COVID-19 ORAL ANTIVIRAL TREATMENT, GENERAL UPDATES, AND CO-CIRCULATION WITH INFLUENZA

DECEMBER 16, 2021

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New York State Department of Health

OUR UNDERSTANDING OF COVID-19 IS EVOLVING RAPIDLY -
THIS PRESENTATION IS BASED ON OUR KNOWLEDGE AS OF DECEMBER 15, 2021 at 5PM
OUTLINE

1. RECENT EPIDEMIOLOGY, NYS & NYC
2. COVID-19 ORAL ANTIVIRAL TREATMENT
3. GENERAL UPDATES, AND CO-CIRCULATION WITH INFLUENZA
OUTLINE

RECENT EPIDEMIOLOGY, NYS & NYC
Positive Tests Last 3 Months, All NY State Counties

Weekly Case Rates by Vaccination Status, NYC

Cases per 100,000 people (for week ending on listed date)

Unvaccinated

Citywide

Vaccinated

Recent data may be incomplete.

https://www1.nyc.gov/site/doh/covid/covid-19-data.page#daily
New Daily Cases by Vaccination Status, NY State
Adults 18 year and older

New Daily Hospital Admissions by Vaccination Status, NY State
Adults 18 year and older

Daily Hospitalization Summary, NY State
9/14/2021 – 12/13/20201

https://coronavirus.health.ny.gov/daily-hospitalization-summary
Daily Hospitalization Summary by Region, NY State
9/14/2021 – 12/13/20201

https://coronavirus.health.ny.gov/daily-hospitalization-summary
COVID-19, NYC, 3/1/2020-12/15/2021

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

NYC Health Department, COVID-19 data
<table>
<thead>
<tr>
<th>People with at least one Vaccine Dose</th>
<th>People with completed Vaccine Series</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Total Population (CDC) (^1)</td>
<td>% of Total Population (CDC) (^1)</td>
</tr>
<tr>
<td>81.1%</td>
<td>70.5%</td>
</tr>
<tr>
<td>% of 18+ Population (CDC) (^1)</td>
<td>% of 18+ Population (CDC) (^1)</td>
</tr>
<tr>
<td>93.5%</td>
<td>82.0%</td>
</tr>
<tr>
<td>Total (^2)</td>
<td>Total (^2)</td>
</tr>
<tr>
<td>15,209,777</td>
<td>13,595,167</td>
</tr>
<tr>
<td>% of Total Population (^3)</td>
<td>% of Total Population (^3)</td>
</tr>
<tr>
<td>75.5%</td>
<td>68.0%</td>
</tr>
<tr>
<td>Age 18+ (^2)</td>
<td>Age 18+ (^2)</td>
</tr>
<tr>
<td>13,877,474</td>
<td>12,531,636</td>
</tr>
<tr>
<td>% of 18+ Population (^3)</td>
<td>% of 18+ Population (^3)</td>
</tr>
<tr>
<td>86.9%</td>
<td>79.0%</td>
</tr>
</tbody>
</table>
Percent of Population Vaccinated in New York State
By Age, as of 12/14/2021

**AT LEAST ON VACCINE DOSE**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>5-11</th>
<th>12-17</th>
<th>18-25</th>
<th>26-34</th>
<th>35-44</th>
<th>45-54</th>
<th>55-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.6%</td>
<td>70.5%</td>
<td>77.3%</td>
<td>80.2%</td>
<td>87.9%</td>
<td>83.9%</td>
<td>92.1%</td>
<td>&gt;99.0%</td>
<td>89.5%</td>
<td></td>
</tr>
</tbody>
</table>

**COMPLETED VACCINE SERIES**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>5-11</th>
<th>12-17</th>
<th>18-25</th>
<th>26-34</th>
<th>35-44</th>
<th>45-54</th>
<th>55-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.3%</td>
<td>63.3%</td>
<td>60.3%</td>
<td>71.6%</td>
<td>80.5%</td>
<td>77.7%</td>
<td>85.6%</td>
<td>91.3%</td>
<td>90.3%</td>
<td></td>
</tr>
</tbody>
</table>

Percent of New York City Residents Vaccinated by Race/Ethnicity

ALL AGES WITH AT LEAST 1 DOSE

- Not yet vaccinated (21.3%)
- At least 1 dose (78.7%)

ALL AGES FULLY VACCINATED

- Not yet vaccinated (21.3%)
- Partially vaccinated (7.8%)
- Fully vaccinated (70.9%)

