

Covid-19 Update: New Year, New Variant

Maryland Department of Health Maryland Primary Care Program Program Management Office

5 January 2022



When you're going through hell - just keep on going!

— Winston Churchill —

AZQUOTES



Agenda



- Current Surge Data
- Vaccines



- Therapeutics
- Testing
- New CDC Quarantine and Isolation Guidelines
- Takeaways: Triple Play Strategy
- Questions from Last Webinar
- Guest Presentation: MDH Communications



Questions & Answers Session



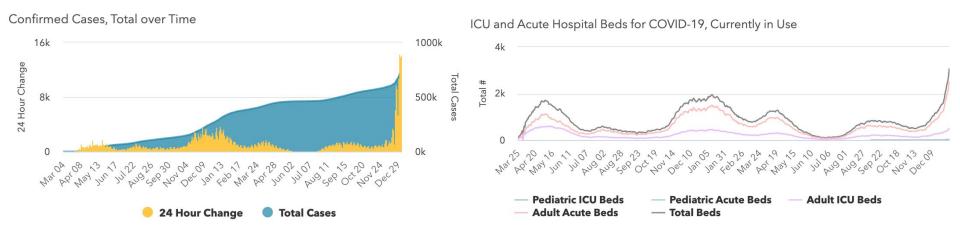
Action Steps: What you can do now Primary Care Triple Play

- Vaccines: Outreach to patients who are unvaccinated or due for boosters and schedule a vaccine appointment
- 2) Testing: Test patients at your practice as needed, and order free POC tests from MDH <u>here</u>
- **3)** Therapeutics: Refer patients to oral antivirals and monoclonals, if eligible, as early as possible
- 4) Practice self care for yourself and your staff

Current Surge Data



Cases and Hospitalizations in Maryland



- Confirmed cases: 776,230 (24hr change = +10,286)
- Testing % positive: 28.56% (24hr change = 1.12%)
- Currently hospitalized: 3,118 (24hr change = +61)
- Current outbreaks: 1,296

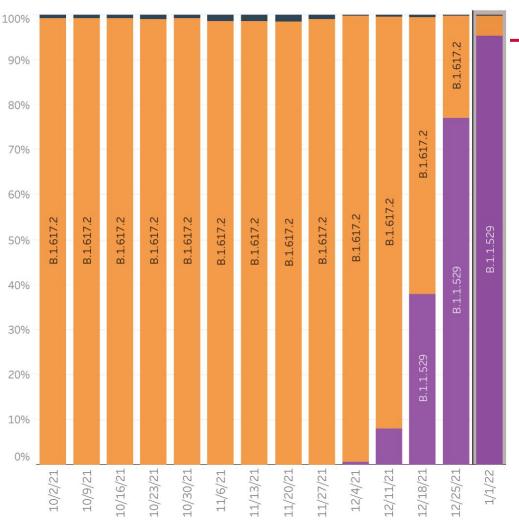
6

Hospitals at Maximum Capacity

- Staffing shortages leads to bed reductions
- Sharp increase in Covid-19 patients
- Staff fatigued and infected
- Rising pediatric hospitalizations
- Flu cases beginning to spike up



United States: 9/26/2021 - 1/1/2022



** ** Omicron in the U.S.

WHO label	Lineage #	US Class	%Total	95%PI	
Omicron	B.1.1.529	VOC	95.4%	92.9-97.0%	
Delta	B.1.617.2	VOC	4.6%	2.9-7.0%	
Other	Other*		0.0%	0.0-0.1%	

As of 1/1, CDC estimates Omicron makes up 95.4% of Covid cases

Region 3: 93.8%, MD: 88.5%

Updated: 1/4/2021

Source: CDC

8

Omicron Compared to Delta

Omicron

- More transmissible
- Fewer hospitalizations
- Fewer deaths
- Vaccine resistance to initial infection, remains protective against severe disease
- Monoclonal resistance

