

**Table 3: Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Bamlanivimab and Etesevimab Together (1:2 Molar Ratio)**

| Lineage with Spike Protein Substitution | Key Substitutions Tested[a] | Fold Reduction in Susceptibility |
|---|---|---|
| B.1.1.7 (UK origin) | N501Y | no change[b] |
| B.1.351 (South Africa origin) | K417N + E484K + N501Y | 215[c] |
| P.1 (Brazil origin) | K417T + E484K + N501Y | >46[c] |
| B.1.427/B.1.429 (California origin) | L452R | 9[d] |
| B.1.526 (New York origin)[e] | E484K | 31 |

[a] For variants with more than one substitution of concern, only the substitution(s) with the greatest impact on activity is(are) listed. For B.1.351, P.1 and B.1.427/B.1.429, spike variants reflective of the consensus sequence for the lineage were tested.
[b] No change: <5-fold reduction in susceptibility.
[c] Bamlanivimab and etesevimab together are unlikely to be active against variants from this lineage. No activity observed at the highest concentration tested for the P.1 variant.
[d] Etesevimab retains activity against this variant.
[e] Isolates of the B.1.526 lineage harbor several spike protein amino acid substitutions, and not all isolates contain the E484K substitution (as of February 2021). This assay was conducted using pseudotyped VLPs with the E484K substitution only.

https://www.fda.gov/media/145802/download

**Table 6: Pseudotyped Virus-Like Particle Neutralization Data for SARS-CoV-2 Variant Substitutions with Casirivimab and Imdevimab Together**

| Lineage with Spike Protein Substitution | Key Substitutions Tested | Fold Reduction in Susceptibility |
|---|---|---|
| B.1.1.7 (UK origin) | N501Y[a] | no change[d] |
| B.1.351 (South Africa origin) | K417N, E484K, N501Y[b] | no change[d] |
| P.1 (Brazil origin) | K417T + E484K[c] | no change[d] |
| B.1.427/B.1.429 (California origin) | L452R | no change[d] |
| B.1.526 (New York origin)[e] | E484K | no change[d] |
| B.1.617.1/B.1.617.3 (India origin) | L452R+E484Q | no change[d] |
| B.1.617.2 (India origin) | L452R+K478T | no change[d] |

[a] Pseudotyped VLP expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: del69-70, del145, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H.
[b] Pseudotyped VLP expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: D80Y, D215Y, del241-243, K417N, E484K, N501Y, D614G, A701V.
[c] Pseudotyped VLP expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I, V1176F
[d] No change: ≤2-fold reduction in susceptibility.
[e] Not all isolates of the New York lineage harbor the E484K substitution (as of February 2021).

https://www.fda.gov/media/145611/download

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# 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
  - For other treatment sites check Department of Health and Human Services (HHS) Therapeutics Distribution locator
- NYC Health+Hospitals
  - Visit ExpressCare.nyc and click “Talk to a Doctor Now” or call 212-COVID19 (212-268-4319)
- 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 5/6/21)
  - $450/reimbursement for mAb administration in most health care settings
  - $750/reimbursement when administered in the beneficiary's home