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</td>
<td>93%</td>
<td>86%</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>56%</td>
<td>50%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>72%</td>
<td>63%</td>
</tr>
<tr>
<td>Native American/Alaska Native</td>
<td>99%</td>
<td>99%</td>
</tr>
<tr>
<td>White</td>
<td>61%</td>
<td>57%</td>
</tr>
</tbody>
</table>

* Race/ethnicity data includes all eligible New Yorkers

Vaccination Coverage Compared to Recent Average Daily COVID-19 Percent Positive by NYC Zip Code


https://www1.nyc.gov/site/doh/covid/covid-19-data.page#maps as of 12/15/2021
The information presented here is preliminary and based on regular discussions with Federal partners. The content is subject to change based upon official EUA release.
Oral Antivirals to Treat COVID-19
Clinical Use and Indications

• Two oral antivirals under FDA review to treat non-hospitalized, symptomatic adults diagnosed with COVID-19 who are at increased risk of progressing to severe illness
  • Paxlovid (Pfizer) - Reduced risk of hospitalization by ≥88%
  • Molnupiravir (Merck) - Reduced risk of hospitalization by 30%

• Target certain surface proteins on SARS-CoV-2 to prevent efficient replication of the virus in host cells

• Both would be taken twice daily x 5 days

• Supplies will be limited, and providers should prioritize oral antivirals for patients unable to receive monoclonal antibody (mAb) treatment
Paxlovid (PF-07321332; ritonavir)

- **Phase 2/3 placebo-controlled clinical trial, interim analysis (N=2,246)**
  - High-risk, non-hospitalized adults, mild to moderate symptoms for ≤5 days
  - Primary endpoint: hospitalization or death

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Hospitalized (D#28)</th>
<th>Death</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paxlovid</td>
<td>1039</td>
<td>8 (0.8%)</td>
<td>0</td>
<td>88% (p&lt;0.0001)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>bid x 5d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>1046</td>
<td>66 (6.3%)</td>
<td>12 (1.1%)</td>
<td></td>
</tr>
</tbody>
</table>

- **Subgroup analysis of patients treated within 3 days of symptom onset = 89%**
- Adverse events similar between treatment and placebo group, fewer emergent events in treatment group (1.6% vs. 6.6%)

Molnupiravir (MK-4482, EIDD-2801)

- Phase 3 placebo-controlled clinical trial, interim analysis (N=775)
  - High-risk, non-hospitalized adults, mild to moderate symptoms
  - Symptom onset within 5 days
  - Excluded pregnancy, verified by a negative pregnancy test

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Hospitalized or Death (D#29)</th>
<th>Percent Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Molnupiravir</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bid x 5d</td>
<td>709</td>
<td>48 (6.8%)</td>
<td>30% (p=0.0218)</td>
</tr>
<tr>
<td><strong>Placebo</strong></td>
<td>699</td>
<td>68 (9.7%)</td>
<td></td>
</tr>
</tbody>
</table>

- Efficacy against variants Gamma, Delta, Mu (40% of cases sequenced)
- Adverse event similar between treatment and placebo group

Oral Antivirals to Treat COVID-19
Expected Eligibility With EUA

• Therapy will likely only be available for people who meet all the following conditions:
  • Age 18 years and older
  • Have a medical condition or other factors that increase their risk for severe illness
    • Consider race and ethnicity when assessing individual risk. Longstanding systemic health and social inequities may put individual patients at increased risk of getting sick and dying from COVID-19
  • In addition to receive the therapy, patients need to:
    • Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test
    • Have mild to moderate COVID-19 symptoms
    • Be within 5 days of symptom onset
    • Not be hospitalized or receiving oxygen therapy due to COVID-19
  • Pregnant and lactating women were excluded from clinical oral antiviral trials
Monoclonal Antibodies and Other Outpatient Therapeutics

There are several COVID-19 oral antivirals under development, but anti-SARS-CoV-2 monoclonal antibodies are currently the only therapeutic authorized for:

- Treatment of non-hospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease.
- Post-exposure prophylaxis (PEP) for people at high risk of progressing to severe COVID-19.

Monoclonal antibodies are made in a laboratory and work as substitute antibodies that can help fight an infection before the body mounts its own immune response. The antibodies are directed against specific targets on the spike protein of SARS-CoV-2. Blocking viral entry into cells. They are recommended by the National Institute of Health COVID-19 Treatment Guidelines for outpatient treatment of COVID-19 and post-exposure prophylaxis (PEP).

