New York State and New York City Health Departments

HEALTH CARE PROVIDER WEBINAR

MONKEYPOX UPDATES

August 4, 2022





Eugene P. Heslin, MD, FAAFP
First Deputy Commissioner and
Chief Medical Officer
New York State Department of Health

Mary Foote, MD, MPH
Medical Director / Healthcare Systems Support Branch Director
New York City Department of Health and Mental Hygiene

The information presented is based on our knowledge as of 7/20/22 and is subject to change

Agenda

- Updates on the current outbreak
- Clinical guidance
- Vaccination
- Resources





Updates on the current outbreak

Monkeypox Declared a Public Health Emergency

- The number of people diagnosed with monkeypox continues to rise in New York City (NYC), New York State, the US and other countries.
- On July 23, 2022, the World Health Organization declared MPX a Public Health Emergency of International Concern
- On July 28, the New York State Department of Health declared monkeypox an Imminent Threat to Public Health and, on July 29, the State declared a State Disaster Emergency
- On July 30, the NYC Department of Health and Mental Hygiene declared monkeypox a Public Health Emergency, and on August 1, the City declared a State of Emergency





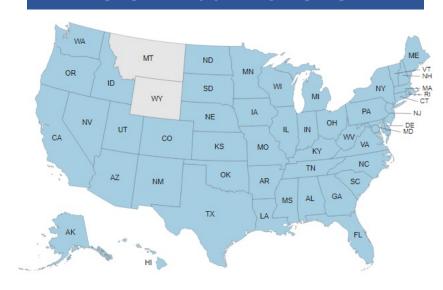
SITUATION REPORT IN NEW YORK STATE As of August 3, 2022

NEW YORK STATE - 1666 CASES

- 1,558 in New York City
- 2 in Albany County
- 1 in Broome County
- 1 in Chemung County
- 1 in Columbia County
- 5 in Dutchess County
- 4 in Erie County
- 1 in Greene County
- 6 in Monroe County

- 11 in Nassau County
- 1 in Niagra County
- 3 in Orange County
- 4 in Rockland County
- 1 in St Lawrence County
- 22 in Suffolk County
- 2 in Sullivan County
- 2 in Tompkins County
- 41 in Westchester County

U.S. - 6617 CASES





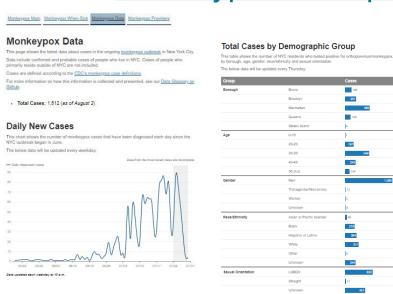




New Monkeypox Data Pages

Up-to-date data about cases can be found online for

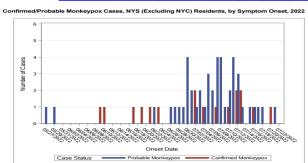
NYC Monkeypox Data page and NYS Monkeypox (ny.gov)



Department

of Health

Cifywide



Confirmed/Probable Monkeypox Cases, in NYS (Excluding NYC)

		(%)	The second of	N	(%)
Total	80	100%	Gender ¹ , ²		-
Age Group		1	Male	78	98%
Under 18 years	. 0		Female	0	
18-24 years	5		TGNCNB	1	1%
25-29 years	17		Unknown	1	1%
30-34 years	18		Sexual Orientation 1		- 17
35-39 years	16		Straight	3	4%
40-44 years	9			59	
45-49 years	6	89	Lesbian or gay		
50-54 years	7	99	Bisexual	12	
55 years and above	2	39	Unknown	6	8%
			N (%)		
	Race and	Ethnic		-	-

Hispanic/Latino
White, non-Hispanic
Black/African American, non-Hispanic

Unknows

Missing

American Indian or Alaskan Native



Public Health Response

- Ample testing capacity at 5 commercial labs that can test >50,000 specimens weekly
 - LabCorp, Mayo, Aegis Science, Sonic Healthcare and Quest
- Testing for Orthopoxvirus at Wadsworth Center (and NYC PHL)
 - Positive results = probable cases presumed to be monkeypox
 - Then may be then confirmed monkeypox by CDC testing
 - Rapid review of additional tests to expand provider testing capacity
 - · Wadsworth has additional capacity as well with prior DOH approval
- Supporting local health departments with tools and consultation for case investigation and contact tracing/monitoring





