

Maine DHHS

COVID-19 Vaccines & Therapies Clinical Updates

Amy Belisle, MD, MBA, MPH, ME DHHS

Isaac Benowitz, MD, ME CDC

Lisa M. Letourneau, MD, MPH, ME DHHS

Stephen Sears, MD, MPH, ME CDC

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COVID-19 Clinician Discussion

- COVID-19 vaccines - recent updates & boosters
- mRNA vaccines for immunocompromised (“4th shot”)
- COVID-19 vaccine after COVID infection
- Timing of vaccines after mAb therapies
- NEW: Pfizer vaccine for 5-11yo’s
- Co-administration of COVID & annual flu vaccines
- COVID-19 monoclonal antibody therapies
- Coming soon: COVID-19 oral antiviral medication(s)
- Q&A

Current COVID-19 Vaccines

Pfizer BioNTech

- mRNA vaccine
- Trial with >44,000 in multp countries
- Efficacy in initial trials 94.5%
- Minimal adverse reactions
- 2nd dose at 21D
- FDA apprvd for ≥16yo
- FDA auth'd for 5-15yo
- Booster auth'd >18yo
- Can be refridg'd for 30D

Moderna

- mRNA vaccine
- Trial with >30,000 in US
- Efficacy in initial trials 94.1%
- Minimal adverse reactions
- 2nd dose at 28D
- FDA auth'd for ≥18yo
- Booster auth'd
- Can be refridg'd for 30D

J&J/Janssen

- Viral vector vaccine
- Trial with >43,800 in multp countries
- Efficacy in initial trials >66.1% overall, 72% US
- Minimal adverse reactions
- Single dose
- FDA auth'd for ≥18yo
- Booster auth'd
- Can be stored at room temp

COVID-19 Vaccines: Boosters

- FDA EUA & US CDC now recommend booster dose for individuals receiving all 3 auth'd vaccines
- Pfizer & Moderna: give booster at 6+ months for...
 - 65 years and older
 - Age 18+ who live in [long-term care settings](#)
 - Age 18+ who have [underlying medical conditions](#)
 - Age 18+ who work or live in [high-risk settings](#)
- J&J: give booster at 2+ months for all 18yrs & older
- Any of vaccines can be used for booster vaccination, regardless of vaccine product used for primary vaccination (“Mix & Match”)

mRNA COVID-19 Vaccines for Immunocompromised

- US CDC recommends 3rd dose mRNA vaccines for [moderately or severely immunocompromised indiv's](#)
- 3rd dose should be at least 28D after 2nd dose
- These individuals now also eligible for booster (i.e. 4th dose) of mRNA vaccine at least 6 months after completing their 3rd mRNA vaccine dose
- Recommendation for additional dose for immunocompromised does *NOT* currently apply to those who initially received J&J vaccine

COVID-19 Vaccine After COVID Infection

- US CDC recommends COVID-19 vaccine for all individuals 5+ yrs, *regardless of history of symptomatic or asymptomatic SARS-CoV-2 infection*
- Includes people with prolonged post-COVID-19 symptoms
- Applies to primary series doses, additional primary doses, and booster doses
- Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended
- Vaccine can be given anytime after acute illness & isolation period completed
- Current evidence about the optimal timing between SARS-CoV-2 infection and vaccination is insufficient to inform guidance

Timing of COVID-19 Vaccine After COVID Monoclonal Antibody Tx

- US CDC recommends temporarily deferring COVID-19 vaccine for individuals who received COVID-19 monoclonal antibodies (mAbs) for COVID post-exposure prophylaxis or treatment, to avoid potential interference with vaccine-induced immune response
- Timing varies with indication for use of mAb:
 - mAbs used for post-exposure prophylaxis: defer COVID-19 vaccination for 30 days
 - mAbs used for COVID-19 treatment: defer COVID-19 vaccination for 90 days
- However, if passive antibody products and COVID-19 vaccine dose are administered within recommended deferral periods (30 or 90 days), vaccine dose does not need to be repeated

