COVID-19
HEALTH CARE PROVIDER UPDATE:
MONOCLONAL ANTIBODIES FOR TREATMENT AND PREVENTION OF COVID-19 IN NYC
FEBRUARY 19, 2021

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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 February 18, 2021, 5 PM.
CONTINUING MEDICAL EDUCATION

CME Accreditation Statement for Joint Providership
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OUTLINE

LATEST EPIDEMIOLOGY

UPDATES AND GUIDANCE

MONOCLONAL ANTIBODIES FOR TREATMENT AND PREVENTION OF COVID-19 IN NYC

QUESTIONS AND PANEL DISCUSSION
LATEST EPIDEMIOLOGY AND GUIDANCE

Madhury (Didi) Ray, MD, MPH
Critical Care Planning Lead
COVID-19 Response
NYC Department of Health and Mental Hygiene
Current Status of the COVID-19 Pandemic

• Worldwide: over 110.5 million cases; over 2.4 million deaths
  • Incidence is decreasing in most countries and territories
  • The only World Health Organization region reporting increasing cases is the Middle East

• U.S.: over 28 million cases; over 502,000 deaths
  • Case counts have declined for the past 5 weeks
  • Hospitalizations and deaths are also decreasing nationwide
  • Nonetheless, daily counts remain higher than those seen during peak of summer 2020 wave

• New York City (NYC): over 580,000 cases; over 23,500 confirmed deaths
  • Cases are declining; hospitalizations and deaths have stabilized
COVID-19 Cases, NYC

- Case counts have trended downward during the past few weeks
- Latest 7-day average of cases from complete data: ~4,600 per day

*Probable cases are: (a) people with a positive COVID-19 antigen test; (b) people with COVID-like illness who had exposure to a known case of COVID-19; (c) people who died and had COVID or a similar term listed on their death certificate but did not have a positive laboratory test for COVID-19.

Data from the most recent days are incomplete (gray bar). Data are preliminary and subject to change.
COVID-19 Hospitalizations, NYC

- Hospitalizations have stabilized and possibly begun to decline
- 7-day average (dark line) is ~370/day

Data from the most recent days are incomplete (gray bar). Data are preliminary and subject to change.
COVID-19 Deaths, NYC

- Confirmed deaths are shown in light gray, probable deaths in darker gray
- Deaths appear to have stabilized during past few weeks
- 7-day average: ~80 deaths (confirmed + probable)/day

Data from the most recent days are incomplete (gray bar). Data are preliminary and subject to change.
COVID-19 Vaccine Updates, U.S.

- Approximately 12% of U.S. population has received at least one dose of a COVID-19 vaccine
  - Pace of vaccination has increased in recent weeks
  - Current week: winter storms have slowed distribution across the country, including in New York
- Federal retail pharmacy distribution program was launched; weekly allocations are increasing
- New federal program will provide vaccine supply directly to Federally Qualified Health Centers
- Biden administration announced having secured sufficient vaccine supply for adult population
- Food and Drug Administration (FDA) will review emergency use authorization (EUA) for Johnson & Johnson’s COVID-19 vaccine candidate February 26, 2021
- FDA amended EUA for Pfizer BioNTech vaccine to reflect 6 doses per vial (previously 5)
  - Increments for ordering vaccine in the NYC Citywide Immunization Registry (CIR) were changed accordingly
  - If it is not possible to obtain 6 doses, there is an option to report this in the CIR

Updated CDC Clinical Considerations for Currently Authorized COVID-19 Vaccines

• Contraindications and precautions clarified
  • Persons with a reaction to a vaccine or injectable therapy containing multiple components, one of which is also an mRNA COVID-19 vaccine component, but for whom it is unknown which component caused the immediate allergic reaction, have a precaution to vaccination

• Information on delayed, local injection-site reactions after first dose updated
  • Delayed-onset local injection site reactions (e.g., erythema, induration, pruritis) beginning a few days through the second week after administration of first vaccine dose have been reported
  • Not felt to be a risk for anaphylaxis; neither a contraindication nor a precaution to the second dose

• Recommendations for preventing, reporting, and managing vaccine administration errors added

CDC recommendations 2/10/2021 [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
Updated CDC Recommendations for Vaccinated Persons Exposed to Someone with COVID-19

