COVID-19
Chicago Long Term Care Roundtable

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Long Term Care Roundtable

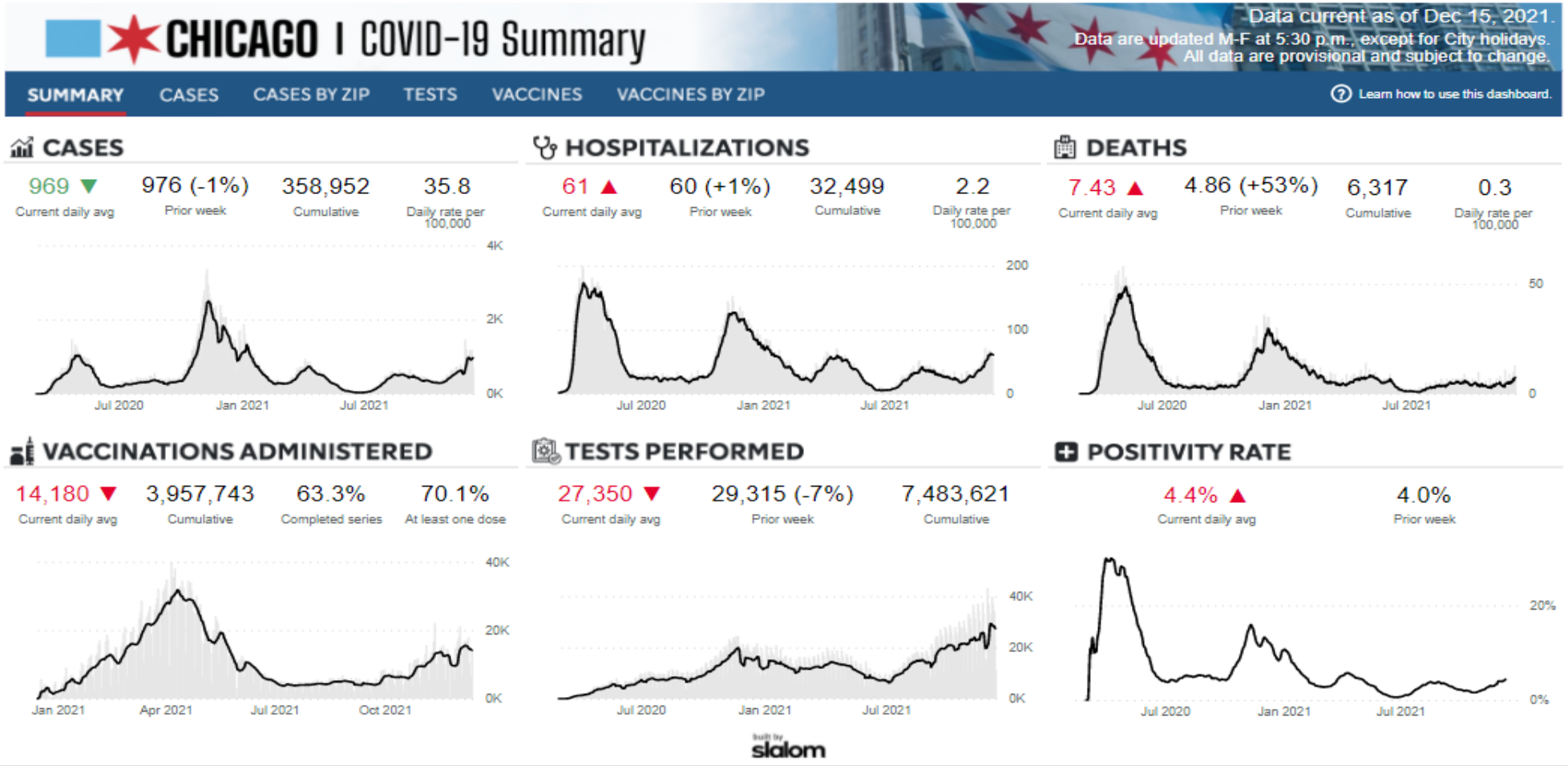
12.16.21

Outline

- COVID-19 Epidemiology
- COVID-19 treatment options
- Monoclonal antibodies review
- Eligibility to receive mAbs
- Review of clinical evidence
- Clinical considerations
- Access to monoclonal antibodies
- Questions & Answers

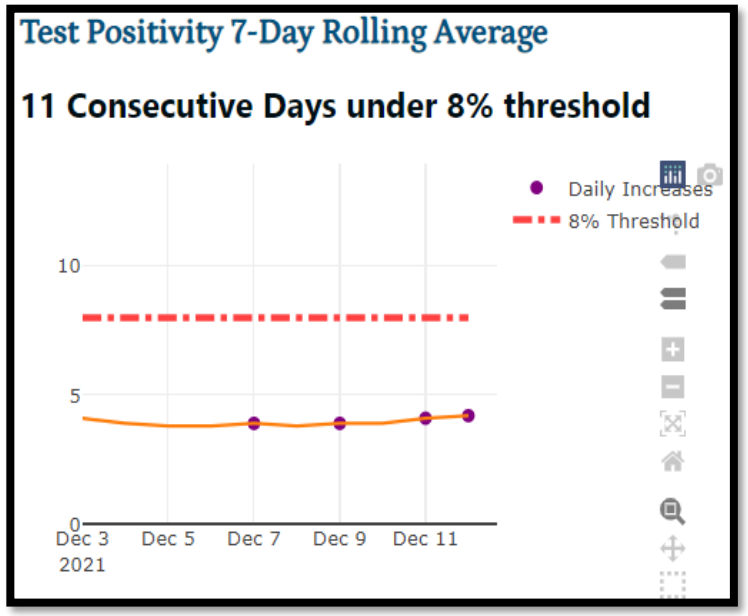
Chicago Dashboard

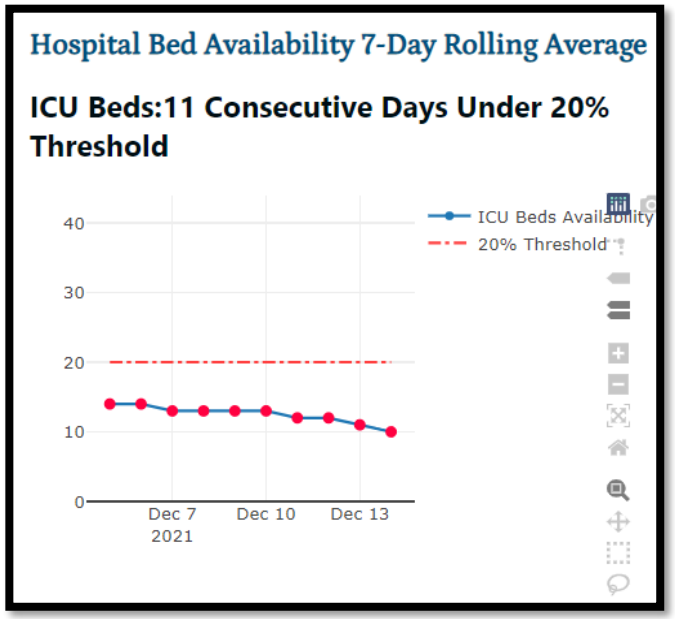
Data are updated M-F at 5:30 p.m., except for City holidays