Pfizer COVID-19 Vaccine for 5-11yo's

- FDA authorized, US CDC recommends Pfizer vaccine for 5-11yo's
- Impacts ~28 million youth in US, 96,000 in Maine
- Vaccination was ~91% effective in preventing COVID-19 among children aged 5-11 yo
- Given as reduced dose
- Like adults, given in 2-dose series, 21D apart
- Maine Immunization Program released guidance on [Pediatric Pfizer COVID19 Availability and Ordering.pdf](#)

COVID-19 Vaccination for 5-11yo's: Fast Facts

- Pfizer-BioNTech vaccine for children 5-11yo has same active ingredients as adult vaccine, but given at lower dose
- Note: vaccine dosages are based **on age** and not size or weight
- Safety data from clinical trial shows children may have some side effects from COVID-19 vaccination
 - *Suggested talking point:* “These side effects are normal signs that their body is building protection. They may affect your child’s ability to do daily activities, but they should go away in a few days”
- Serious side effects are rare but may occur
- Cases of myocarditis & and pericarditis have been reported after Pfizer-COVID-19 vaccination with children 12–17 yo; reactions are rare (~54 cases per million doses)
- Pfizer COVID vaccine can be co-administered with flu and other childhood vaccines *at the same time*
- COVID-19 vaccine recommended for all ages 5yo+, even after natural COVID-19 infection


COVID-19 Vaccination Sites for 5-11yo's

- Multiple state partners working with schools and vaccine providers to identify partners for school vaccine clinics
- Builds on previous work with schools for H1N1 and Flu Vaccines
- Depending on geographic location, child vaccines to be provided at
 - School locations
 - Community clinics
 - Retail pharmacies (some)
 - EMS providers
 - Medical practices
 - Hospital clinics
 - Public Health Nursing
 - Pop-Up Clinics, coordinated with CDC Public Health District Liaisons
- DOE has released [Updated School Location Vaccine Clinic \(SLVC\) Toolkit](#)



COVID-19 Vaccine Dosing and Schedule

Primary series



Primary and additional primary doses vaccine manufacturer	Age of recipient (years)	Vial cap color denoting formulation	Concentration of mRNA per primary dose	Primary dosage injection volume	Number of doses in primary series (Interval between doses)	Additional primary dose in immunocompromised people (Interval since second dose)	Interval between last primary (including additional) to booster dose
Pfizer-BioNTech	5–11	Orange	10 µg	0.2 ml	2 (21 days)	Not recommended	Booster not recommended
Pfizer-BioNTech	12–17	Purple	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)	Booster not recommended
Pfizer-BioNTech	≥18	Purple	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)	≥6 months
Moderna	≥18	Not applicable	100 µg	0.5 ml	2 (28 days)	1 (≥28 days)	≥6 months
Janssen	≥18	Not applicable	5×10 ¹⁰ viral particles	0.5 ml	1 (Not applicable)	Not applicable	≥2 months

[Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)

Maine Youth Covid-19 Vaccination Rates

(Will be updated with 5-11 data on 11/9/21)