• Quarantine recommendations for vaccinated persons updated
  • Vaccinated persons not required to quarantine after exposure to someone with COVID-19 if they are:
    • Fully vaccinated against COVID-19 (≥ 2 weeks following completion of series) AND
    • Within 3 months following final dose in series AND
    • Asymptomatic
  • Inpatients and residents in health care settings should continue to quarantine following an exposure
  • These recommendations have not been adopted in New York State, but the Governor has stated an intent to do so

CDC recommendations 2/10/2021  https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
COVID-19 Vaccine Campaign Updates, NYC

- Starting February 15, 2021, people with underlying conditions or who are pregnant are eligible to receive vaccination in NY State
  - If vaccine provider has records showing person has eligible condition, that serves as proof of eligibility
  - Vaccine recipients do NOT need to obtain documentation of underlying condition from a provider
  - Complete list of eligible groups: nyc.gov/covidvaccinedistribution

- NYC’s plan to vaccinate older adults:
  - Senior vaccination clinics launched at retirement communities and senior buildings this week
  - Focused efforts to vaccinate health aides and other caregivers are ongoing
  - In-home vaccination program planned for when Johnson & Johnson vaccine becomes available

New York City Certification of Eligibility for COVID-19 Vaccine Due to Medical Condition

New Yorkers ages 16 and older with the following conditions are eligible for the COVID-19 vaccine, as documented or diagnosed by their health care provider:

- Cancer (current or in remission, including 9/11-related cancers)
- Chronic kidney disease
- Pulmonary disease, including but not limited to, COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), pulmonary fibrosis, cystic fibrosis, and 9/11-related pulmonary diseases
- Intellectual and developmental disabilities including Down syndrome
- Heart conditions, including but not limited to heart failure, coronary artery disease, cardiomyopathies or hypertension (high blood pressure)
- Immuno-compromised state (weakened immune system) including but not limited to solid organ transplant or from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medicines or other causes
- Severe obesity (body mass index of 40 kg/m2 or higher) or obesity (body mass index between 30 kg/m2 and 40 kg/m2)
- Pregnancy
- Sickle cell disease or thalassemia
- Type 1 or 2 diabetes mellitus
- Cerebrovascular disease (affects blood vessels and blood supply to the brain)
- Neurologic conditions including but not limited to Alzheimer’s disease or dementia
- Liver disease

I hereby certify that I have one or more of the medical conditions listed above as documented or diagnosed by my health care provider and that, to the best of my knowledge, the information upon which this certification is based is true and accurate, under penalty of law.

Print name: ___________________________ Signature: ___________________________ Date: ___________________________

If vaccine recipient is 16 to 17 years old or otherwise unable to certify:

Print name of Guardian: ___________________________ Signature of Guardian: ___________________________ Date: ___________________________
1,399,055
Total doses administered

852,963
Dose 1 administered by NYC-run programs

408,944
Dose 2 administered by NYC-run programs

137,148
Doses administered by federal pharmacy programs in NYC

NYC COVID-19 Vaccine Tracker
2/18/2021, 12 a.m.

Data are reported by providers to the Citywide Immunization Registry and may be delayed. Data updated daily: https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page
### Characteristics of Adults Vaccinated Against COVID-19 in NYC, Feb 18, 2021

- Figures show percent of NYC adults (18+) vaccinated by demographic group, based on population estimates.
- All percents are percents of the demographic group.
- Race/ethnicity unknown for 28%.
  - Improved from 40% unknown two weeks ago.

#### Borough Vaccination Rates

<table>
<thead>
<tr>
<th>Borough</th>
<th>Partially Vaccinated</th>
<th>Fully Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staten Island</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Manhattan</td>
<td>7%</td>
<td>8%</td>
</tr>
<tr>
<td>Queens</td>
<td>0%</td>
<td>5%</td>
</tr>
<tr>
<td>Brooklyn</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Bronx</td>
<td>3%</td>
<td>4%</td>
</tr>
</tbody>
</table>

#### Age Group Vaccination Rates

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Partially Vaccinated</th>
<th>Fully Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>75+</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>65-74</td>
<td>18%</td>
<td>8%</td>
</tr>
<tr>
<td>65-64</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>45-54</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>35-44</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>25-34</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>18-24</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