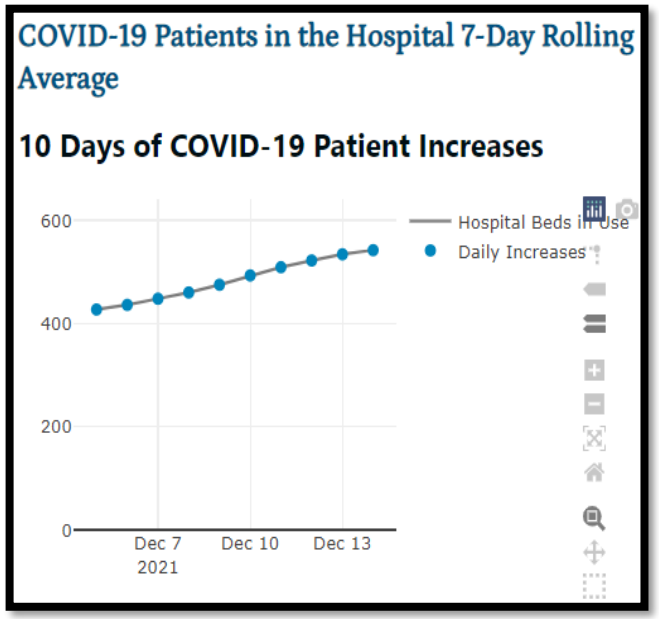


Source: https://www.chicago.gov/city/en/sites/covid-19/home/covid-dashboard.html

IDPH Regional Resurgence Metrics: Region 11

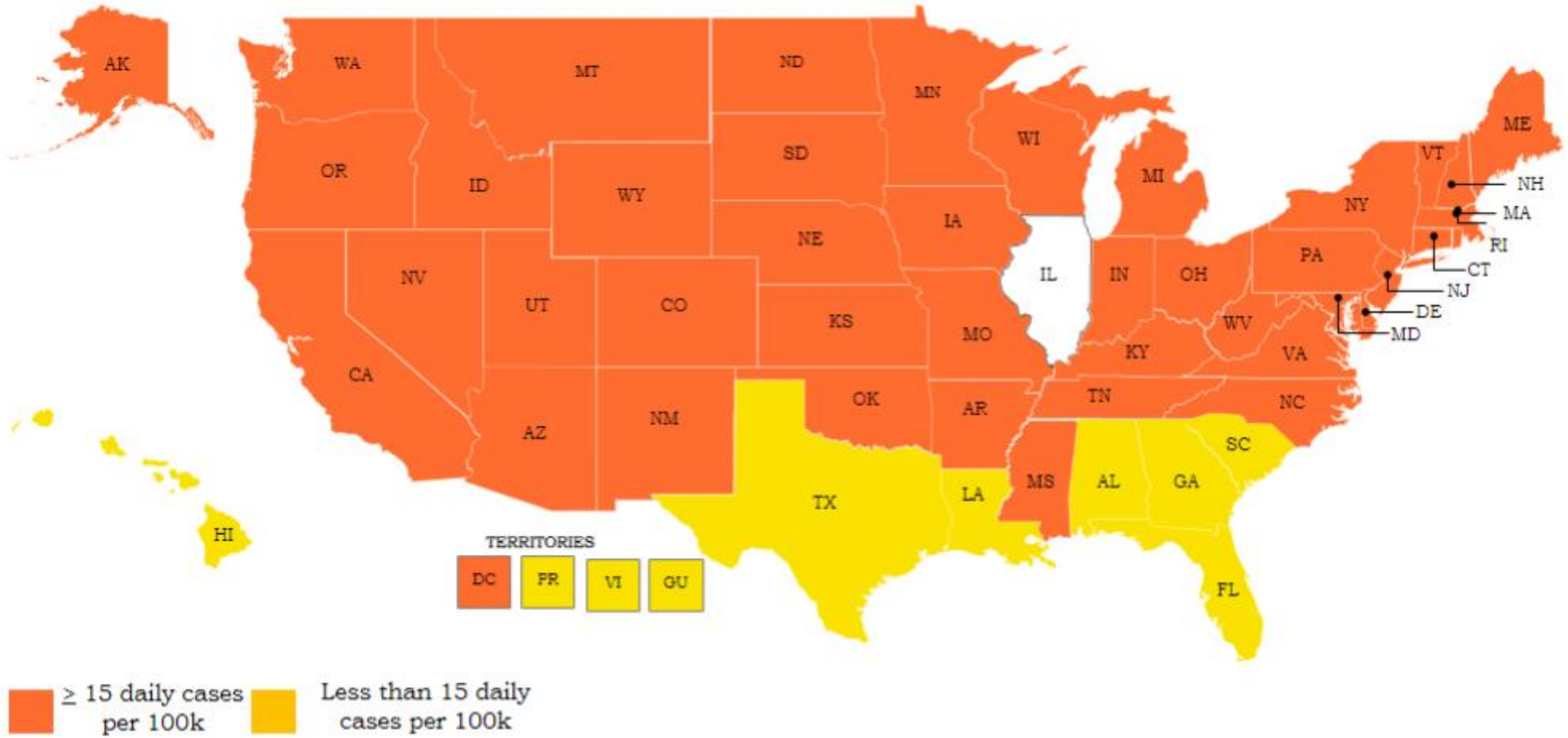




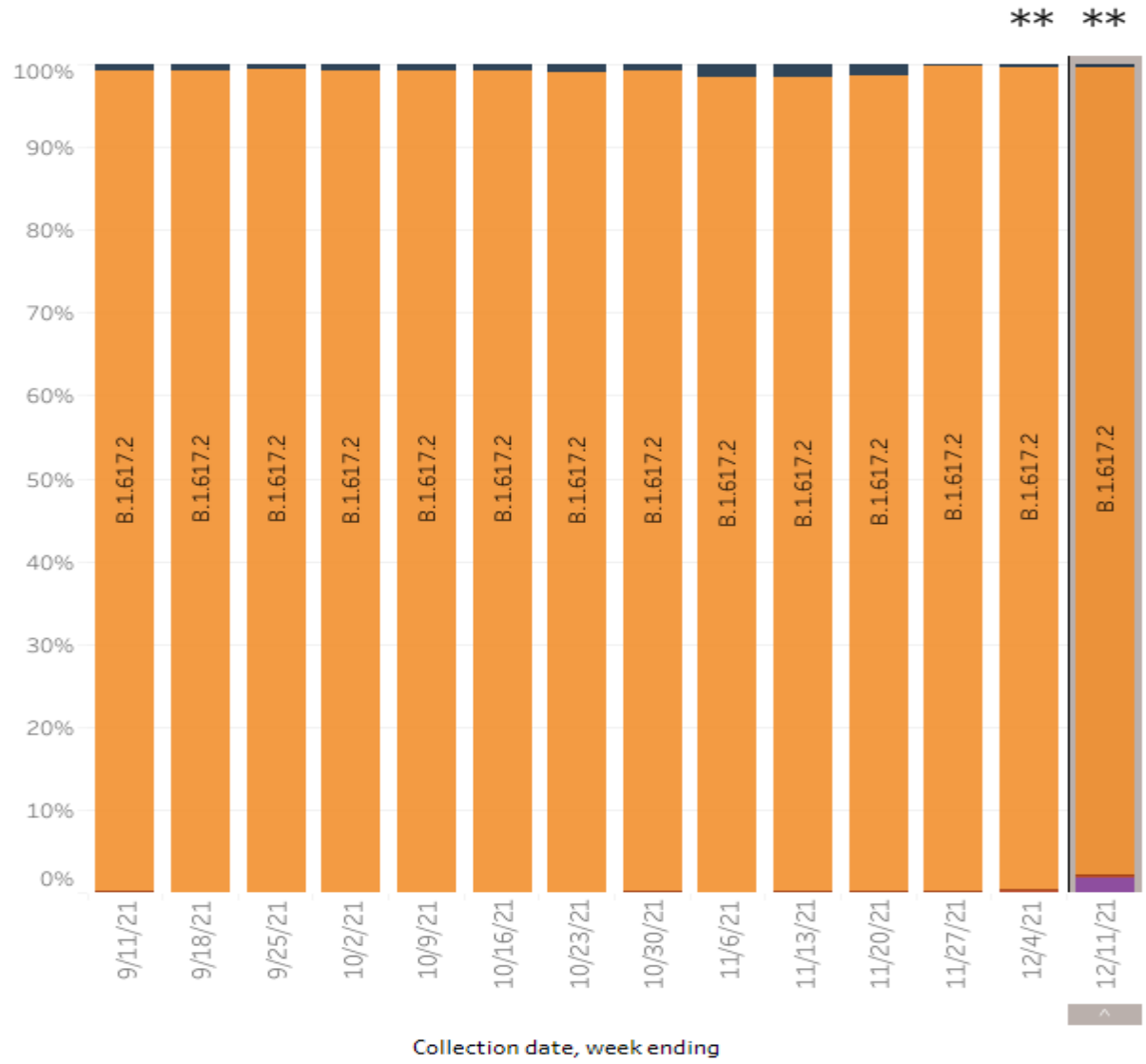


Source: https://www.dph.illinois.gov/regionmetrics?regionID=11

Chicago's COVID-19 Travel Advisory: 42 States, D.C.



HHS Region 5: 9/5/2021 – 12/11/2021



HHS Region 5: 12/5/2021 – 12/11/2021 NOWCAST

Region 5 - Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin

WHO label	Lineage #	US Class	%Total	95%PI
Delta	B.1.617.2	VOC	97.6%	84.9-99.9%
	AY.1	VOC	0.1%	0.0-0.2%
	AY.2	VOC	0.0%	0.0-0.0%
Omicron	B.1.1.529	VOC	2.0%	0.0-16.4%
Other	Other*		0.3%	0.2-0.6%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.3-AY.125 and their sublineages are aggregated with B.1.617.2. BA.1 and BA.2 are aggregated with B.1.1.529.

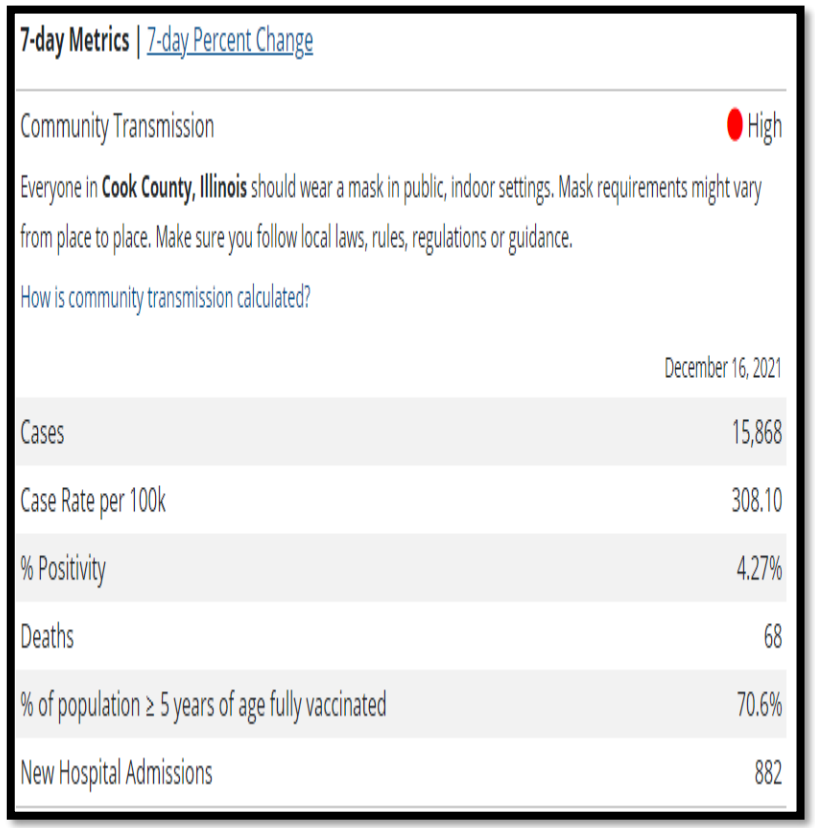
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Chicago COVID-19 Community Transmission and Risk Matrix

	VERY HIGH TRANSMISSION	HIGH TRANSMISSION	SUBSTANTIAL TRANSMISSION	LOWER TRANSMISSION	LOW TRANSMISSION
COVID-19 CASES DIAGNOSED PER DAY Chicago residents - 7-day rolling daily average	800+ **Current: 903** Stable	400 - 799	200 - 399	20 - 199	<20
COVID-19 TEST POSITIVITY Chicago residents - 7-day rolling daily average	10%+	6.6 - 9.9%	5.0 - 6.5%	2 - 4.9% **Current: 4.2%** Increasing	<2%
HOSPITAL BEDS (NON-ICU) OCCUPIED BY COVID PATIENTS Chicago hospitals - 7-day rolling daily average	1250+	750 - 1249	250 - 749 **Current: 441** Increasing	100 - 249	<100
ICU BEDS OCCUPIED BY COVID PATIENTS Chicago hospitals - 7-day rolling daily average	400+	300 - 399	100 - 299 **Current: 135** Increasing	20 - 99	<20

Source: Chicago Department of Public Health, data current as of December 14, 2021. These metrics represent general community COVID transmission and should not be applied to individual settings that have mitigation practices in place.