Delta

- Highly transmissible but less than Omicron
- Higher ratio hospitalizations
- Higher ratio of deaths
- Vaccine highly effective
- Monoclonals highly effective



From: Characteristics and Outcomes of Hospitalized Patients in South Africa During the COVID-19 Omicron Wave Compared With Previous Waves

JAMA. Published online December 30, 2021. doi:10.1001/jama.2021.24868

Table 2. Outcomes of Patients Admitted With a Positive COVID-19 Result in the 4 Waves^a

	No. (%) of patients				
	Wave 1 (n = 2628)	Wave 2 (n = 3198)	Wave 3 (n = 4400)	Wave 4 ^b (n = 971)	P value
Receiving oxygen therapy	2119 (80.3)	2624 (82.0)	3260 (74.0)	171 (17.6)	<.001
Receiving mechanical ventilation	431 (16.4)	259 (8.0)	548 (12.4)	16 (1.6)	<.001
Admission to intensive care	1104 (42)	1172 (36.6)	1318 (29.9)	180 (18.5)	<.001
Length of stay, median (IQR), d	8.0 (9)	7.8 (8)	7 (9)	3 (3)	<.001
Deaths	520 (19.7)	790 (25.5)	1284 (29.1)	27 (2.7)	<.001

^a Wave 1: June 14-July 6, 2020; wave 2: December 1-23, 2020; wave 3: June 1-23, 2021; wave 4: November 15-December 7, 2021.

DEPARTMENT OF HEALTH

Table Title:

Outcomes of Patients Admitted With a Positive COVID-19 Result in the 4 Waves^{aa} Wave 1: June 14-July 6, 2020; wave 2: December 1-23, 2020; wave 3: June 1-23, 2021; wave 4: November 15-December 7, 2021, **Constant Science Science Constant S**



^b Seventy-two patients (7%) still admitted.

Maryland Public Health Emergency

- On 1/4, Governor Hogan declared a <u>30 day state of</u> <u>emergency</u>
 - Press Conference recording
 - Actions:
 - Authorization of Maryland Secretary of Health to Regulate Hospital Personnel, Bed Space, and Supplies
 - Expansion of EMS workforce
 - Mobilization of 1,000 Members of the Maryland National Guard
 - > Opening 20 New Hospital-Adjacent Testing Sites Across the State
 - > Authorization of Booster Shots for 12-to-15-Year-Olds
 - Note: This is Maryland policy, the CDC is expected to make an announcement about this today, 1/5
 - Calls For Federal Action on Monoclonal Antibodies, Rapid Tests, COVID-19 Antiviral Pills
 - Calls on Maryland Employers to Incentivize Vaccinations and Boosters, Encourage Masks or Face Coverings

11

Vaccines



Action Steps: Providing and Referring for Vaccines

- Join the Maryland Primary Care Vaccine Program
 - Enroll in ImmuNet, set up EHR reporting, and register in ImmuNet to be a COVID-19 vaccine administrator
- Vaccinate (primary series and boosters) at your practice
- If you cannot vaccinate at your practice, outreach to your patients to recommend vaccination and boosters. Refer patients to a <u>vaccinating site</u> or request a <u>mobile vaccination clinic</u> via this <u>form</u>
 - Vaccination site list has a filter available for 5-11 y.o. vaccination sites

FDA Pfizer EUA Expansion on Boosters

- On 1/3, the <u>FDA expanded its Pfizer EUA</u> for boosters:
 - Shortened window between primary series and <u>booster</u> to five months
 - Recommended by CDC as of 1/4
 - Allow for a <u>third primary series dose</u> for certain <u>immunocompromised children</u> 5 through 11 years of age 28 days after second dose
 - Recommended by CDC as of 1/4
 - Expand the use of a single booster dose to include use in individuals 12 through 15 years of age
 - ACIP is reviewing this today, 1/5