State of Maine COVID-19 Vaccination Dashboard

Data as of: Oct 25, 2021

All

Eligible 12+

71,199
Doses Administered

37,336
First Dose

33,860
Final Dose

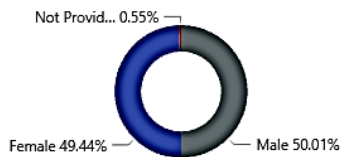
0
Additional/Booster Dose

63.16%
Population First Dose %

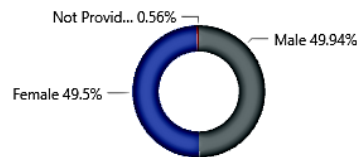
57.28%
Population Final Dose %

59,112
Census Population

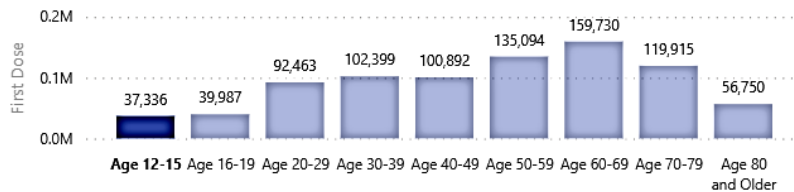
First Dose by Gender



Final Dose by Gender



First Dose by Age Group



Final Dose by Age Group



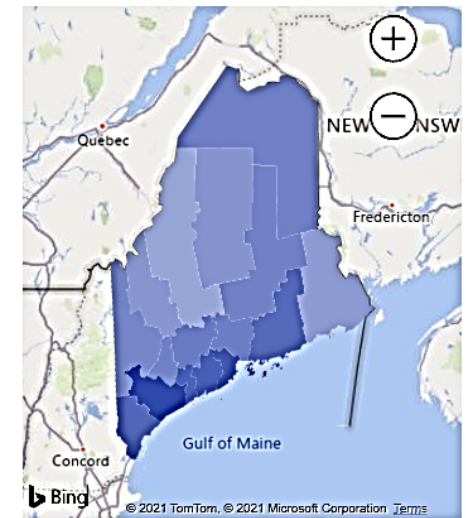
First Dose by Race and Ethnicity

Race	First Dose
American Indian or Alaska Native	372
Asian	925
Black or African American	1,589
Native Hawaiian or Pacific	128
Not Provided	1,662
Other	5,109
White	27,551
Total	37,336

Final Dose by Race and Ethnicity

Race	Final Dose
American Indian or Alaska Native	332
Asian	856
Black or African American	1,407
Native Hawaiian or Pacific	116
Not Provided	1,419
Other	4,594
White	25,136
Total	33,860

Vaccinations by County



COVID Vaccination Summary

COVID Vaccination Trends

COVID Vaccination County Listing

COVID-19 Vaccine Messaging for Child Vaccination

- **Virtual Community Forum: “Pediatricians Share: What Parents Need to Know about COVID-19 Vaccine for Children”**
 - Tues, Nov 9th, 6PM
 - Virtual forum featuring Maine pediatricians sharing information about COVID-19 vaccine for children and offering advice for parents on what to consider when making decision to vaccinate
 - Register at mecap.org/events
- **Child Vaccine Video Contest**
 - Maine DHHS, DOE inviting Maine youth 5-17 yo to submit 30-second videos that they believe will encourage other children, along with their parents, to get COVID-19 vaccine
 - Deadline for submission is Nov 22 (6PM)
 - Information on submitting an entry available [HERE](#)
 - Winner will be announced Dec 1, 2021

COVID-19 Vaccines for Younger Children: AAP Resources for Providers and Families

- Policy Statement: [COVID-19 Vaccines in Children and Adolescents](#)
- AAP News: [COVID-19 vaccine for children ages 5-11 receives final approval](#)
- News Release: [American Academy of Pediatrics Applauds CDC Advisory Committee's Approval of Safe, Effective COVID-19 Vaccine for Children Ages 5-11](#)
- HealthyChildren.org: [COVID-19 Vaccine Checklist for Kids Age 5 and Up](#)
- [Vaccine: What Pediatricians Can Do Now](#)
- AAP.org: [COVID-19 Vaccine Implementation in Pediatric Practices](#)
- AAP.org: [COVID-19 Vaccine Administration: Getting Paid](#)
- AAP.org: [Considerations for COVID-19 Vaccination Clinics Through Pediatric Practices](#)
- AAP.org: [About the COVID-19 Vaccine: Frequently Asked Questions](#)
- AAP.org: [COVID-19 Vaccine Confidence Campaign Toolkit](#)
- AAP.org: [Becoming a COVID-19 Vaccinator Video Series](#)
- AAP.org: [Children and COVID-19 Vaccination Trends](#)
- Free PediaLink Course: [Effective COVID-19 Vaccine Conversations](#)
- HealthyChildren.org: [The Science Behind COVID-19 Vaccines: Parent FAQs](#)
- Animated video on YouTube: [COVID-19 and kids: How mRNA vaccines work](#)
- Animated video on YouTube: [How mRNA COVID-19 vaccines were developed](#)