# NYC Health Department mAb Resources

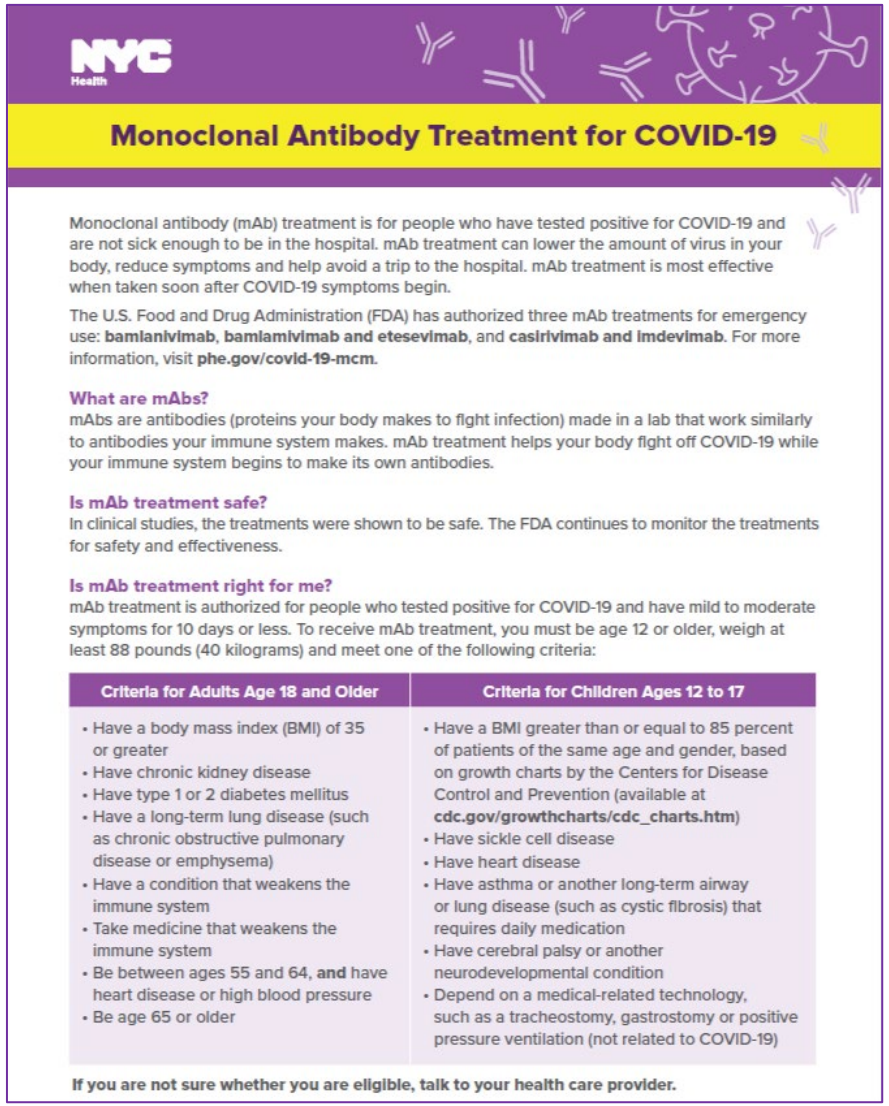
NYC Health

**Dear Colleague: COVID-19 Monoclonal Antibody (mAb) Treatment in the Outpatient Setting**

**Overview**

- mAbs are authorized for emergency use for *non-hospitalized* patients with mild to moderate COVID-19 at high risk of progression to severe disease
- When given early after symptom onset, monoclonal antibody (mAb) treatments can decrease the risk of hospitalization and death due to COVID-19
- Treatment sites and referral information can be found at hitesite.org/monoclonalantibody
- Outpatient facilities interested in providing mAb infusions can make requests through the federal Special Projects for Equitable and Efficient Distribution (SPEED) program

https://www1.nyc.gov/site/doh/covid/covid-19-providers.page



NYC Health

**Monoclonal Antibody Treatment for COVID-19**

Monoclonal antibody (mAb) treatment is for people who have tested positive for COVID-19 and are not sick enough to be in the hospital. mAb treatment can lower the amount of virus in your body, reduce symptoms and help avoid a trip to the hospital. mAb treatment is most effective when taken soon after COVID-19 symptoms begin.

The U.S. Food and Drug Administration (FDA) has authorized three mAb treatments for emergency use: **bamlanivimab**, **bamlamivimab and etesevimab**, and **casirivimab and imdevimab**. For more information, visit **phe.gov/covid-19-mcm**.

**What are mAbs?**
mAbs are antibodies (proteins your body makes to fight infection) made in a lab that work similarly to antibodies your immune system makes. mAb treatment helps your body fight off COVID-19 while your immune system begins to make its own antibodies.

**Is mAb treatment safe?**
In clinical studies, the treatments were shown to be safe. The FDA continues to monitor the treatments for safety and effectiveness.

**Is mAb treatment right for me?**
mAb treatment is authorized for people who tested positive for COVID-19 and have mild to moderate symptoms for 10 days or less. To receive mAb treatment, you must be age 12 or older, weigh at least 88 pounds (40 kilograms) and meet one of the following criteria:

| Criteria for Adults Age 18 and Older | Criteria for Children Ages 12 to 17 |
|---|---|
| • Have a body mass index (BMI) of 35 or greater<br>• Have chronic kidney disease<br>• Have type 1 or 2 diabetes mellitus<br>• Have a long-term lung disease (such as chronic obstructive pulmonary disease or emphysema)<br>• Have a condition that weakens the immune system<br>• Take medicine that weakens the immune system<br>• Be between ages 55 and 64, **and** have heart disease or high blood pressure<br>• Be age 65 or older | • Have a BMI greater than or equal to 85 percent of patients of the same age and gender, based on growth charts by the Centers for Disease Control and Prevention (available at **cdc.gov/growthcharts/cdc_charts.htm**)<br>• Have sickle cell disease<br>• Have heart disease<br>• Have asthma or another long-term airway or lung disease (such as cystic fibrosis) that requires daily medication<br>• Have cerebral palsy or another neurodevelopmental condition<br>• Depend on a medical-related technology, such as a tracheostomy, gastrostomy or positive pressure ventilation (not related to COVID-19) |

**If you are not sure whether you are eligible, talk to your health care provider.**

NYC Health

# Additional COVID-19 Resources

## COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccine:
  - Providers:
    - General 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**

## Next NYC Health Department provider webinar

- Friday, June 18, 1 p.m. (sign up on provider page)

# 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.