Updates on Testing – NYC Public Health Laboratory

- Submit specimens through commercial laboratories when possible
- Continues to offer testing for NYC residents
- Soon will be accepting swabs stored in viral transport media (VTM) in addition to dry swabs. An announcement will be sent via the eOrder application
- Courier services will not be available starting August 19.
 Providers and facilities will need to arrange their own transportation of specimens for monkeypox testing to PHL





- 98% gay or bisexual men, median age 38 years, 75% White, 41% with HIV
- Sexual activity presumed route of transmission for most (95%)
- Rash in 95%
 - 64% <10 lesions, 73% anogenital lesions, 41% mucosal lesions, 54 (%) single genital lesion
- Systemic features preceding rash included
 - Fever (62%), lethargy (41%), myalgia (31%), headache (27%) and lymphadenopathy (56%)
- Concomitant sexually transmitted infections for 29%
- Among 23 patients with clear exposure history, median incubation of 7 days (range 3 to 20 days)







- Antiviral treatment given to 5% of patients
- Hospitalization for 70 (13%) for
 - Pain management mostly for severe anorectal pain (21 persons); soft-tissue superinfection (18); pharyngitis limiting oral intake (5); eye lesions (2); acute kidney injury (2); myocarditis (2); and infection-control purposes (13).
- Monkeypox viral DNA detected in semen of 29 of 32 patients





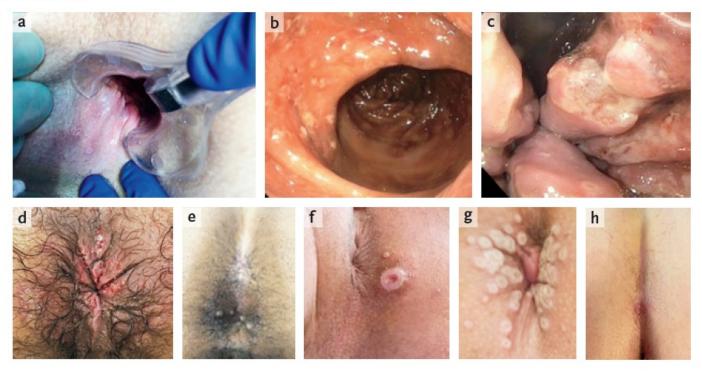


Evolution of Cutaneous Lesions



Thornhill 2022, N Engl J Med; https://www.nejm.org/doi/full/10.1056/NEJMoa2207323

Perianal, Anal, and Rectal Lesions



Thornhill 2022, N Engl J Med; https://www.nejm.org/doi/full/10.1056/NEJMoa2207323

Clinical Guidance



Clinical Considerations for Treatment and Prophylaxis in People with HIV

- Unknown if people with HIV have different incubation or prodromal phase of illness
 - Two historical case series found no difference in patients with HIV compared to those without HIV
- European countries where most patients are on ART have noted no deaths or excess in hospitalizations thus far among monkeypox patients with HIV
- Patients with advance or uncontrolled HIV may have a higher risk for more severe or prolonged disease
- Vaccination, medical treatment and close monitoring are a priority for this population
 - Patients taking ART should continue treatment; if not they may start ART
 - Patients can receive TPOXX, though some interactions with ART may occur
 - Patients can receive JYNNEOS vaccine

Clinical Considerations for People Who are Pregnant or Breast/Chest feeding

- It is unknown if pregnant people are more susceptible to Monkeypox virus or if infection is more severe in pregnancy. However, smallpox, also an orthopoxvirus, was associated with more severe illness during pregnancy, including hemorrhagic complications and death
- Adverse pregnancy outcomes, including spontaneous pregnancy loss and stillbirth, have been reported in cases of confirmed monkeypox infection during pregnancy
- Monkeypox virus can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth
- Must separate baby from parent to prevent transmission
- Breast feeding may be delayed unknown if virus is present in breast milk

Clinical Considerations for People Who are Pregnant or Breast/Chest feeding

- Can treat with TPOXX though with limited data in pregnancy
 - Reach out to LHD if encounter a case in pregnancy
 - No fetal effects seen at high doses in animal studies
 - Seen in breast milk at high doses in animal studies
 - Levels in breast milk may not treat infant for monkeypox
- Can receive vaccine
 - Animal studies show no effects on pregnancy no human data