CDC COVID Data Tracker: Cook County



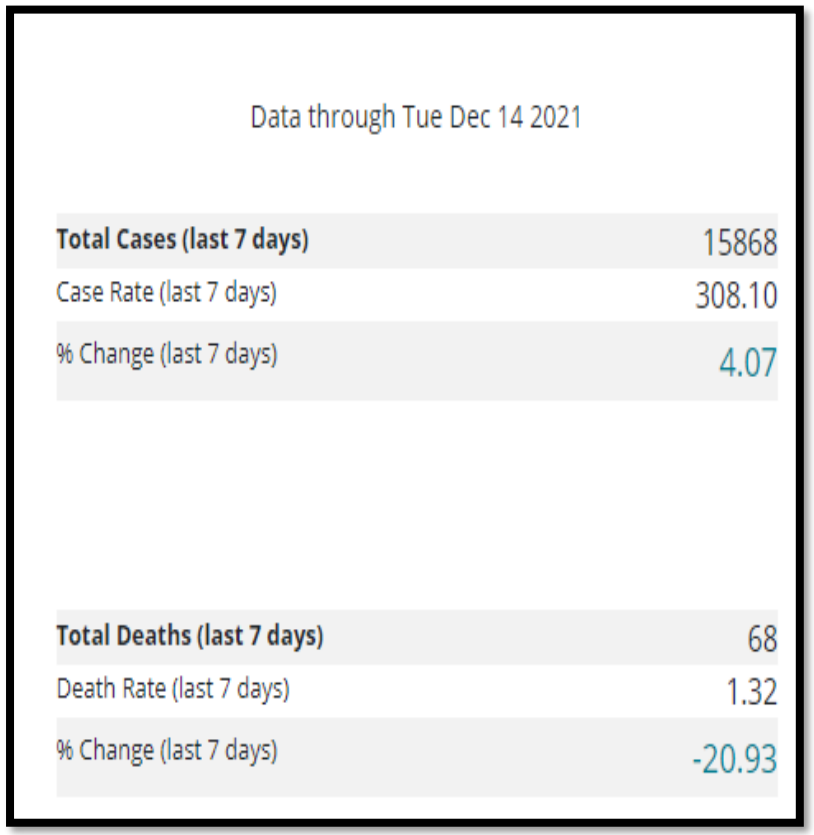
7-day Metrics | 7-day Percent Change

Community Transmission — High

Everyone in **Cook County, Illinois** should wear a mask in public, indoor settings. Mask requirements might vary from place to place. Make sure you follow local laws, rules, regulations or guidance.

How is community transmission calculated?

	December 16, 2021
Cases	15,868
Case Rate per 100k	308.10
% Positivity	4.27%
Deaths	68
% of population ≥ 5 years of age fully vaccinated	70.6%
New Hospital Admissions	882



Data through Tue Dec 14 2021

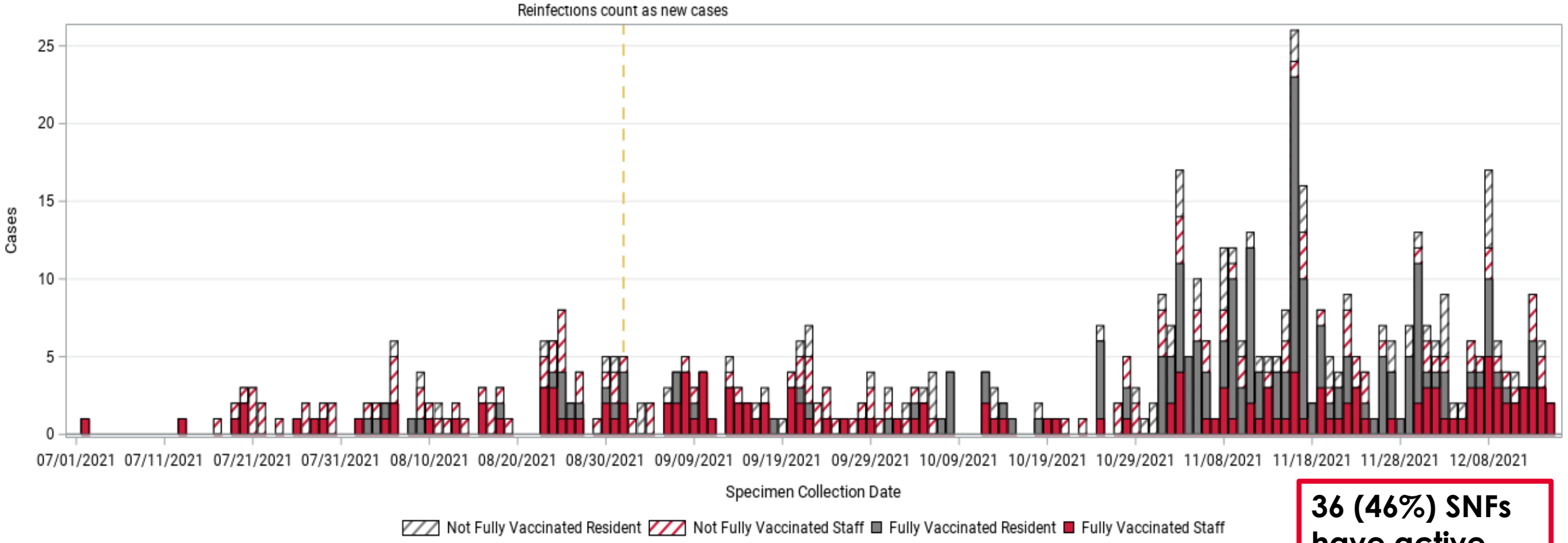
Total Cases (last 7 days)	15868
Case Rate (last 7 days)	308.10
% Change (last 7 days)	4.07
Total Deaths (last 7 days)	68
Death Rate (last 7 days)	1.32
% Change (last 7 days)	-20.93

Source: https://covid.cdc.gov/covid-data-tracker/#cases_community

Data as of 12/15/2021

SNFs are experiencing an increase in COVID-19 cases and outbreaks

(July 1, 2021 – Dec. 15, 2021)



36 (46%) SNFs have active outbreaks

Data Sources: INEDSS (Illinois state) and REDCap (facility self report)

A fully vaccinated case occurs when the positive test specimen was collected at least two weeks after the individual completed their COVID vaccination

Fully vaccinated cases may be underestimated due to delayed reporting

CMS Vaccine mandate

- The 5th U.S. Circuit Court of Appeals on Wednesday revived the health care worker vaccine mandate in 26 states which means the vaccine mandate still holds in Illinois
- all eligible staff should have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment, or other services by December 6, 2021.
- All eligible staff must have received the necessary shots to be fully vaccinated – either two doses of Pfizer or Moderna or one dose of Johnson & Johnson – by January 4, 2022.

CHICAGO

Monoclonal Antibodies (mAbs) for Treatment and Prevention of COVID-19

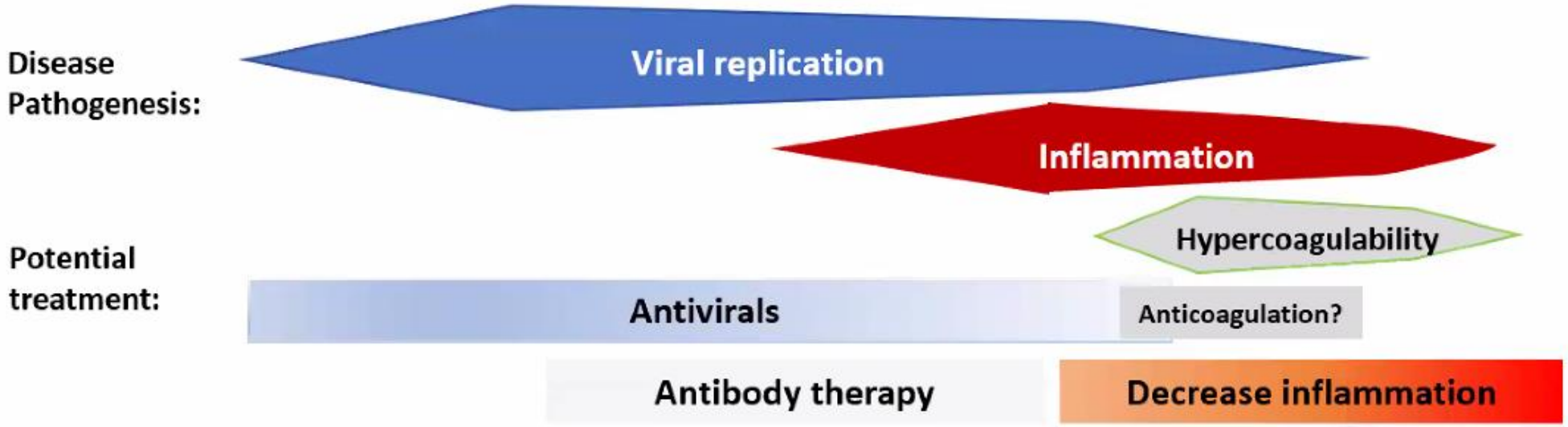
Opportunities for Using mAbs

- Month of November: 77 Chicago SNFs reported in NHSN
  - Almost all facilities reported 0 residents treated with mAbs during that time
  - Only 2 facilities reported use of mAb
  - 33 facilities in outbreak
    - ~160 cases in residents
    - ~73 cases in staff
    - How many contacts?