COVID-19 Vaccine Messaging for Women & Children

- [CDC Health Alert \(HAN\) \(9/29/21\)](#): US CDC **recommends urgent action** to increase COVID-19 vaccination among people who are pregnant, recently pregnant (including those who are lactating), who are trying to become pregnant now, or who might become pregnant in the future.
- The Maine CDC has two [COVID vaccine ads](#), focused on [women](#) and [children](#).





COVID-19 mAb Therapies: What's New

- On 9/15/2021, HHS/ASPR [announced change](#) from direct ordering to weekly state-based allocations
- Surge in Delta variant, coupled with low vaccination rates in certain areas of US, contributed to rapid 20X increase in mAb orders from June to Sept 2021, with subset of states accounting for ~70% of mAb orders, stressing overall supply
- Change made to assure fairness & efficiency of distribution to all areas of US
- US govt now determines weekly distribution amounts for each state
- Beginning 9/17/2021, Maine DHHS has been determining allocation of Maine mAb doses weekly (~500-700 doses/wk)

COVID-19 mAb Therapies for Non-Hospitalized Individuals

Bamlanivimab + Etesevimab (Lily)

- FDA EUA for treatment of mild-mod COVID-19 in adults & children >12yo (≥40 kg) who are at high risk for progression to severe COVID-19, including hosp or death
- Less active against beta & gamma variants
- In vitro studies support effectiveness for delta variant
- 09/02/2021: FDA resumed given combined frequency of variants resistant to bam-ete is ≤5% nationwide
- Can be admin'd IV only
- Available from federal supply

Casirivimab + Imdevimab (REGEN-COV)

- FDA EUA for treatment of mild-mod COVID-19 in adults & children >12yo (≥40 kg) who are at high risk for progression to severe COVID-19, including hosp or death
- Still provides protection against Delta variant
- Can be admin'd via IV infusion or subcu injection (IV preferred)
- Available from federal supply

Sotrovimab (Xevudy - GSK)

- FDA EUA for treatment of mild-mod COVID-19 in adults & children >12yo (≥40 kg) who are at high risk for progression to severe COVID-19, including hosp or death
- Can be admin'd IV only
- Available from federal supply

Maine mAb Clinical Prioritization

- Maine mAb provider sites asked to prioritize mAb for...
 - Treatment of individuals diagnosed with SARS CoV 2 infection, *AND*
 - Post-exposure prophylaxis for individuals in high-risk congregate settings – i.e., LTC, correctional institutions
- Focus on those at high risk for dev'ing severe COVID-19:
 - Unvaccinated or incompletely vaccinated [individuals at high risk of progressing to severe COVID 19](#) – e.g.
 - ≥65yo, BMI >25, pregnancy, CKD, DM, immunosuppressed, HF, CAD, COPD, Sickle Cell disease, neurodevelopment disorders (e.g., CP), medical devices (e.g., trach)
 - Vaccinated individuals not expected to mount an adequate immune response (e.g., immunocompromised)

Considerations for Determining Dose Allocations to Sites

- ME DHHS goal: Preserve hospital/ICU capacity by preventing progression to severe disease
- Considerations for determining site allocations:
 - Ensure equitable, statewide geographic access
 - Consider COVID-19 case and hospitalization rates
 - Consider regional vaccination rates
 - Consider sites most likely to treat individuals...
 - In areas with high unvaccinated rates
 - At high risk of progressing to severe disease – i.e., ≥65yo, BMI>25, pregnancy, CKD, DM, immunosuppressed, HF, CAD, COPD, Sickle Cell disease, neurodevelopment disorders (e.g., CP), medical devices (e.g., trach)