Clinical Considerations for Monkeypox in Children and Adolescents

- Disease is usually mild and self limited but can be severe
 - Especially in those with history of dermatitis or exfoliative skin conditions
 - Under the age of 8 years
 - Immunocompromised
- Keep skin lesions covered and prevent children from scratching lesions or touching their eyes - may result in auto-inoculation
 - Optimal fluid intake should be encouraged, particularly with extensive skin involvement causing additional fluid losses
- Can treat with TPOXX though should monitor kidney function
- Vaccine is not licensed for use in children –single dose can be given with IND approval from FDA

Updated Interim NYC Guidance for Treatment of Monkeypox

- Released August 2, 2022, with additional updates as new information available
 - https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf
- Provides instruction on supportive care and symptom treatment for providers
- Elaborates on clinical indications in which treatment with tecovirimat might be considered
- Revised overview and step by step instructions for prescribing or obtaining tecovirimat for patients in NYC





Interim New York State guidance for Monkeypox

- Released on July 8 with updates to be updated as new information becomes available
 - NYSDOH Health Alert Notice for providers in New York State July 8, 2022 (PDF)

 Elaborates on clinical indications in which treatment with tecovirimat might be considered





Tecovirimat – NYC Experience

Experience in NYC to date:

- About 30% meet criteria for tecovirimat.
- Most common indication is severe proctitis
 - Other indications include painful anal or penile lesions, bacterial superinfection, painful oral lesions
- Prescribed for over 500 patients
- Significant improvement reported after just a few days of starting treatment
- No significant adverse events reported
 - Some reports of headache and nausea







Tecovirimat – How to obtain Treatment

- The CDC's IND protocol was recently simplified to make it easier for any provider to prescribe TPOXX
 - Allows the use of telemedicine for all patient encounters (initial and follow-up visits) as long as the patient can submit the signed consent form electronically
 - Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities.
 - Fewer forms are required under the IND, and they can all be returned to CDC after treatment begins.







Prescribing Tecovirimat

- Revised overview and step by step instructions for prescribing or obtaining tecovirimat for patients in NYC
 - https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypoxtreatment-guidance-interim.pdf
 - Health Advisory #16: Accessing Tecovirimat for People with Monkeypox
- Obtaining tecovirimat for patients in NYS
 - Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC







2022 Health Advisory #16: Accessing Tecovirimat for People with Monkeypox

- Many people with monkeypox in New York City (NYC) have developed complications
 including proctitis, which can progress to become severe and debilitating, and lesions in
 anatomical sites at risk of scarring or other permanent sequelae. Supportive care,
 including pain control, is a mainstay of treatment.
- Tecovirimat (TPOXX) is an antiviral medication available through the Centers for Disease Control and Prevention (CDC) that is being used to treat monkeypox infection under CDC's Expanded Access Investigational New Drug (IND) protocol. To date, tecovirimat has been prescribed for over 400 patients in NYC.
- Recently the FDA and CDC simplified this protocol so that treatment with tecovirima
 can begin upon obtaining informed consent from the patient. No pre-registration is
 required and evaluations can be done by telemedicine. Additional forms must be
 submitted to CDC after initiating treatment.
- Providers are urged to take the necessary steps to prescribe tecovirimat when indicates
 for the patients that have a positive test result for are awaiting test results and have a
 clinically compatible illness). Not providers who want to prescribe tecovirimat and can
 adhere to the IND protocol can email Mptherapoutice(Pheath ner, gov for information
 on free delivery to natients or or request sucinies for a pharmacy at their facility.
- For more information about monkeypox, visit the NYC Department of Health and Mental Hydiono's Mankeypox information for Providers we have

gust 2, 2022

Dear Colleagues,

The number of people diagnosed with monkeypox continues to rise in figer or GE to MOT, but and other countries (on help 32, 2002; the World Health Department on decisee MON'S a <u>Public Health Temperature</u> on help 32, but New York State Department of Health Decision and Contribution of the MOT and the Health Decision and Contribution to Modify and Application of the State Department of Health Decision and Contribution and Contri

Tecovirimat – Prescribing in NYC

- In NYC, to prescribe TPOXX
 - First obtain the Informed Consent Form
 - Then email the NYC Health Department at <u>MPXtherapeutics@health.nyc.gov</u> to receive an automated reply with instructions including how to arrange to have individual prescriptions delivered to the patient by the NYC pharmacy courier service.
 - Complete and submit to CDC the required <u>Patient Intake Form</u> and <u>FDA</u>
 <u>Form 1572</u> Enrollment Form
 - Conduct two follow-up visits and submit the required <u>Clinical Outcome</u>
 Forms to CDC
 - Report life-threatening or serious adverse events associated with tecovirimat