#### Sex Vaccination Rates

<table>
<thead>
<tr>
<th>Sex</th>
<th>Partially Vaccinated</th>
<th>Fully Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Male</td>
<td>5%</td>
<td>4%</td>
</tr>
</tbody>
</table>

#### Race/Ethnicity Vaccination Rates

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Partially Vaccinated</th>
<th>Fully Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>NH/PI</td>
<td>11%</td>
<td>10%</td>
</tr>
<tr>
<td>White</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>AI/AN</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Asian</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Latino</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Black</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

**Race/Ethnicity:** AI/AN: American Indian or Alaska Native, NH/PI: Native Hawaiian or Other Pacific Islander. The Latino category includes people of any race, all other categories exclude those who identified as Hispanic or Latino. Unknown demographics are excluded from these figures. Among adult NYC residents who have received at least one dose of COVID-19 vaccine, 25% have unknown race/ethnicity.

**Data are preliminary and subject to change.**
Percent of NYC Adults Vaccinated, by ZIP Code, Feb 18, 2021

Data are preliminary and subject to change.
Emerging SARS-CoV-2 Variants

• B.1.1.7 variant
  • Emerged in UK, December 2020; approximately 50% more infectious than other common variants
  • Preliminary UK studies suggest it is associated with a higher risk of hospitalization and death
  • Number of cases identified in U.S. is doubling every 10 days
  • Several cases identified in NYC residents to date

• B.1.351 variant
  • First identified in South Africa, December 2020
  • Several cases identified in U.S. to date, one in a Connecticut resident hospitalized in NYC

• P.1 variant
  • Emerged in Brazil, January 2021
  • First identified in U.S. in late January; not identified in NYC to date

• To date, studies suggest antibodies generated in response to vaccination will recognize these variants
  • Preliminary studies suggest several currently available vaccines, including Pfizer-BioNTech and Moderna, may have decreased efficacy against B.1.351
  • Area of ongoing study
  • Strain-specific boosters are under investigation

1. New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) on COVID-19 variant B.1.1.7
Updated CDC Guidance on Use of Masks to Prevent SARS-CoV-2 Transmission and Exposure

• CDC conducted experiments to assess benefit of:
  • Fitting a cloth mask over medical procedure mask
  • Knotting ear loops of medical procedure mask and tucking extra material close to face
• Both methods improved source control and reduced wearer exposure
  • Implication: close fit is important to prevent the spread of COVID-19
• Greatest impact (~95% reduction in risk) seen when both the infected person and the uninfected contact used tightly fitted masks
• CDC has updated its [guidance](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html) on wearing masks accordingly

Updated NYC Guidance for Public on Face Coverings

- Emphasizes importance of wearing a face covering and snug fit
- Provides guidance on effective types of face coverings, including optional use of two face coverings (a cloth covering over a disposable mask) or higher grade mask
- Stresses using face coverings whenever leaving home, and at home when a household member is ill or exposed or when receiving visitors

Available at https://nyc.gov/site/doh/covid/covid-19-prevention-and-care.page
Celebrating Black History Month
COVID-19 Partners Making History
Mosholu Community Health Center

- Brings COVID-19 safety information and resources to community members
- Leads local Bronx youth teams that:
  - Conduct Covid-19-related canvassing in high-priority NYCHA developments
  - Develop bilingual public service announcements
  - Conduct outreach in unconventional places, like local bowling alleys
- Pre-pandemic, their food pantry distributed an average of 800 bags of food/month; now, they distribute an average of 250/day
- Secures grant funding to bring emergency funds to hundreds of families
Housing Works´ Youth Prevention Services Program

• Uses a peer-to-peer model to distribute information on COVID-19 safety, testing and vaccines in Brooklyn and Upper Manhattan

• Leads outreach that centers on COVID-19 education and proactive engagement in neighborhoods where there are obstacles to physical distancing

• Distributes information and personal protective equipment provided by H+H through its networks

• Promotes COVID safety initiatives by leveraging social media platforms and digital marketing expertise

“I do a lot of prevention work and you do not get to see the impact made during the moments. With COVID, you see the impact right away.”