If you start treatment soon after the onset of symptoms, monoclonal antibodies can decrease the risk of hospitalization and death due to COVID-19 by as much as 70% to 85% and reduce hospital length of stay and emergency department visits.

As PEP, the antibodies can reduce the risk of developing symptomatic COVID-19 by 60%.

Providers should refer all eligible symptomatic patients for this treatment, regardless of a patient's vaccination status.

- [Visual Abstract: Refer Patients for Monoclonal Antibody Therapy for COVID-19](PDF, September 2021)
Oral Antivirals to Treat COVID-19
Distribution NYS and NYC

• Initial supplies have been purchased by U.S. Government
  • Will be provided to States/treatment sites for free
• Initial allocations to states will be extremely limited
  • Focus will be on ensuring *equitable* access for *highest risk* outpatients
  • Sites able to provide mAbs (e.g., hospital EDs) will likely be lower priority to receive at first
  • Biweekly allocations
  • Similar to all initial new product allocations, delivery is a push to the counties and boroughs, this is not going to be a request system
Oral Antivirals to Treat COVID-19
Distribution NYC

• Initially in NYC, oral medications will only be distributed by Alto Pharmacy
  • Retail pharmacy selected through competitive process to ensure equitable access for all New Yorkers
  • Allows easier supply management, reducing burden on patients and providers
• Will offer free courier delivery across all five boroughs
  • COVID-19 antiviral prescriptions should be routed to Alto Pharmacy
  • Once received, patients can schedule delivery on the Alto mobile app, by text or by phone
  • Prescriptions confirmed by 5 pm weekdays or 1pm on weekends are delivered the same day
• As supplies increase, additional pharmacies will be added as access points based on local needs
Oral Antivirals to Treat COVID-19
Prescribing NYC

• For e-prescribing add Alto Pharmacy to your electronic medical record (EMR)
• Locate Alto Pharmacy in your ePrescribing platform or EMR, by searching on any of the following data points:
  • Name: Alto Pharmacy
  • Address: 100 Park Ave, Front E, New York, NY 10017
  • NPI: 1417578899
  • NCPDP: 5831866
  • Ensure search filters do not include a mileage or radius limit and that you are not on a “favorites” or “recently viewed” filter
• Alternatively, Alto Pharmacy accepts prescriptions via phone (800) 874-5881 or fax at (415) 484-7058
Oral Antivirals to Treat COVID-19
Prescribing NYC

• Verify patient phone number and address for delivery in the chart
• Record patient’s race/ethnicity in the note for pharmacist section
• Send prescription to Alto Pharmacy
• Advise patient they will receive a call or text message from the pharmacy ((800) 874-5881) to schedule delivery. The patient must respond to the call or text to confirm delivery
• For questions or concerns, contact Alto Pharmacy at (800) 874-5881
• The amount of product New York State receives will be distributed to counties and regions using an algorithm that will be based on multiple factors, including:
  • Population density
  • At-risk population (e.g., unvaccinated population)
  • COVID-19 case burden
• First initial phase:
  • Push system of distribution
  • 2-3 pharmacy sites per county
  • Prioritizing communities within each county with a high Medicaid population
  • Partnering with Federal Retail Pharmacy Partners
• As supplies increase, additional pharmacies will be added as access points
• Initial allocation, paired with utilization data, will be used to determine future allocations

• Sites will be required to adhere to a daily reporting requirement

• Reporting of product will support the release of a product finder tool supported by the Federal Government (details TBD)
OUTLINE

GENERAL UPDATES, AND CO-CIRCULATION WITH INFLUENZA
New SARS-CoV-2 Variant of Concern: Omicron (B.1.1.529) Variant

• First detected in Botswana November 11, 2021, and South Africa on November 14, 2021; now numerous countries and states
• Omicron cases have been detected in NYC and elsewhere in New York State, including in people without travel history
• Assume community transmission of this variant is occurring, however, delta remains the dominant strain in New York and NYC
New SARS-CoV-2 Variant of Concern: Omicron (B.1.1.529) Variant

• About 50 mutations compared to original SARS-CoV-2 virus, > 30 within spike protein of the virus

• We know more about what we don’t know that what we know, studies are underway, expect to know more in the coming weeks
  • Preliminary evidence suggests it is highly transmissible
  • Spectrum of illness not yet described, unknown if more severe illness compared to other variants