Boosters

What did you get?	When are you eligible for a booster?	Who is eligible for a booster?	What should you get for your booster?
Pfizer	5 months after 2nd dose	16+	Pfizer or Moderna
Moderna	6 months after 2nd dose	18+	Pfizer or Moderna
181	2 months after single dose	18+	Pfizer or Moderna

- COVID-19 Vaccine Booster Guide for PCPs
- After ACIP review and CDC final recommendations, the Booster Guide will be updated

15



CRISP Booster Eligible Filter

Select Filter

Not Vaccinated/1 Dose Received patients 75 and older

Not Vaccinated/1 Dose Received patients 65 and older

Not Vaccinated/1 Dose Received patients age 16 to 64 with one or

more chronic conditions

Not Vaccinated/1 Dose Received patients age 16 to 64

Eligible for booster dose

Note: this filter does not currently filter out deceased patients. Use the "Expired" column in the Vaccine Tracker to further filter out deceased patients. A fix for this is in the works.

New CRISP Vaccine Tracker filter shows patients due for a booster who have not yet received one. Use the filter to find your patients to outreach for booster doses



5-11 Pediatric Pfizer Vaccine

- Two dose regimen, dose 2 can be administered 21 days after dose 1
- Different product from 12+
- Will require reconstitution
- Available for direct ordering beginning 1/6!
 - > Thursday orders will be delivered the following Mon-Wed
 - > 100 dose quantities
 - > Ordering limits are in place based on provider specialty
 - If you need additional vaccine supplies, please submit a request to <u>mdh.covidvax@maryland.gov</u> with your pin, number of requested doses, and justification for additional doses
 - Shipping information will come from Pfizer not MDH

Outreaching to Patients

- Information and education
 - Public Health Collaborative toolkit for 5-11 Pfizer vaccines
 - > <u>Public Health Collaborative toolkit</u> for COVID-19 boosters
 - > <u>Public Health Collaborative messaging</u> for Omicron variant
- Communication resources
 - The National Hispanic Medical Association <u>Vaccinate for</u> <u>All Toolkit</u> (available in <u>Spanish</u>)
 - Vaccine Outreach Call Script
 - Vaccine Communication & Outreach Strategies in Primary Care

Therapeutics



Covid Therapeutics

Timing is critical — the sooner the better

- Monoclonal Antibody Sotrovimab and possibly bam/etes and Regen-COV
 - Prioritize patients per <u>NIH prioritization guidelines</u>
- Oral Antivirals Paxlovid and Molnupiravir
 - > Early prescribed treatment
 - > Refer patients
- Long acting IM Prophylaxis Evusheld (AstraZeneca)
 - > Prophylaxis for immunocompromised
 - Hospital allocation only currently



20

Action Steps: Referring to Treatment

Refer highest risk eligible patients to monoclonal antibody treatment

See appendix for referral resources

- POC test and prescribe oral agents
 - Confirm inventory before prescribing
- Use NIH guidelines for treatment recommendations
- The earlier the better



Monoclonal Antibody Therapy

- In short supply and high demand increasing in late January
- Sotrovimab resilient against Omicron
- Reminder: Bam/ete and Regen-Cov are ineffective against Omicron, and only used where Omicron not expected (80% cutoff point suggested)
- Ensure referrals are fully and accurately completed to avoid rejection
 - Ex: Missing reason for referral (specific condition isn't listed, BMI status and number not listed), cannot read provider name
- Prioritize patients (see next slide)

Monoclonal Antibody Referrals

Referral Options

- Option 1: <u>CRISP eREFERRAL for</u> <u>Monoclonal Antibody Infusion</u>
- Option 2: <u>Maryland Referral Form</u> <u>for Monoclonal Antibody Infusion</u> <u>Treatment</u> (Updating to include sites where PEP is available)
- Some sites allow patients to self-refer for evaluation (listed on referral materials)



Monoclonal Antibody Checklist

The Maryland Department of Health (MDH) provides this clinical criteria checklist as a resource for referring or administering monoclonal antibodies (mAb). There are currently three products suthorized under Emergency Use Authorization (EUA): Bundminimah and Encormab, EEGEN-COV, and Sourimah.¹ Monoclonal antibodies are currently indicated for two purposes certain individuals with active COVID-19 and as a post-exposure prophylaxis in vulnerable persons (e.g., not fully vaccinated or immunocompromised) who are at high-risk for progression to severe COVID-19.