Tecovirimat – Prescribing in NYS

- In NYS, to prescribe TPOXX
 - First obtain and complete the <u>FDA Form 1572</u> (only done once for each Facility)
 - Then email the NYS Health Department at <u>mpxtreatment@health.ny.gov</u> to receive further instructions
 - Every patient requires a complete <u>Informed Consent Form</u> prior to receiving
 Tecovirimat
 - Complete and submit to CDC the required <u>Patient Intake Form</u> and Enrollment Form
 - Conduct two follow-up visits and submit the required <u>Clinical Outcome Forms</u> to CDC
 - Report life-threatening or serious adverse events associated with tecovirimat





Vaccination





Health Department Vaccine Supply

- Ensuring supply of JYNNEOS vaccine for post-exposure prophylaxis
- As of July 28, New York State had received 60,000 doses
 - Distributions are made to local health departments who decide how to distribute among local populations
- Announced July 28, 110,000 additional doses will arrive in next four to six weeks
 - 80,000 New York City; allocation will not arrive in one lump sum
 - 30,000 rest of state





Health Department Vaccine Clinics – PEP++

- People aged 18 or older who meet all of the following criteria are eligible to get vaccinated at a Health Department clinic
 - Gay, bisexual, or other man who has sex with men, and/or transgender, gender non-conforming, or gender non-binary
 - Have had multiple or anonymous sex partners in the last 14 days
 - Do not have symptoms of monkeypox, or diagnosed with monkeypox
- NYC prioritizing first doses for PEP++ so more people can get first doses and have some protection
- The JYNNEOS vaccine is a two-dose vaccine, with the second dose administered at least four weeks
 after the first dose.
- Antibody protection begins in the days and weeks after their first dose and full immunity is expected two
 weeks after the second dose. It is OK to wait longer than four weeks for the second dose. The Health
 Department will contact people when second doses are available.
- NYS continues to follow the CDC two dose regimen





Health Department Vaccine Clinics – PEP++

- Vaccination is free and available regardless of immigration status
 - Appointments being released on a rolling basis based on vaccine supply with some appointments reserved for patients and clients of clinical and non-clinical partners
- For information on the NYC vaccine program
 - Visit <u>nyc.gov/monkeypox</u> for information including on how to make an appointment in NYC
- For information on the NYS vaccine program, please visit
 - Visit <u>Monkeypox Vaccination (ny.gov)</u> for information on where vaccine is available in NYS.
 - Local county health departments that have received a supply will administer the vaccine directly and are
 establishing their own appointment processes. Please refer to county webpages for more information. (Current
 counties outside of New York City: <u>Albany County</u>, <u>Erie County</u>, <u>Monroe County</u>, <u>Nassau County</u>, <u>Rockland County</u>,
 <u>Saratoga County</u>, <u>Sullivan County</u>, <u>Suffolk County</u>, <u>Westchester County</u>



NYC Health Department Vaccine Clinics – PEP++



NYCity's vaccine portal

In NYC, 23,000 new first dose appointments will go online on the City's vaccine portal today, **Thursday, August 4 at 6pm**.

To ensure equitable access to vaccine

- An additional doses will be administered to people referred by community partner organizations, health care providers and close contacts
- Five new vaccine clinics have opened at:
 - The Livonia (Brooklyn)
 - The Jefferson (Brooklyn)
 - Long Island City (Queens)
 - NYC Health + Hospitals/Kings (Brooklyn)
 - NYC Health + Hospitals/Gotham Health, Gouverneur (Manhattan)



Resources

Resources

- NYSDOH: Monkeypox (ny.gov)
- Palm Card
- Information Card
- SMS text notification to 81336:
 English MONKEYPOX
 Spanish MONKEYPOXESP
- NYC: nyc.gov/monkeypox
- TextMONKEYPOX" to 692-692 or, for Spanish, text "MONKEYPOXESP
- CDC
- CDC HAN 472: Update for Clinicians on Monkeypox in People with HIV, Children and Adolescents, and People who are Pregnant or Breastfeeding
- CDC HAN 471: Update for Clinicians on Testing and Treatment for Monkeypox
- Monkeypox and Sexual Health
- Isolation & Prevention Practices
- Information for Providers on Obtaining and Using TPOXX for treatment of monkeypox