• Vaccines
  • Expect decreased neutralization from vaccine and prior infection
  • Expect vaccines to remain effective against severe illness and death
New SARS-CoV-2 Variant of Concern: Omicron (B.1.1.529) Variant

- Omicron’s emergence underscores the need for COVID-19 prevention measures for all New Yorkers, including those who are fully vaccinated. Remind patients to:
  - Complete a primary COVID-19 vaccination series
  - Get a COVID-19 booster
  - Wear a mask in indoor public settings; consider the type of mask or respirator to use
  - Get tested for COVID-19 if symptomatic or recently exposed to someone with COVID-19, and before and after attending a gathering or travel
  - Stay home when sick, including when symptoms are mild
  - Take other measures to prevent exposure and transmission
- Continue to follow existing quarantine, isolation and testing guidance

CDC Nowcast Estimate of Proportion of SARS-CoV-2 Variants by HHS Region, USA
12/5/2021-12/11/2021

Region 2 = New Jersey, New York, Puerto Rico, and the Virgin Islands

Overall:
- Delta = 86.4%
- Omicron = 13.1%

Map showing regional proportions.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
Omicron and Monoclonal Antibodies

• Bamlanivimab + etesevimab
  • Active against Delta (B.1.617.2)
  • **May have significant loss of activity against Omicron**
• Casirivimab + imdevimab (REGEN-COV)
  • Active against Delta
  • **May have significant loss of activity against Omicron**
• Sotrovimab
  • **Likely active against all variants of concern including Omicron**

The U.S. Food and Drug Administration on December 3, 2021, revised the EUA of bamlanivimab and etesevimab. Now authorized to administer together in ALL pediatric patients, including newborns for:

- **Treatment** of mild to moderate COVID-19 with positive COVID-19 test who are at high risk for progression to severe COVID-19, including hospitalization or death
- **Post-exposure prophylaxis** for prevention of COVID-19 in those at high risk of progression to severe COVID-19, including hospitalization or death
Long-Acting Antibody Combination Therapy

• EVUSHELD - Pre-exposure prophylaxis LAAB from AstraZeneca
  • FDA Authorized
  • Combination of tixagevimab (AZD8895) and cilgavimab (AZD1061)
  • Derived from B-cells donated by convalescent patients after SARS-CoV-2 virus infection
  • 77% reduction in risk of symptomatic COVID-19
    • 75% of participants had co-morbidities that put them at high risk for severe COVID-19 including people who are immunocompromised and may have a reduced immune response to vaccination

Long-Acting Antibody Combination Therapy

• Intramuscular (IM) injection of each of the 2 products, every 6 months
• For persons 12 years of age and older who weigh at least 88 pounds [40 kg]] in persons who are:
  • Not currently infected with SARS-CoV-2 and no recent close contact with someone who is infected with SARS-CoV-2 and
  • Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments and
  • May not mount an adequate immune response to COVID-19 vaccination or
    • For whom vaccination with an available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine or ingredient

Expanded CDC COVID-19 Booster Recommendations

• CDC strengthened the recommendation on booster doses on November 29 and FDA expanded the Pfizer EUA on December 9
  • Everyone ages 18 years and older should get a booster dose six months after their initial Pfizer or Moderna series, or two months after their initial Johnson & Johnson vaccine
  • Based on expansion, NYC DOHMH recommends that adolescents ages 16-17 years should receive a Pfizer booster dose six months after their initial Pfizer series

Coronavirus (COVID-19) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-Olds | FDA
NYS COVID-19 Executive Order #11

• Declares a disaster emergency in NYS
  • Increasing transmission and hospitalizations
  • Limit non-essential elective procedures for in hospitals or systems with limited capacity as of December 9
    • Does NOT apply to single specialty facilities (e.g., cancer treatment facility), non-hospital owned ambulatory surgery centers, office-based surgery practices, or free-standing diagnostic and treatment centers
  • Coordinated, collaborative approach to ensure hospital capacity meets regional needs while maintaining the long-term resiliency of the State’s healthcare infrastructure

Influenza Season Updates

• Influenza activity in Southern hemisphere has been low to date
  • This may not be predictive of what will occur in U.S.
• Offer flu and COVID-19 vaccines together, if possible
• Start testing patients with influenza-like illness for flu and COVID-19
• Start messaging to high-risk patients:
  • Get vaccinated for flu and COVID-19
  • Get tested for flu and COVID-19 immediately if symptoms develop
  • Important to access **timely** treatment for COVID-19 or flu if needed