Current Maine mAb Infusion Providers

- Currently 40 Maine registered sites receiving mAb doses:
 - Hospitals: 21
 - Specialty Pharm/Infusion Providers: 6
 - Urgent Care Center: 6
 - Primary Care Practices: 5 (3 FQHCs)
 - Corrections: 2 (DOC, 1 County Jail)
- Subset of 32 sites take referrals for mAb infusion

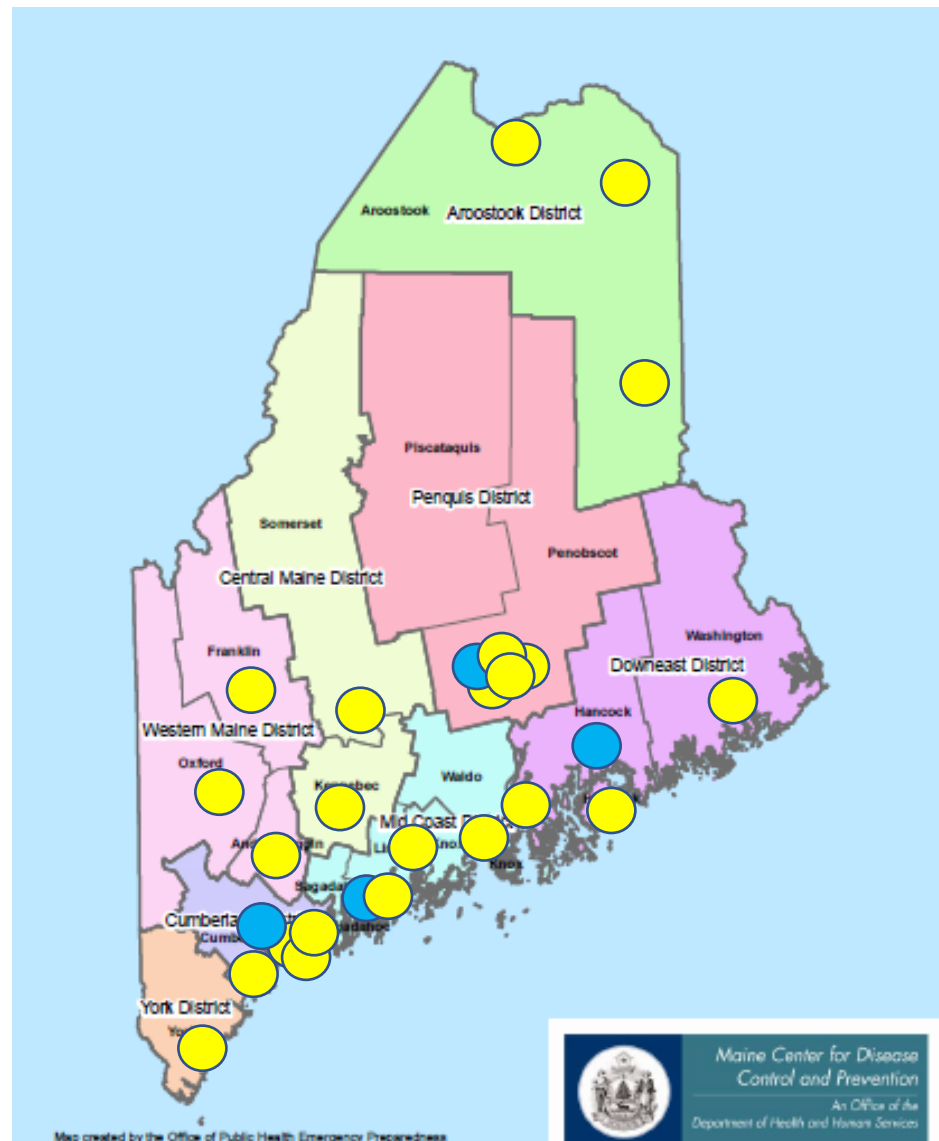
Current Maine mAb Infusion Providers

Statewide/ regional providers:

- Amber Specialty Pharmacy
- Guardian
- New England Life Care
- OmniCare
- MVH
- Pharmerica

Multi-site providers:

- ConvientMD



NICA Infusion Center Locator Tool

The screenshot displays the NICA Infusion Center Locator Tool interface. The top navigation bar includes the NICA logo and the text "INFUSION CENTER LOCATOR". Below this is a search bar containing the zip code "04426" and a "SEARCH" button. A dropdown menu shows "100 miles".