monkeypox. This means understanding the symptoms, how it spreads, and what to do it stees that may appear o s or in other areas such Be Aware. thest, or face. These may nce to common sexual **Your Community** (STh) and other ts like poison by Cares! ich as fever, headache and fatigue. These before or after the rash Protect yourself and your community by staying ypox spread? through close, physical iduals. This includes: informed about onkeypox sores or monkeypox. Visit: al who has monkeyp or oral fluids from rypox, particularly for health.nv.gov/ contact with someone monkeypox or a long period of time through contact with

n clothing bedding

en used by someone

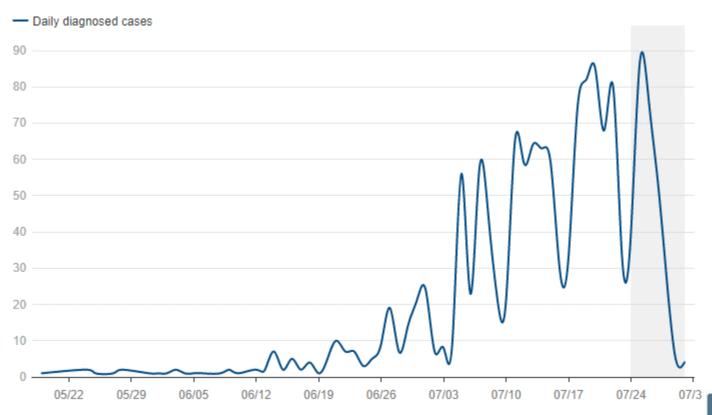




THANK YOU

Additional slides providing detail for reference

Cases of Monkeypox by Date of Diagnosis, NYC

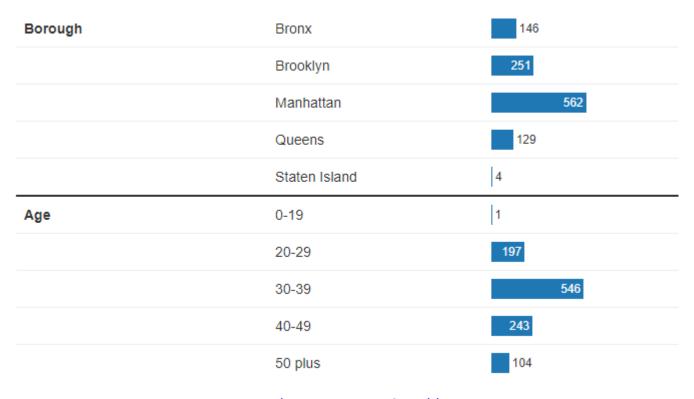




Monkeypox Data - NYC Health

NYC Demographic Data

As of July 29, 2022 (N= 1,092 cases)

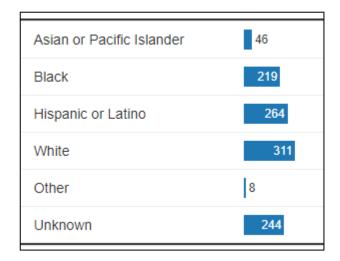


Monkeypox Data - NYC Health

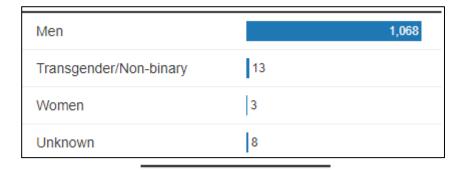
NYC Demographic Data

As of July 29, 2022 (N= 1,092 cases)

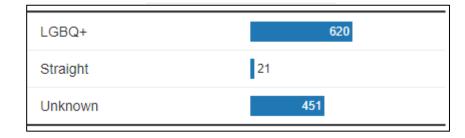
Race/Ethnicity



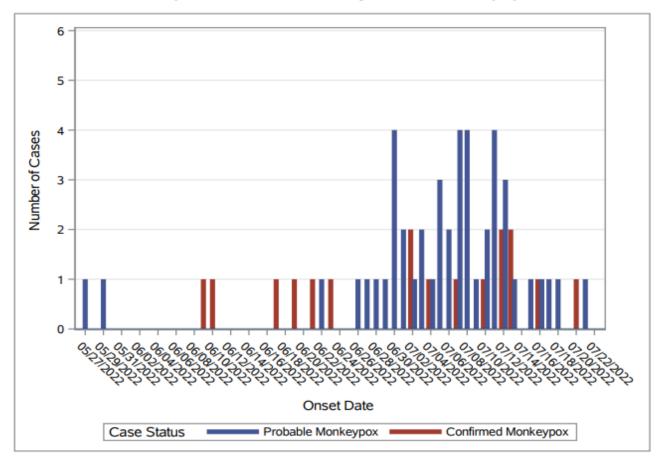
Gender



Sexual Orientation



Confirmed/Probable Monkeypox Cases, NYS (Excluding NYC) Residents, by Symptom Onset, 2022