Updated CDC guidance on flu testing and treatment: [https://www.cdc.gov/flu/professionals/diagnosis/index.htm](https://www.cdc.gov/flu/professionals/diagnosis/index.htm)
Influenza Surveillance NYS by Region
WIDESPREAD - Week Ending December 4, 2021

https://www.health.ny.gov/diseases/communicable/influenza/surveillance/
https://www1.nyc.gov/site/doh/providers/health-topics/flu-alerts.page
Influenza Surveillance NYS by Region
Week Ending December 4, 2021

https://www.health.ny.gov/diseases/communicable/influenza/surveillance/
https://www1.nyc.gov/site/doh/providers/health-topics/flu-alerts.page
Respiratory Virus Results, Selected NYC Labs
November 28-December 4, 2021

https://www.health.ny.gov/diseases/communicable/influenza/surveillance/
Influenza Season Updates
CDC Testing strategies during co-circulation SARS-CoV-2

• Options for testing respiratory specimens in patients with acute respiratory illness
  • Outpatient clinical and emergency department
    • Test for SARS-CoV-2 and use judgement to clinically diagnose influenza and prescribe antiviral treatment of influenza if needed, OR
    • Test for both SARS-CoV-2 and influenza viruses
  • Hospitalized or Nursing Home
    • Test for both SARS-CoV-2 and influenza viruses

• Do not order viral culture for initial or primary diagnosis of influenza
• Do not order serology for influenza
• When influenza is circulating, prescribe empiric oseltamivir based on a clinical diagnosis of influenza for patients with progressive illness or risk factors for influenza complications
  • Prescribe even if symptoms have been present > 48 hours

https://www.cdc.gov/flu/professionals/diagnosis/
Influenza Season Updates

CDC Testing strategies during co-circulation SARS-Cov-2

Testing Guidance for Clinicians When SARS-CoV-2 and InfluenzaViruses are Co-circulating

Based upon local public health surveillance data and testing at local healthcare facilities

1. **Specimen Collection**
   - Implement recommended infection prevention and control measures and collect respiratory specimens for influenza and SARS-CoV-2 testing. There are two sample types: nasopharyngeal and oropharyngeal. 

2. **SARS-CoV-2 and influenza testing**
   - **SARS-CoV-2 testing** is performed on all samples. 
   - **Influenza testing** is performed if the patient has influenza-like symptoms. 

3. **Treatment**
   - Antiviral treatment for influenza is recommended for patients with influenza-like symptoms. 
   - For patients with suspected community-acquired pneumonia who do not require hospitalization, see antibiotic treatment guidelines. 

https://www.cdc.gov/flu/professionals/diagnosis/
Influenza Season Updates
Testing strategies during co-circulation SARS-CoV-2

• For more information about influenza vaccines and antivirals for influenza treatment and prophylaxis visit:
  • NYS and NYC Health Department provider influenza pages
  • NYC Community Health Information for Influenza Prevention and Control
  • CDC

https://www.health.ny.gov/diseases/communicable/influenza/seasonal/providers/
https://www1.nyc.gov/site/doh/providers/health-topics/influenza.page
https://www.cdc.gov/flu/professionals/index.htm
Tips for a Safer Holiday Season

Advise your patients to:

• Get COVID-19 vaccination and boosters

• Get tested before and after gatherings and travel
  
  • If using a rapid antigen test before a gathering, time it as close possible to the actual gathering

• Antigen tests are not as sensitive as PCR and perform best when a person is actively shedding virus

**NYSDOH - Provider COVID-19 Resources**


**NYC DOHMH - Provider COVID-19 Resources**

- Provider page: [https://www1.nyc.gov/site/doh/covid/covid-19-providers.page](https://www1.nyc.gov/site/doh/covid/covid-19-providers.page)

- Monoclonal antibodies/outpatient therapeutics: [nyc.gov/health/covidprovidertherapeutics](https://nyc.gov/health/covidprovidertherapeutics)


- Dear Colleague COVID-19 newsletters - sign up for City Health Information subscription at: [nyc.gov/health/register](https://nyc.gov/health/register)

- NYC Health Alert Network - sign up at: [https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page](https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page)

- Provider Access Line: **866-692-3641**