- Lots of opportunity to use this treatment.

Treatment Across the COVID-19 Spectrum

Stage/ Severity:	Asymptomatic/ Presymptomatic	Mild Illness	Moderate Illness	Severe Illness	Critical illness
	+ SARS-CoV-2 test but no symptoms	Mild symptoms (eg fever, cough, taste/smell changes); no dyspnea	O_2 saturation >=94%, lower respiratory tract disease	O_2 saturation <94%, respiratory rate >30/min; lung infiltrates >50%	Respiratory failure, shock, multi-organ dysfunction/failure



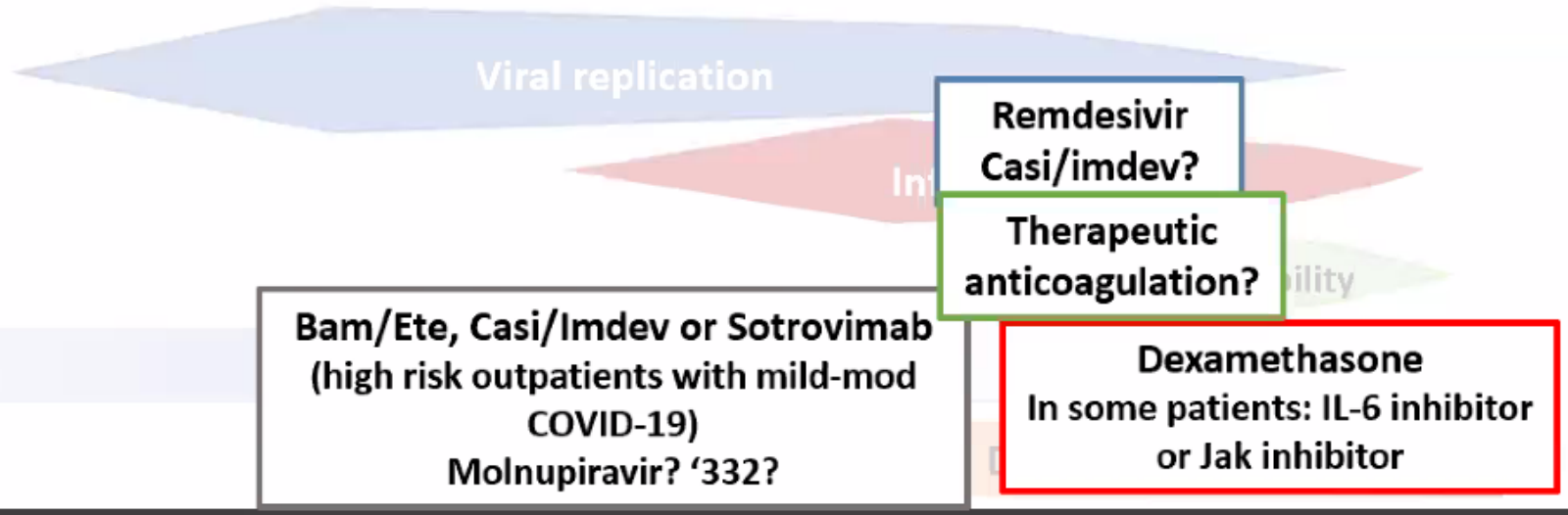
Gandhi RT, CID, 2020
Gandhi RT, Lynch J, del Rio C. NEJM 2020

Prophylaxis and Treatment Across the COVID-19 Spectrum

Exposure	Asymptomatic/ Presymptomatic	Mild Illness	Moderate Illness	Severe Illness	Critical illness
	+ SARS-CoV-2 test but no symptoms	Mild symptoms (e.g., fever, cough, taste/smell changes); no dyspnea	O_2 saturation ≥ 94%, lower respiratory tract disease	O_2 saturation <94%, respiratory rate >30/min; lung infiltrates >50%	Respiratory failure, shock, multi-organ dysfunction/failure

Pre-exposure prophylaxis:
COVID-19 VACCINES
Tixagevimab/ Cilgavimab?

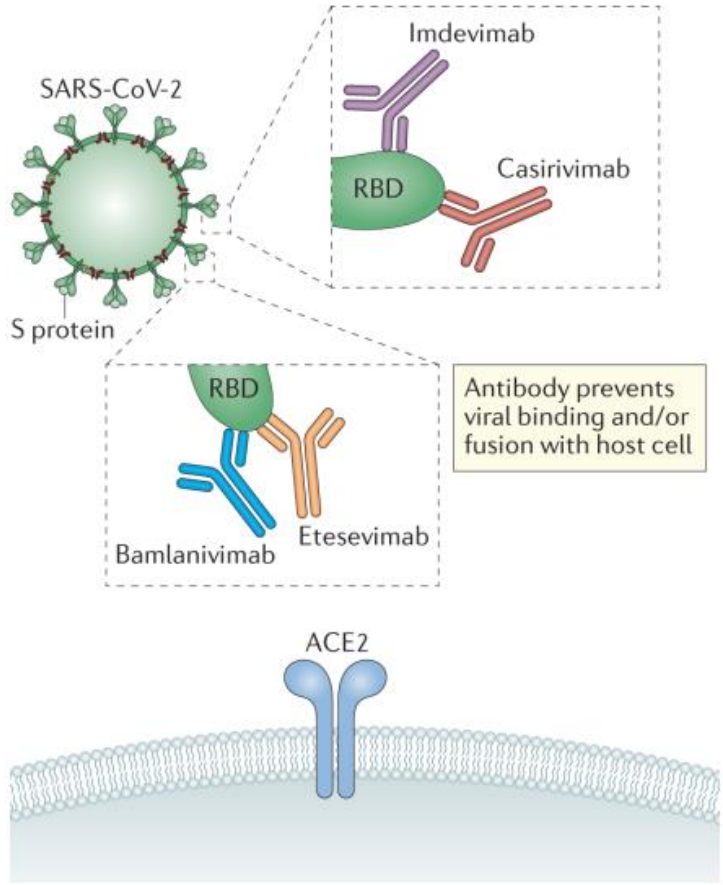
Post-exposure prophylaxis:
Bam/Ete,Casi/Imdev (high risk, not fully vaccinated or immunosuppressed)



Gandhi RT, CID, 2020
Gandhi RT, Lynch J, del Rio C. NEJM 2020

What are Monoclonal Antibodies?

- "mono" means **one**
- "clonal" means an **identical copy**
- Monoclonal antibodies are like endogenous antibodies but are made in a lab; not from pooled human plasma
- Targets spike protein to prevent viral entry into cells



Taylor et al. Neutralizing monoclonal antibodies for treatment of COVID-19 Nat Rev Immunol; 2021:382-393

Rationale for Use of mAbs

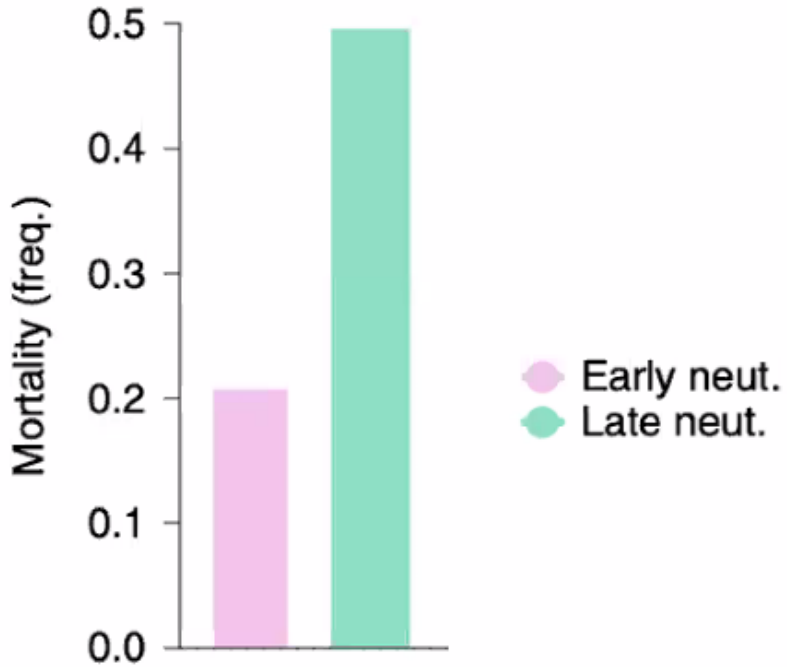
- Delayed production of neutralizing antibodies correlate with fatal COVID-19
- Monoclonal antibody therapy can:
  - Keep symptoms from getting worse and shorten their duration
  - Lower risk of hospitalization and death by 70-85%
  - As post-exposure prophylaxis (PEP), it can lower the risk of symptomatic infections
  - Reduce stress on the healthcare system
- Recommended for use by:
  - National Institutes of Health (NIH)
  - Infectious Disease Society of America (IDSA)

Lucas C et al. Delayed production of neutralizing antibody correlates with fatal COVID-19, 2021, Nat Med; 27: 1178-1186.

Anti-SARS-CoV-2 Monoclonal Antibodies for Treatment: Rationale

- Delayed production of neutralizing antibodies correlates with fatal COVID-19

- Would providing passive immunity through antibody therapy improve clinical outcomes?