- Susan Zhou
Program Coordinator, YPSP
Monoclonal Antibodies (mAb) for Treatment and Prevention of COVID-19 in NYC

Theodros Seyoum, MD, MPH
Health Systems Support Branch
COVID-19 Response
NYC Department of Health and Mental Hygiene
Outline

• Introduction
• What are Monoclonal Antibodies (mAb)?
• FDA-authorized Monoclonal Antibody Therapeutics for COVID-19
  • Scientific Evidence
  • Eligibility Criteria
  • Safety
• Access to Monoclonal Antibody Treatment
• Equitable Allocation of Monoclonal Antibody Treatment
• Conclusion
Introduction

• Treatment options for patients hospitalized with COVID-19
  • Remdesivir
  • Dexamethasone
  • Convalescent plasma

• Treatment options for outpatients with COVID-19
  • Monoclonal antibodies (mAb)

• mAb treatment in outpatient setting is an interim strategy before widespread vaccination is achieved
  • Decrease the severity of infection
  • Reduce human costs
  • Reduce overall stress on the healthcare system
Interventions depend on stage of COVID-19 illness

Objective: optimize therapeutic use to prevent or shorten hospitalizations

- **No Illness**: Healthy, no infection
- **Exposed/Asymptomatic Infected**: Not hospitalized, no limitations
- **Early Symptomatic**: Not hospitalized, with limitations
- **Hospital Admission**: Hospitalized, no active medical problems
- **Hospital Admission**: Hospitalized, not on oxygen
- **Hospital Admission**: Hospitalized, on oxygen
- **ICU Admission**: Hospitalized, high flow oxygen (or invasive ventilation)
- **ICU Admission**: Hospitalized, mechanical ventilation (ECMO)

**Antiviral therapies**
- Remdesivir (FDA approved)
- Convalescent Plasma (EUA issued)
- Dexamethasone
- Baricitinib (with remdesivir)

**Monoclonal Antibodies**

Monoclonal Antibodies

• Polyclonal antibodies = convalescent plasma
• Monoclonal antibodies = laboratory produced molecules engineered to serve as substitute antibodies against a specific target on a pathogen
• Development of mAbs
  • Identifying and expressing genes from B cells derived from convalescent patients
  • Target mAb for SARS-Cov-2 spike protein, which the virus uses to gain entry into host cells

combatcovid.hhs.gov
Monoclonal Antibody Therapeutics for COVID-19

Approved Products

• Eli Lilly
  • Bamlanivimab 700 mg
  • Bamlanivimab 700 mg + etesevimab 1,400 mg – cocktail administered as a single dose

• Regeneron
  • Casirivimab 1,200 mg + imdevimab 1,200 mg – cocktail administered as a single dose

Clinical Considerations

• Given via a one-time intravenous (IV) infusion
  • 16-60 min infusion time
  • 60 min observation

• Requires positive viral test for SARS-CoV-2 [nucleic acid amplification test (NAAT) or antigen test]

• Must be given within 10 days of symptom onset
Scientific Evidence – Bamlanivimab (Eli Lilly)

BLAZE-1 Trial Phase 2
• Hospitalization + ED visits significantly decreased
  • Most benefit in patients at higher risk (10% vs. 3%)
• Time to symptom improvement reduced (8 days vs. 6 days)

BLAZE-2 prevention trial
• Included 41 COVID-19 positive nursing home residents in treatment arm (BAM vs. placebo)
• Four COVID-related deaths (all in placebo arm)

| Hospitalization/ED Visit: All Participants |
| ----------------------------------------- | --- | --- | --- |
| Treatment                             | N  | Events | Proportion |
| Placebo                               | 156 | 9      | 6%         |
| Pooled antibody                       | 309 | 5      | 2%         |

| Hospitalization/ED Visit: Participants at Higher Risk of Hospitalization |
| -------------------------------------------------- | --- | --- | --- |
| Treatment                      | N  | Events | Proportion |
| Placebo                        | 69 | 7      | 10%        |
| Pooled antibody                | 136| 4      | 3%         |

BLAZE-1 trial Phase 2 - Bamlanivimab +/- Etesevimab vs. placebo

• Compared with placebo, change in viral levels at day 11 not statistically significant for **bamlanivimab monotherapy**
• Significant decrease in viral levels in **bamlanivimab-etesevimab** group
• Hospitalization/ED visits:
  • placebo: 5.8% (9 events)
  • bam 700 mg 1% (1 event)
  • bam 2800 mg 1.9% (2 events)
  • bam 7000 mg 2% (2 events)
  • bam/etesevimab 0.9% (1 event)