Track 2 - Post-Exposure Pronhylaxis		
Track 2 - Post-Exposure Prophylaxis		
1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO, STOP; YES, proceed to number 2.		
 Does the patient meet high-risk exposure criteria as define by CDC Quarantine and Isolation guidance?² If NO, Proceed to Number 3; YES, proceed to number 4. 		
 Is the patient at high risk of exposure to an individual infected with COVID-19 in the same institutional setting? If NO, STOP; VES, proceed to number 4. 		
4. Is the individual <u>NOT</u> fully vaccinated? ³ If NO (individua is fully vaccinated), <u>Proceed to Number 5</u> ; YES (individua is not fully vaccinated), proceed to number 6.		
 Is the individual anticipated to <u>NOT</u> mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g. immunocompromised or taking immunosuppressive medications)? If NO, STOP: YES, proceed to number 6. 		
6. If exposure occurred within the past 96 hours, patient meets eligibility criteria; proceed with administration or referral. Patients who meet eligibility criteria can be referred to facilities geographically spread access. Maryland for equilable access. To refer a patient, please use the CRISP platform effectival Taol on the Maryland Department of Health (MDH) <u>Maryland Referral Form</u> .		

¹ Seconcised with a set advanced to prost-exposure prophylactic administration and is only commercially available at that time. ² Occoccuster with mixtured advanced and defined as a being within the feet for a stated 1 stratuset or mere, providing one at home to someone who is sick, having direct physical contact with the prostne flagging or kissing, for example, sharing enting or draiking transits, or being exposed to respiratory dougles from a mixed promot (sectoring or coupling, for example), so this weble for advanced data in the stratum of the

⁴ For further information as what qualifies an individual as high risk please see slide 39 of the Monoclonal Antibody Clinical Implementation Guide available at: https://www.ehe.uov/energecv/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.ndf.



NIH Guidelines on Prioritization Patient Level

- Treatment only now
 - > No PEP with Sotrovimab
- Unvaccinated over vaccinated
- Other priorities to consider
 - > Early in course
 - > B cell abnormalities
 - Solid organ transplants
 - Severe underlying conditions

NIH Guidance on Outpatient Therapeutic Preferences

- 1) Paxlovid first when no contraindications
- 2) Sotrovimab when available
- 3) Remdesivir off label
- 4) Molnupiravir if no other
- 5) Bam/etes or Regen-Cov if Delta

<u>NIH guidelines link</u>



Oral Antiviral Agents Overview

- Paxlovid FDA EUA and Molnupiravir FDA EUA
- State allocations began arriving this week
- Dedicated pharmacies across state list provided in "Clinician Letter" from Monday 12/27
 - Prescribed medication use DEA number (or NPI)
- Start within 5 days of symptoms sooner the better
- Proof of positive Covid test
 - Can be any type of Covid test
- No cost to patients for treatment
 - Delivery fees may apply



26

Oral Agent Inventory Confirmation

- Check inventory prior to ordering to ensure availability:
 - > Check website at <u>MedChi.org</u> updated regularly
 - See appendix for list of 30 retail pharmacies
 - Real-time inventory 1-866-935-0867 (new number!)
- Use DEA number when prescribing
- If no DEA, use NPI number