Lucas C et al, Nat Med. 2021 May 5. doi: 10.1038/s41591-021-01355-0. PMID: 33953384.

mAbs for Treatment of COVID-19

- Three authorized products under emergency use authorization (EUA)
  - Bamlanivimab 700mg (milligram) and Etesevimab (**BAM/ETE**) 1400 mg (combination)
  - Casirivimab 600mg and Imdevimab 600mg (REGEN-COV or **CASI/IMDE**)
  - Sotrovimab 500mg
- Given through a one-time intravenous (IV) infusion
  - 16-60 minutes infusion time
  - One hour observation time
- REGEN-COV can be given via subcutaneous injection but IV preferred
- REGEN-COV approved for pediatric use in ALL ages, Nov 2021
- Can be administered in outpatient or hospital settings

Eligibility

Who is Eligible to Receive Treatment

- Monoclonal antibodies are authorized for treatment of patients who meet all of the following criteria:
  - **Not hospitalized** due to COVID-19
  - Have **mild** to moderate COVID-19 symptoms, not requiring new or increase in 0_2 therapy
  - Have a positive COVID-19 diagnostic test
    - Can be molecular test (such as a PCR) or antigen test
  - 12 years of age or older; **BAM/ETE approved for ALL ages**
  - Weigh at least 88 pounds (40 kilograms); **BAM/ETE weight-based dosing**
  - Are at high risk for progressing to severe COVID-19 illness or hospitalization

Medical Conditions of Factors That May Place Patients at Higher Risk for Severe COVID-19

- Advanced age, older than 65
- Obesity or being overweight (for example, BMI ≥25 kg/m2 for adults or children with BMI ≥85th percentile of patients of same age and gender based on Centers for Disease Control and Prevention (CDC) growth charts).
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or currently receiving immunosuppressive treatment
- Cardiovascular disease or hypertension
- Chronic lung disease (for example, chronic obstructive pulmonary disorder [COPD], moderate-to-severe asthma, interstitial lung disease and pulmonary hypertension)

More information on medical conditions

Medical Conditions of Factors That May Place Patients at Higher Risk for Severe COVID-19

- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes, severe congenital anomalies)
- Dependence on medical-related technologies (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
- Asthma, reactive airway, or other chronic respiratory disease (for example, cystic fibrosis) that requires daily medication
- If vaccinated, the more immunosuppressed group would qualify; think about for prevention!

Eligibility for Monoclonal Antibody Treatment to Prevent Severe COVID-19

***Risk conditions for severe disease:**

- Older age (65 and older)
- Chronic respiratory disease
- Diabetes
- Cardiovascular disease
- Chronic kidney disease
- Immunosuppressive disease or treatment
- Obesity
- Hypertension

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
IDPH
PROTECTING HEALTH, IMPROVING LIVES

Anti-SARS CoV-2 Monoclonal Abs for Post-Exposure Prophylaxis

U.S. FOOD & DRUG ADMINISTRATION

- Casirivimab/imdevimab (subcutaneous or intravenous) and bamlanivimab/etesevimab (iv) authorized in individuals who are at high risk for progression to severe COVID and are:
  - Not fully vaccinated or not expected to mount adequate immune response to COVID vaccination (e.g., immunosuppressed individuals) AND
    - Have been exposed* to individual with COVID

      or

    - At high risk of exposure because of occurrence of COVID in same institutional setting (e.g., nursing home, prison)

*Within 6 feet for >=15 min, providing care at home, direct contact, exposed to respiratory droplets of infected person

- Within 7 days of exposure; studies used 96 hours from exposure to measure efficacy

Scientific Evidence

TREATMENT

- Dougan et al, *N Engl J Med* 2021 Jul 14
- Weinreich et al, REGEN-COV2, a Neutralizing Antibody Cocktail in Outpatients with COVID-19, *N Engl J Med* 2021; 384:238-251
- https://www.medrxiv.org/content/10.1101/2021.05.19.21257469v2.full.pdf
- Gupta et al, Early COVID-19 Treatment with SARS-CoV2 Neutralizing Antibody Sotrovimab 2021

PEP

- Cohen M et al, Effect of Bamlanivumab vs Placebo on Incidence of COVID-19 Among Residents and Staff of Skilled Nursing and Assisted Living Facilities: A Randomized Clinical Trial, JAMA. 2021;326(1):46-55
- O'Brien, et al. Subcutaneous REGEN-COV Antibody Combination to Prevent COVID-19 N Engl J Med 2021 Aug 4; NEJM0a2109682

Federal Response Playbook: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf

Do Monoclonal Antibodies Work?

- Clinical trials: mAb treatment proven to **reduce relative risk of admission by 70%**

Anti-SARS-CoV-2 Monoclonal Abs for Treatment

- Phase 3 placebo-controlled trials in non-hospitalized patients with mild to moderate COVID and ≥1 risk factor for severe disease

Antibody	% Reduction Hospitalization/Death
Bamlanivimab/etesevimab*	70%
Casirivimab/Imdevimab*	70%
Sotrovimab*	85%

- Real world (1 study)
  - Decreased likelihood of emergency care or hospitalization over 30% (OR, 0.69)
  - Weighted probability that a given patient would require an emergency department visit or hospitalization decreased significantly (0.7% per day)
  - Mortality was 0.2% (n=1) in the mAb group compared with 1% (n=71) in placebo
  - Adverse events occurred in 1.2% (n=7) and 0.3% (n=2) were considered serious

Webb et al Open Forum Infectious Disease July 2021

What is the impact of SARS-CoV-2 variants on mAbs?

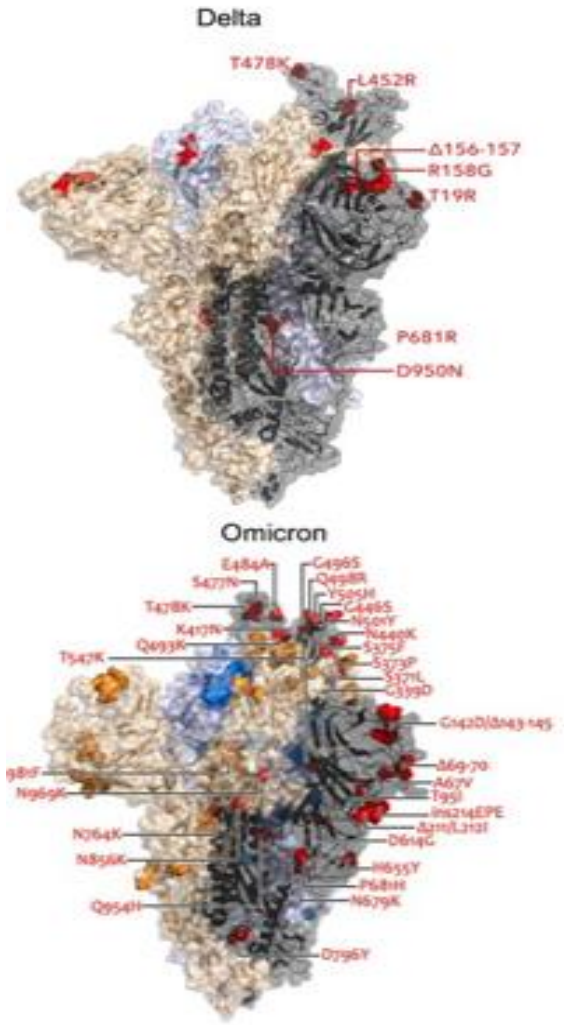
- **Bam**lanivimab + **Ete**sevimab
  - Active against Delta
  - Not active against Gamma (P.1) or Beta (B.1.351) variants
- **Casi**virimab + **Imde**vimab (REGEN-COV0 and Sotrovimab)
  - Active against all variants of concern; pending evaluation of Omicron
- Use of BAM/ETE was on hold in September due to Beta and Gamma variants but were taken OFF HOLD in October due to lower prevalence of these variants.
- Delta variant currently 99% of sequenced cases in Chicago

What is the impact of SARS-CoV-2 variants on mAbs?

- As of 12/2/21
- No virus-specific data available to assess whether mAbs treatments will retain efficacy against the Omicron variant.
- Based on data from other variants with fewer changes in the receptor binding domain (RBD), the expectation is that the Omicron variant will remain susceptible to some mAbs, while others may have less potency.
- Mutations within the RBD are most relevant for mAbs available for EUA.
- Mutations in the monoclonal antibody binding site do not always result in a loss of binding or neutralization. **Importantly, data are needed with the full spectrum of spike protein changes to understand the impact on available monoclonal antibody therapeutics.**

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html

Many of omicron's mutations are in the Spike gene



COG-UK Mutation Explorer

COG-UK Mutation Explorer

Region 5: IL, IN, MI, MN, OH, WI
It's all still Delta (For now)

Region 5 - Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin

WHO label	Lineage #	US Class	%Total	95%PI
Delta	B.1.617.2	VOC	99.9%	99.8-100.0%
	AY.1	VOC	0.0%	0.0-0.1%
	AY.2	VOC	0.0%	0.0-0.0%
Omicron	B.1.1.529	VOC	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.1%

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Clinical Considerations

Exclusion Criteria

- mAbs are not authorized for use in patients who:
  - Are hospitalized due to COVID-19;
  - 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
- mAbs can be given to eligible patients hospitalized for reasons other than COVID 19

Timing of Therapy

- Treatment (**cases**) is most effective when given:
  - Early in symptom progression
  - As soon as possible after confirmation of a positive COVID-19 test result, ideally 48 hours but within 10 days of symptom onset
  - Earlier administration is likely associated with greater efficacy; no current definition of what constitutes a "delay"
- PEP(**contacts**) optimal time is not defined, but in the clinical trial therapy was given within 96 hours of exposure, but within 7 days of exposure
- Consider signing up to have doses on hand