Gottlieb RL et al, JAMA, 2021
Scientific Evidence – Bamlanivimab + Etesevimab (Eli Lilly)

- **BLAZE-1 trial Phase 3** - Bamlanivimab + Etesevimab vs. placebo
  - n=1035 high risk outpatients within 3 days of a positive SARS-CoV-2 test
  - 70% risk reduction of COVID-related hospitalizations and deaths (7% vs 2%)
  - 10 deaths in placebo, none in treated group
  - Reduced viral load at day 7 and improved symptoms

<table>
<thead>
<tr>
<th>COVID-19 Hospitalization/Death by Any Cause (day 29)</th>
<th>Death (day 29)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment</strong></td>
<td><strong>N</strong></td>
</tr>
<tr>
<td>--------------</td>
<td>-----</td>
</tr>
<tr>
<td>Placebo</td>
<td>517</td>
</tr>
<tr>
<td>Bam + Ete</td>
<td>518</td>
</tr>
</tbody>
</table>

Fact sheet for providers: EUA for Bamlanivimab and Etesevimab
Scientific Evidence – Casirivimab/Imdevimab (Regeneron)

• Phase 1/2 clinical trials
  • Reduced viral load, largest reduction seen with higher viral loads at baseline
  • Reduced medical visits and hospitalizations compared to the placebo group (2% vs 4%)
    • Greater reductions among high-risk patients (3% vs 9%)
  • Time to symptom improvement was one day less in the treatment group (6 days vs. 5 days)

Ongoing Prevention Trials

• Phase 3 BLAZE-2 prevention trial (bamlanivimab) - nursing homes
  • 80% lower risk of developing symptomatic COVID-19

• Phase 3 REGN-COV2 prevention trial (Casirivimab-Imdevimab) - household contacts (N=~3,000)
  • Initial data from first 400 participants
  • 100% prevention of symptomatic infection
  • ~50% lower overall rates of infection (symptomatic and asymptomatic)
  • Evaluated via subcutaneous (SC) or intramuscular (IM) injection rather than IV infusion

Lily press release; Regeneron press release
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 test (NAAT) 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 and/or hospitalization
## Eligibility Criteria

**Adults**
- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/other chronic respiratory disease.

**Pediatrics**
- Are 12 – 17 years of age AND have
  - BMI ≥85th percentile for their age and gender based on [CDC growth charts](https://www.cdc.gov/growthcharts/), OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
Exclusion Criteria

• mAbs are not authorized for use in patients who:
  • Are hospitalized due to COVID-19, OR
  • Require oxygen therapy due to COVID-19, OR
  • Receive chronic oxygen therapy due to an underlying comorbidity and require an increase in baseline oxygen due to COVID-19

• They can be given to eligible patients hospitalized for reasons other than COVID-19
Safety and Adverse Events

- Most common adverse event is nausea
- Infusion-related reactions have been reported
- Rare anaphylaxis and serious infusion-related reactions have been observed
- Adverse events that are potentially attributable to mAbs use must be reported to the FDA
Access to Monoclonal Antibodies

- MAbs are provided to patients and facilities free of cost through federal program
- Distributed to hospitals via the States
- Outpatient access via Department of Health and Human Services (DHHS) Special Projects for Equitable and Efficient Distribution (SPEED) program
  - Outpatient settings that are able to provide infusions on-site
  - Includes FQHCs, long-term care facilities, hemodialysis providers, and correctional facilities

https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx
Referring Patients for Monoclonal Antibody Treatment

• Greater New York Hospital Association (GNYHA) developing list of hospitals and networks providing mAbs
  • [https://hitesite.org/monoclonalantibody](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](http://ExpressCare.nyc) and click “talk to a doctor now”
  • Call 212-COVID19 (212-268-4319) and press 9 for monoclonal antibody treatment
  • Hours of Virtual Express Care: 9 a.m. – 9 p.m., 7 days a week
  • Infusion sites in Manhattan: Bellevue; Queens: Queens; Brooklyn: Coney Island, Kings County; Bronx: Jacobi
  • If not tested at H+H, need to bring proof of positive test result.