The left sidebar features a "Filter by Medication" section with three radio buttons: "All COVID-19 Antibody Therapy Sites" (selected), "REGEN-COV", and "Sotrovimab". Below this, the details for the "MDI Hospital - Island Infusion Center" are shown, including a location pin icon, "78 miles", and the address "10 Wayman Ln, Bar Harbor, ME".

The main area is a map of the Northeastern United States, showing parts of Quebec, New Brunswick, Maine, and New Hampshire. Several infusion centers are marked with blue circular icons. The map includes labels for cities like Quebec City, Fredericton, Saint John, and Portland, as well as geographical features like the Bay of Fundy and White Mountain National Forest. The map is powered by Google Maps, as indicated by the "Google" logo at the bottom.

At the bottom of the page, there is a footer with the text "NICA Locator Sponsored by:" followed by logos for "REGENERON" and "gsk".

<https://covid.infusioncenter.org/>

Opportunities to Increase Use of mAb Therapies

- Identify individuals at high risk for developing severe disease at time of testing
- Promote awareness, education with providers to identify appropriate patients, make referrals
- Promote awareness education with patients/public
- Promote NICA Treatment Locator site link

Coming Soon: Oral Anti-Viral Drugs (AVDs)

- Molnupiravir
 - Merck has submitted EUA application; expect FDA decision by end-Nov, US CDC rec by early Dec
 - Initial data supports reduced risk of hospitalization or death by ~50% compared to placebo for pts with mild-moderate COVID-19 when given within 5d of sx onset
 - Treatment as 800mg (4 X 200mg pills), 2x/d for 5 days
 - Will require confirmed COVID-19 PCR or antigen test
 - Supply initially constrained: feds will be allocating to states, w/ states making local distribution decisions
- Other AVDs also being studied

Q&A

- Questions?
- Other issues?
- **NOTE: ME DHHS/CDC COVID-19 Clinician Info Sessions now held monthly on 2nd Tues/mo at 7:30AM via Zoom:**
<https://zoom.us/j/6218434986?pwd=dEJoNEVRSkVSN2dwZlJ5WEI3WjJsZz09>
Meeting ID: 621 843 4986
Passcode: 338847
One tap mobile:
+13017158592,,6218434986#,,,,,0#,,338847#
- **Next mtg Tues, Dec 14, 7:30AM**



Additional COVID Vaccine Resources

- [Coronavirus Disease 2019 \(COVID-19\) | US CDC](#)
- [US CDC COVID-19 Vaccines Clinical Considerations](#)
- [Maine COVID-19 Vaccines \(maine.gov\)](#)
- [Maine COVID-19 Vaccines FAQ](#)
- [Maine COVID-19 Vaccination Sites](#)
- [Maine COVID-19 Vaccination Dashboard](#)

Presenters

- **Amy Belisle, MD, MBA, MPH**
Maine DHHS, Chief Child Health Officer
Amy.Belisle@maine.gov
- **Isaac Benowitz, MD**
State Epidemiologist, Maine CDC
Isaac.benowitz@maine.gov
T: 207-207.5183
- **Lisa Letourneau, MD, MPH**
Senior Advisor, Healthcare Delivery System Change, ME DHHS
Lisa.Letourneau@maine.gov
C: 207-415-4043
- **Stephen Sears, MD, MPH**
Consulting Epidemiologist, Maine CDC
Stephen.sears@maine.gov
C: 207-458-2351