Safety and Side Effects

- Studies have shown the treatments to be very safe
- Allergic reactions are very rare but can occur during or after IV infusion
- Side effects of mAbs treatment may include:
  - A reaction at the site of the IV/injection, pain, swelling, bleeding, bruising or an infection (~10%)
  - Nausea, vomiting or diarrhea (rare ~1%)
  - Itching, rash or hives
- Patients must be monitored during the treatment and observed for one hour after

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

Provider and Patient EUA Fact Sheets

- Each product under EUA also has an FDA fact sheet for providers and one for patients and caregivets

  - Bamlanivimab and etesevimab
    - Provider fact sheet; https://www.fda.gov/media/145802/download
    - Patient fact sheet; https://www.fda.gov/media/145803/download
    - Patient fact sheet (Spanish); http://pi.lilly.com/eua/span/bam-and-ete-eua-factsheet-patient-span.pdf
  - Casirivimab and Imdevimab (REGEN-COV)
    - Provider fact sheet; https://www.fda.gov/media/145611/download
    - Patient fact sheet; https://www.fda.gov/media/145612/download
    - Patient fact sheet (Spanish); https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-patient-spanish.pdf
  - Sotrovimab
    - Provider fact sheet; https://www.fda.gov/media/149534/download
    - Patient fact sheet; https://www.fda.gov/media/149533/download
    - Patient fact sheet (Spanish); https://www.sotrovimab.com/content/dam/cf-pharma/hcp-sotrovimab-phase2/en_US/sotrovimab-eua-fact-sheet-for-patients-in-spanish.pdf

mAbs and COVID-19 Vaccination

- **Can a patient receive COVID-19 vaccine after getting antibody therapy?**
  - **YES**, but could wait 90 days after receiving monoclonal antibody treatment before getting vaccinated.
    - "Receipt of passive antibody therapy in the past 90 days is not a contraindication to receipt of COVID-19 vaccine. COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated."

- **Should I avoid giving monoclonal antibody to a patient who has tested positive for COVID-19 if they have a booster clinic coming up?**
  - **NO.** Do not delay because of COVID physiology; need to get antibodies early. Vaccine is not effective as treatment (or post exposure prophylaxis).

- **Can a patient get monoclonal antibody therapy if they have already gotten the COVID-19 vaccine?**
  - **YES.** If they have symptoms of COVID-19 and test positive, they can receive monoclonal antibody treatment. There is no delay in mAb if a person received COVID-19 vaccine.

HHS clinical implementation guide for monoclonal antibodies, 9/2/21

What to Do in An Outbreak

- If you don't already have mAb on hand
  - Determine if there is a local infusion site where patients may be transported:
    - https://infusioncenter.org/infusion_resources/nica-monoclonal-antibody-therapies/
    - COVID-19 patients can be transported per CDC guidance but a heads up is needed
  - If not local site or transportation not feasible, contact long term care pharmacy partner or IDPH immediately to have mAb re-allocated from another site for immediate use in an outbreak. CDPH can facilitate this process.

LTC Outbreak Considerations with Respiratory Illness

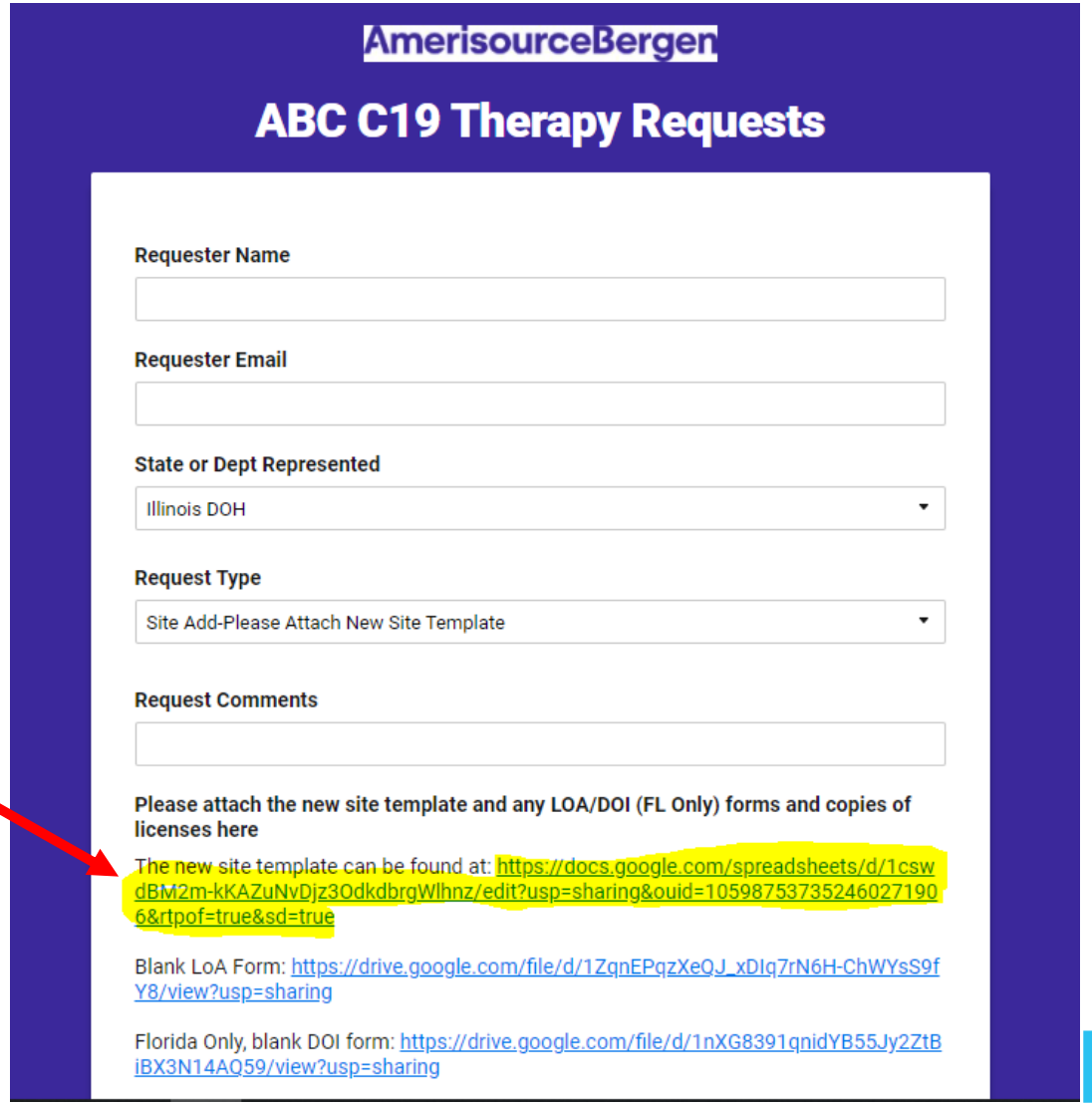
- Place symptomatic residents in Transmission Based Precautions using all recommended PPE for care of a resident with suspected SARS-CoV-2 infection
- Specimens for testing ASAP: confirm diagnosis
- If influenza is circulating
  - Antivirals for treatment and prophylaxis of exposed
- If SARS-CoV-2 is circulating
  - Monoclonals for those not hospitalized and how don't need additional 0_2
- No indication that antivirals for influenza and monoclonals cannot be co-administered. However, rapid diagnostics are encouraged!
- In outbreak, monoclonals work faster than vaccine/boosters

CDC Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-COV-2 and Influenza Viruses are Cocirulating

How Can I access mAbs for my patients?

- New sites that have never ordered mAb before should sign up using this New Site form
  - Consider signing up before mAb is needed.

- Open the spread sheet and add your facility information then upload to the form.



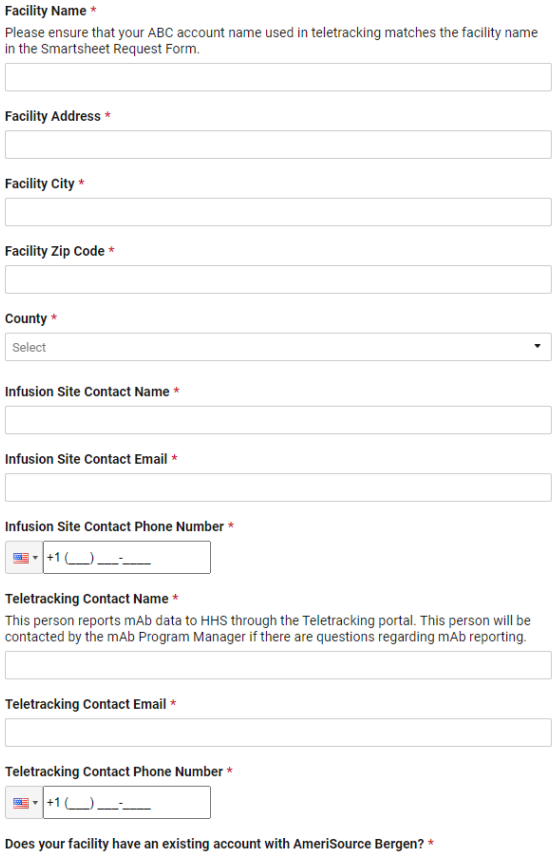
How Can I access mAbs for my patients? (cont.)

- Make a request for product here: [IDPH Monoclonal Antibody Request Form (smartsheet.com)]
- Orders must be made no later than Tuesday for that week's cycle.

IDPH

IDPH Monoclonal Antibody Request Form

If your site does not have an account in Teletracking please register as soon as possible via this link: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx . All sites must document weekly. IDPH will honor a one time request for an allocation without a prior entry in to Teletracking. No further requests for allocations will be granted without evidence of weekly utilization reporting.



Facility Name *
Please ensure that your ABC account name used in teletracking matches the facility name in the Smartsheet Request Form.