• Become a treatment site
  • Learn more via the HHS [monoclonal antibody outpatient administration playbook](#)
Optimal Timing for Monoclonal Antibody Treatment

• Treatment should be given:
  • Early in symptom progression.
  • As soon as possible after a patient has a confirmed positive test result
  • Within 10 days of symptom onset

• Recommend establishing processes to expedite testing and eligibility screening for high-risk symptomatic patients
Equitable Access to Monoclonal Antibody Therapy

• COVID-19 has disproportionately impacted communities of color in NYC
  • Infections, hospitalizations, deaths
  • Vaccination rates
• Treatment with mAbs can mitigate severity of disease and provides a bridge to mass vaccination of the general population
• Potentially life-saving treatment should be prioritized for eligible patients who have less access to healthcare
Conclusions

• mAbs are another tool to combat mild to moderate COVID-19 in high-risk patients
  • Should ensure access for communities most impacted by COVID-19

• Early mAb treatment tends to have better outcomes in preventing disease progression, hospitalizations, long-term sequelae, and death

• No comparative data to determine whether there are differences in efficacy or safety between bamlanivimab vs. casirivimab + imdevimab

• These are investigational products; future data will reveal definitive clinical benefit of these drugs
Monoclonal Antibody Resources

- **SPEED Website:**
  https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx

- **SPEED FQHC Enrollment Guide:**

- **Email:** covidtx@hhs.gov
mAb Administration Baseball Cards (review Resource/Links as well)

• Bamlanivimab:
  https://www.phe.gov/emergency/events/COVID19/investigationMCM/Bamlanivimab/Pages/Bamlanivimab-Baseball-Card.aspx

• Casirivimab/Imdevimab:
  https://www.phe.gov/emergency/events/COVID19/investigationMCM/cas_imd/Pages/Casirivimab-Imdevimab-Baseball-Cards.aspx

• Administration playbooks

  • Federal Response mAb Playbook:


Monoclonal Antibody Treatment Resources

Reimbursement information
- HRSA FAQs for COVID-19 Claims Reimbursement: [https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions](https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions)

General guidance
- CombatCOVID official website: [https://combatcovid.hhs.gov/](https://combatcovid.hhs.gov/)
- mAb product locator tool: [https://protect-public.hhs.gov/pages/therapeutics-distribution/](https://protect-public.hhs.gov/pages/therapeutics-distribution/)
- Bamlanivimab FAQ: [https://www.phe.gov/emergency/events/COVID19/investigationMCM/Bamlanivimab/Pages/bamlanivimab-faq.aspx](https://www.phe.gov/emergency/events/COVID19/investigationMCM/Bamlanivimab/Pages/bamlanivimab-faq.aspx)
- Casirivimab + Imdevimab FAQ: [https://www.phe.gov/emergency/events/COVID19/investigationMCM/cas_imd/Pages/faq.aspx](https://www.phe.gov/emergency/events/COVID19/investigationMCM/cas_imd/Pages/faq.aspx)
- FAQ for non-hospital sites: [https://www.phe.gov/emergency/events/COVID19/investigationMCM/Pages/FAQs-mAB.aspx](https://www.phe.gov/emergency/events/COVID19/investigationMCM/Pages/FAQs-mAB.aspx)
Additional information

- **HHS / ASPR Office Hours (Tue 1-1:30PM EST, Thu 2-2:30PM EST)**
  - Open forum for state and territorial health officers, health care providers and sites of care to reach out on questions for administration of therapies
  - Contact ASPRstakeholder@hhs.gov for inclusion

- **ECHO – Outpatient Therapeutics Mini-Series (Wed 12-1PM EST)** for clinical overview and examples of administration models

- **Regional Emergency Coordinators:**
  - [https://www.phe.gov/Preparedness/responders/rec/Pages/default.aspx](https://www.phe.gov/Preparedness/responders/rec/Pages/default.aspx)
Resources for Monoclonal Antibody Treatment: Introduction to HITESITE.org

Faiza Haq
Assistant Director
Greater New York Hospital Association
Additional COVID-19 Resources

COVID-19 Vaccines
• NYC Health Department - COVID-19 Vaccine:
  • Public: nyc.gov/covidvaccine
  • Providers: nyc.gov/health/covidvaccineprovider
• Citywide Immunization Registry Reporting Assistance
  • https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic
• Vaccine Provider Assistance:
  • Email 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, March 5, 1 p.m. (sign up on provider page)