Confirmed/Probable Monkeypox Cases, in NYS (Excluding NYC)

	N	(%)
Total	80	100%
Age Group		
Under 18 years	0	0%
18-24 years	5	6%
25-29 years	17	21%
30-34 years	18	23%
35-39 years	16	20%
40-44 years	9	11%
45-49 years	6	8%
50-54 years	7	9%
55 years and above	2	3%

	N	(%)
Gender ¹ , ²		1
Male	78	98%
Female	0	0%
TGNCNB	1	1%
Unknown	1	1%
Sexual Orientation 1		
Straight	3	4%
Lesbian or gay	59	74%
Bisexual	12	15%
Unknown	6	8%

	N	(%)
Race and Ethnicity 1		
Hispanic/Latino	28	35%
White, non-Hispanic	25	31%
Black/African American, non-Hispanic	13	16%
American Indian or Alaskan Native	0	0%
Asian or Pacific Islander	2	3%
Other	1	1%
Unknown	8	10%
Missing	3	4%

Summary of 197 Monkeypox Patients From London

- Systemic illness reported among 86.3%, most common symptoms were; fever (61.9%), lymphadenopathy (57.9%), and myalgia (31.5%)
 - 61.5% developed systemic features before the onset of mucocutaneous manifestations
 - 38.5% after
 - 13.7% at the same time
- Other complaints included rectal pain (36.0%), sore throat (16.8%), penile edema (15.7%), oral lesions (13.7%) and tonsillar signs (4.6%)
- 31.5% of patients had a concomitant sexually transmitted infection
- Hospitalization for 10.2% of patients, primarily for management of symptoms
 - most commonly rectal pain and penile swelling





NYC Demographic Data

As of July 29, 2022 (N= 1,558 cases)

Age	
Median Age (range)	35 (20-69)
Unknown	0 (0.0%)
Gender	
Men	624 (97.7%)
Women	1 (0.2%)
TGNCNB	9 (1.4%)
Unknown	5 (0.8%)
Sexual Orientation	
LGBQ+	335 (52.4%)
Straight	9 (1.4%)
Unknown	295 (46.2%)

TGNCNB = transgender, gender nonconforming and nonbinary Unknown = missing or pending case investigation



Borough	
Bronx	73 (11.4%)
Brooklyn	138 (21.6%)
Manhattan	346 (54.1%)
Queens	79 (12.4%)
Staten Island	3 (0.5%)
Unknown	0 (0.0%)
Race/Ethnicity	
Hispanic/Latino	137 (21.4%)
Asian/Pacific Islander	22 (3.4%)
Black/African American	110 (17.2%)
White	198 (31.0%)
Other	2 (0.3%)
Unknown	170 (26.6%)

https://www1.nyc.gov/site/doh/health/health-topics/monkeypox.page

Tecovirimat – contacts in NYC

NYC Providers or facilities should email the NYC Health Department at MPXtherapeutics@health.nyc.gov to:

- Order a supply of tecovirimat to maintain at an onsite pharmacy or
- Requesting instruction and assistance with the IND paperwork or other institutional approvals/review board issues or
- Arrange to serve as a referral site to prescribe tecovirimat for patients who do not have a primary care provider
- Get assistance in referring patients to another provider if unable to complete the required IND forms to prescribe tecovirimat





Tecovirimat – How to obtain Treatment

- Any provider or health care facility or system can prescribe tecovirimat under the CDC's IND protocol
- Tecovirimat is provided at no cost by the federal government and patients should not be charged for the medicine
 - Providers may bill for the encounter
- Providers/investigators can prescribe for individual patients as needed from a dedicated NYC supply managed by a partner pharmacy
- Providers/investigators can also coordinate with the NYC or NYS
 Health Department to request a supply from the strategic national
 stockpile to have on site at a facility or health system pharmacy