Facility Address *

Facility City *

Facility Zip Code *

County *
Select

Infusion Site Contact Name *

Infusion Site Contact Email *

Infusion Site Contact Phone Number *
+1 (___) ___-____

Teletracking Contact Name *
This person reports mAb data to HHS through the Teletracking portal. This person will be contacted by the mAb Program Manager if there are questions regarding mAb reporting.

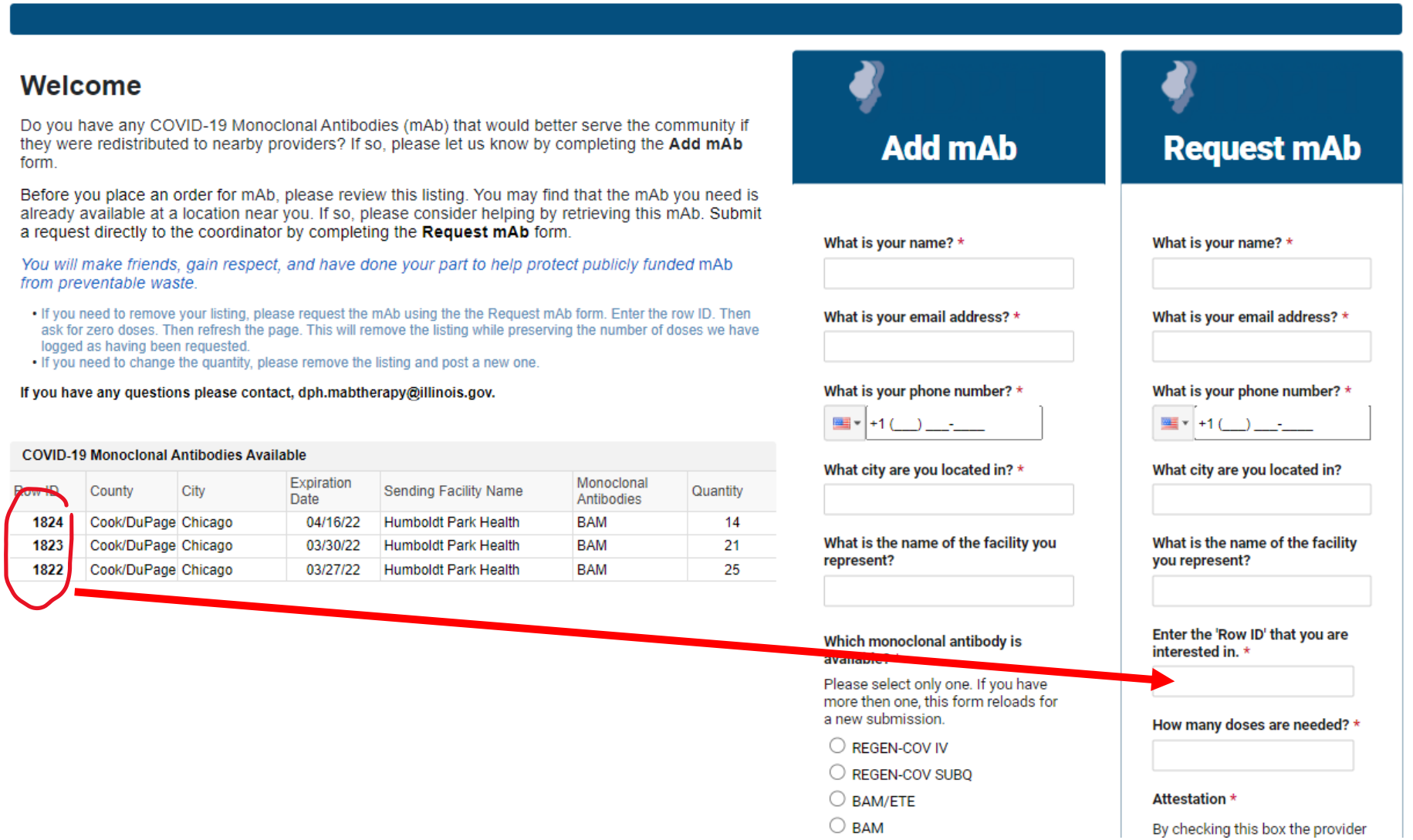
Teletracking Contact Email *

Teletracking Contact Phone Number *
+1 (___) ___-____

Does your facility have an existing account with AmeriSource Bergen? *

For Immediate Access to mAb

- The mAb Matchmaker allows facilities to access doses immediately, or to redistribute mAb if the facility has excess doses.
- IDPH will send an email to both parties once a match is made.



Welcome

Do you have any COVID-19 Monoclonal Antibodies (mAb) that would better serve the community if they were redistributed to nearby providers? If so, please let us know by completing the **Add mAb** form.

Before you place an order for mAb, please review this listing. You may find that the mAb you need is already available at a location near you. If so, please consider helping by retrieving this mAb. Submit a request directly to the coordinator by completing the **Request mAb** form.

You will make friends, gain respect, and have done your part to help protect publicly funded mAb *from preventable waste.*

- If you need to remove your listing, please request the mAb using the the Request mAb form. Enter the row ID. Then ask for zero doses. Then refresh the page. This will remove the listing while preserving the number of doses we have logged as having been requested.
- If you need to change the quantity, please remove the listing and post a new one.

If you have any questions please contact, dph.mabtherapy@illinois.gov.

COVID-19 Monoclonal Antibodies Available

Row ID	County	City	Expiration Date	Sending Facility Name	Monoclonal Antibodies	Quantity
1824	Cook/DuPage	Chicago	04/16/22	Humboldt Park Health	BAM	14
1823	Cook/DuPage	Chicago	03/30/22	Humboldt Park Health	BAM	21
1822	Cook/DuPage	Chicago	03/27/22	Humboldt Park Health	BAM	25

Add mAb

What is your name? *

What is your email address? *

What is your phone number? *

+1 (___) ___-____

What city are you located in? *

What is the name of the facility you represent?

Which monoclonal antibody is available? *

Please select only one. If you have more then one, this form reloads for a new submission.

- REGEN-COV IV
- REGEN-COV SUBQ
- BAM/ETE
- BAM

Request mAb

What is your name? *

What is your email address? *

What is your phone number? *

+1 (___) ___-____

What city are you located in?

What is the name of the facility you represent?

Enter the 'Row ID' that you are interested in. *

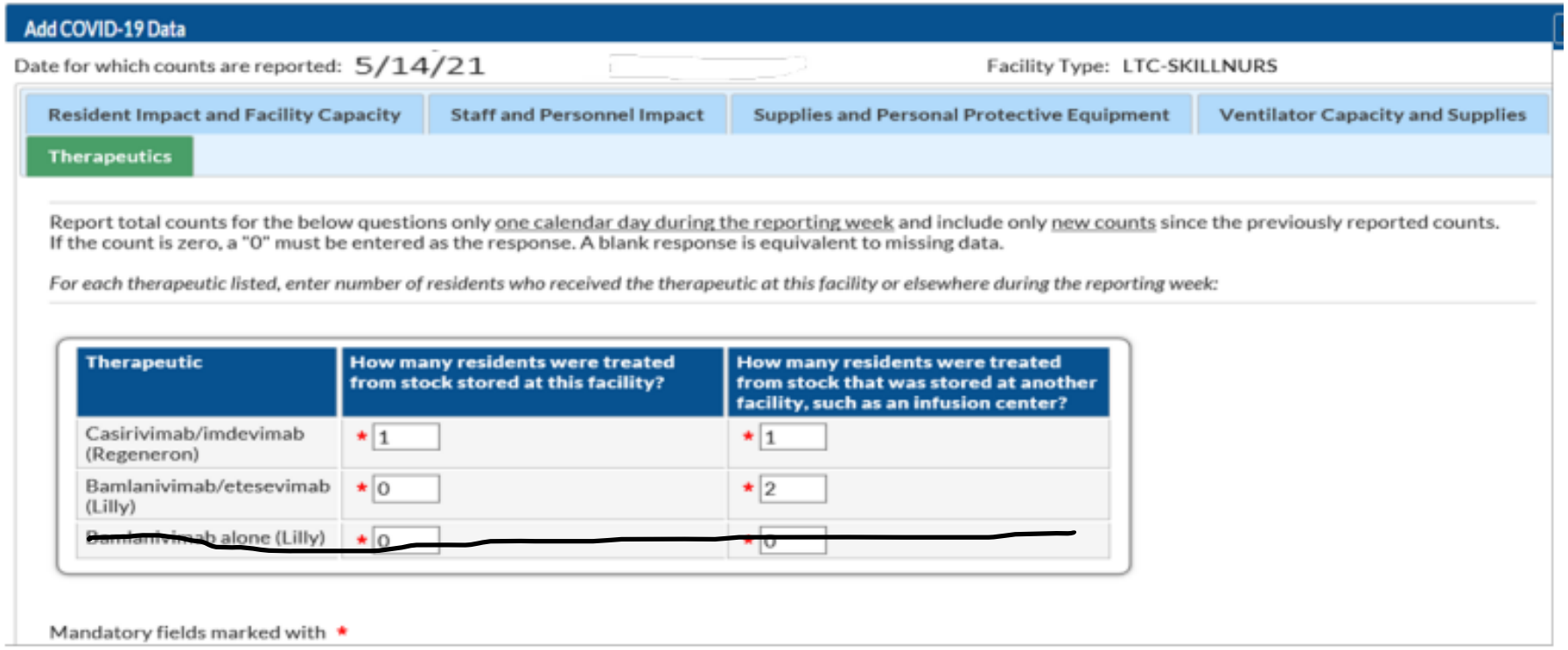
How many doses are needed? *

Attestation *

By checking this box the provider

Reporting mAb use to NHSN: Therapeutic Pathway

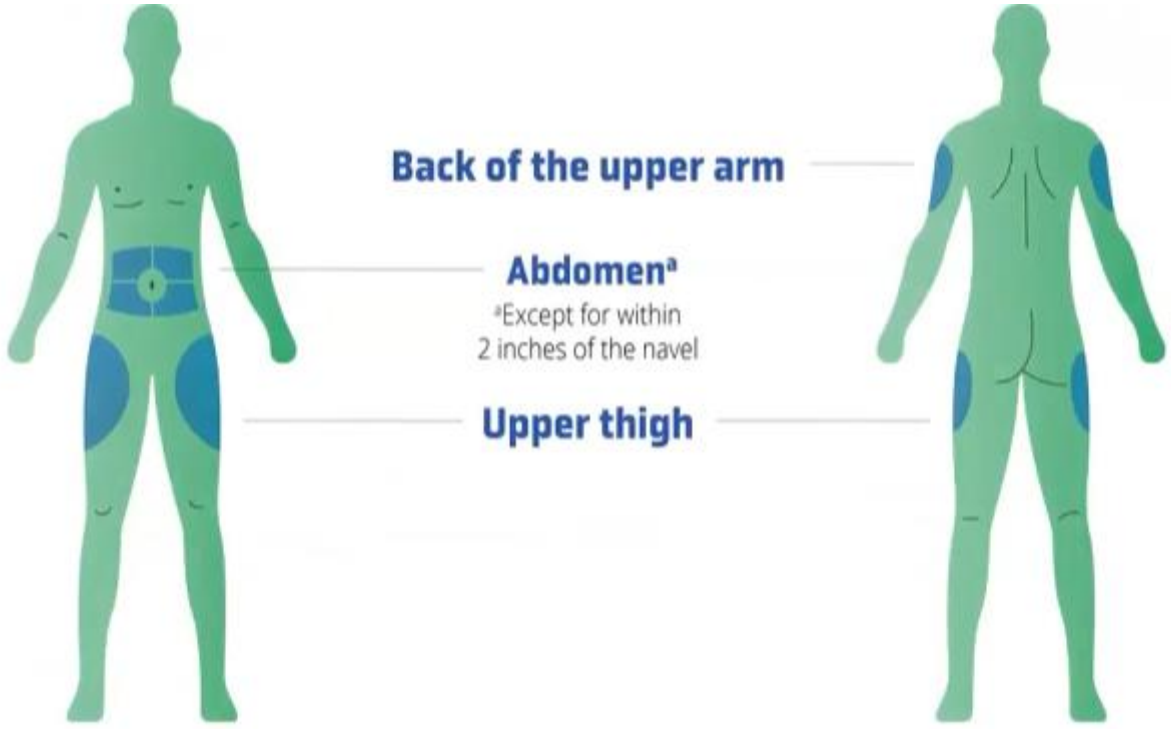
- Report once per week
- Report only **NEW counts**, not cumulative.
- Enter 0 for any therapeutics that were not given.
- Therapeutics Training



Administration and Storage

- **Bam**lanivimab 700mg (milligram) and **Ete**sevimab (BAM/ETE) 1400 mg (Lilly)
  - IV Infusion Only
  - Shelf-life extension of 6 months from expiration date
  - Must be refrigerated at 2°C to 8°C (36°F to 46°F)
- **Casi**rivimab 600mg and **Imde**vimab 600mg (REGEN-COV or CASI/IMDE)
  - Refrigerated at 2°C to 8°C (36°F to 46°F) unopen vials store until exp. Date
  - Can be kept at room temp for 30 days (only give SubQ at room temp)
  - REGEN-COV in both packaging configurations may be used to prepare and administer
    - intravenous infusions
    - subcutaneous injections (4)

REGEN-COV subcutaneous injection



For the administration of 600mg of casrivimab and 600mg of imdevimab. Co-formulated: 2.5mL into FOUR syringes to prepare for subcutaneous injections. If individual vials, CASI 2.5mL in TWO syringes and IMDE 2.5mL in TWO syringes.

Reimbursement and Coverage

- Monoclonal antibodies are expensive but are free through the federal government
  - BAM/ETE ~$1250 cost per dose (IV only)
  - CASI/IMDE ~$1250 cost per dose (IV or Subcut)
  - Sotrivimab ~$2000 cost per dose (IV only)
- Medicare will pay approximately
  - $450 in most settings (including LTCs)
  - $750 in the beneficiary's home or residence

CMS: Coverage of Monoclonal Antibody Products to Treat COVID-19

Medicare

Site of Care[1]	Payable by Medicare	Expected Patient Cost-Sharing
Inpatient Hospital	✓	No patient cost-sharing
Outpatient Hospital or "Hospital without Walls"[2]	✓	No patient cost-sharing
Outpatient Physician Office/Infusion Center	✓	No patient cost-sharing[3]
Nursing Home (See third bullet in Key Facts on CMS enforcement discretion)	✓	No patient cost-sharing
Home	✓	No patient cost-sharing

[1]Services must be furnished within the scope of the product's FDA authorization or approval and within the provider's scope of practice.
[2]Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.
[3]Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn't participate in Medicare.
[4]Certain monoclonal antibody products to treat COVID-19 have been authorized under Food and Drug Administration Emergency Use Authorizations since November 10, 2020. More information including the level II HCPCS codes for the administration/ infusion and post administration monitoring of these products can be found online in the Program Instruction.

Expected Payment to Providers: Key Facts

- Medicare payment for monoclonal antibody products to treat COVID-19 is similar across sites of care, with some small differences.
- Medicare pays for the administration of monoclonal antibody products to treat COVID-19. For example, Medicare will pay a national average of approximately $450 for the administration of certain monoclonal antibody products4 . Home infusion is reimbursed at a higher rate.
- CMS will exercise enforcement discretion to allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law to bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments to Medicare Part A Skilled Nursing Facility residents
- Medicare will pay the provider for these monoclonal antibody products when they are purchased by the provider. Medicare won't pay if the product is given to the provider for free by, for example, a government entity.
- When purchased by the provider, Medicare payment is typically at reasonable cost or at 95% of the Average Wholesale Price (an amount determined by the manufacturer). These payment amounts vary depending on which type of provider is supplying the product. Original Medicare will pay for these products for beneficiaries enrolled in Medicare Advantage.
- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these Frequently Asked Questions.

Additional information can be found at https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-

BILLING CODES

Regeneron product codes

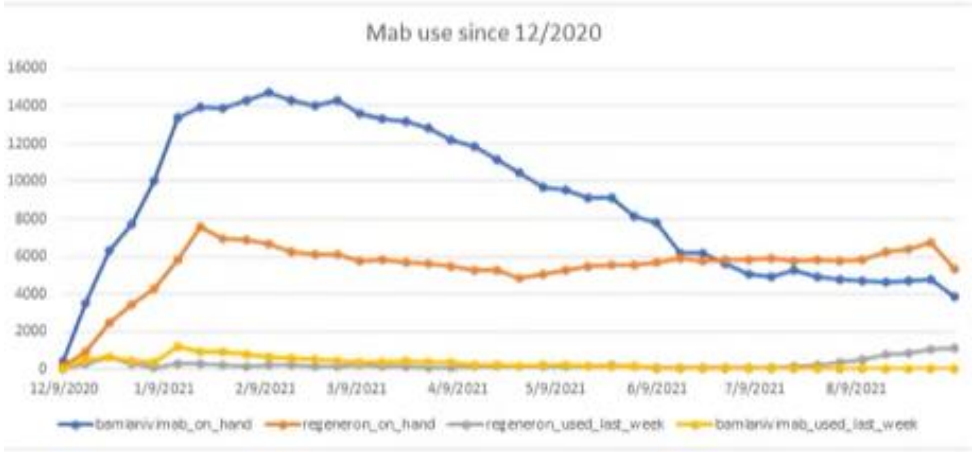
- Q0243:
  - Long descriptor: Injection, casirivimab and imdevimab, 2400 mg
- M0243:
  - Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring
- **M0244:**
  - Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency

Billing Codes cont'd

- **Bamla/ete codes**
  - M0245 : intravenous infusion, includes infusion and post administration monitoring
  - M0246 : same as above but home infusion
- **Sotrovimab codes**
  - M0247:Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
  - M0248:home infusion

What can we do next?

- VACCINATE! Primary series still most important!
- IDPH will stock some mAb doses for urgent use in OUTBREAKS
- Pharmacies can support mAb treatment



IDPH
Illinois Department of Public Health

Coming next….

- Pre exposure prophylaxis—long acting mAb more expensive than vaccine; submitted review to the FDA (Evusheld)
- Oral antivirals
  - Molnupiravir 800mg BID for 5 days given within 5 days of symptom onset
    - FDA advisory committee recommended for approval
    - decreased the risk of hospitalization from COVID-19 by 30%
  - Paxlovid 300mg (2 150mg tablets) of Nirmatrelvir and 100mg tablet of ritonavir given BID for 5 days.
    - reduced risk of hospitalization or death by 89% (within three days of symptom onset) and 88% (within five days of symptom onset) compared to placebo; no deaths compared to placebo in non-hospitalized, high-risk adults with COVID-19
    - FDA advisory committee meeting pending

Conclusion

- Monoclonal antibodies are an **essential tool to prevent progression to severe COVID-19**
  - Important to ensure access for communities most impacted by COVID-19
- The **earlier treatment** is given, the **better** it prevents disease progression, hospitalization and death
- Consider PEP for high risk exposed patients
- CASI/IMDE (REGEN-COV) can now be given **subcutaneously** when anticipated delays in referral to IV infusion centers
- **REGEN-COV and BAM/ETE are FREE** from federal government and reimbursable through CMS
- Ordering of product is currently through IDPH in **biweekly allotments**, reporting through NHSN

Is your facility currently providing Mab to your residents?

Have you started offering Post exposure prophylaxis? On site? Hospital? Not planning to offer?

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