Paxlovid

- FDA authorized an <u>EUA for Paxlovid</u> on 12/22
- USG purchased 10 million courses for first half of 2022
 - > 960 doses for Maryland
- Eligibility
 - Intended for mild-to-moderate Covid in 12+ adults weighing at least 40 kilograms that test positive and are at high risk for progression to severe Covid-19
 - Medication must be initiated within <u>5 days</u> of the onset of symptoms
- Study data
 - Paxlovid appears to cut the risk of hospitalization and death by 89%
- Dosage information in <u>FDA Fact Sheet</u>



Paxlovid Prescribing Details

- Renal impairment adjustments
- Cautions after use regarding oral contraceptives
- Untreated or uncontrolled HIV cautions
- Medication interactions
 - Cytochrome P3A inhibitor
 - > Drugs that use P3A for metabolism may be increased
 - P3A inducing drugs may reduce effectiveness of Paxlovid
 - See Fact Sheet for Healthcare Providers for full prescribing information



Paxlovid is **contraindicated** with **drugs that are highly dependent on CYP3A for** clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions

- Alpha₁-adrenoreceptor antagonist: alfuzosin
- Analgesics: pethidine, piroxicam, propoxyphene
- Antianginal: ranolazine
- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: Dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics: triazolam, oral midazolam

Paxlovid is contraindicated with drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. Paxlovid <u>cannot</u> be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer

- Anticancer drugs: apalutamide
- Anticonvulsant: carbamazepine, phenobarbital, phenytoin
- Antimycobacterials: rifampin
- Herbal products: St. John's Wort

Molnupiravir

- FDA authorized an <u>EUA for Molnupiravir</u> on 12/23
- USG allocating 300,000 courses initially (3.1 million total)
 - > 4,500 doses for Maryland
- Eligibility
 - Intended for mild-to-moderate Covid in 18+ adults weighing at least 40 kilograms that test positive and are at high risk for progression to severe Covid-19
 - Medication must be initiated within <u>5 days</u> of the onset of symptoms
 - Not indicated during pregnancy- needs post use contraception
- Study data
 - Molnupiravir appears to cut the risk of hospitalization and death by 30%

Remdesivir for Outpatient Therapy

- FDA off label use currently only shipping to hospitals
- For individuals 12 years and older and weighing 40 kg or more
- Treatment
 - Remdesivir 200 mg IV on Day 1, followed by Remdesivir 100 mg IV daily on Days 2 and 3
 - Initiated as soon as possible and within 7 days of symptom onset
- Study data
 - 3 consecutive days of IV Remdesivir resulted in an 87% relative reduction in risk of hospitalization or death
 - compared to placebo

32

Evusheld - Long Acting Prophylaxis

- On 12/8, the FDA issued an <u>EUA for Evusheld</u>
 - Moderate to severe immune compromise
 - Unable to take vaccine due to severe allergy to all
 - > IM dosing at 6 month intervals
- Allocation
 - > Began in late December
 - > Allocation directly to hospital partners
 - 888 total doses for next 2 weeks
 - Very limited supply
 - > Referrals done in hospitals
- Clinician letter with hospital information sent out



Testing



Testing Options

- View this <u>comparison tool</u> for Covid testing options
- Rule of Thumb:
 - Symptomatic patient?
 - Conduct a point-of-care test as early as possible once symptomatic
 - > Asymptomatic patient?
 - Conduct a PCR test 5 days <u>after</u> known exposure



Point-of-Care Tests

- Use point-of-care tests to rapidly diagnose patients
- Used for <u>symptomatic</u> patients
- Tests can be conducted outside of a lab setting including congregate care facilities, physician offices, etc. Results typically ready in ~ 15 minutes
- Rapid point-of-care testing toolkit

<u>Action Steps</u>: <u>Order</u> and conduct point-of-care tests for eligible patients



Refer for Testing

- Use <u>this toolkit</u> to guide testing protocols and communication
- Consider PCR testing for asymptomatic patients
 - Review <u>this webinar</u> (beginning at 51:00) for PCR testing options
 - Refer patients for testing at <u>one of these sites</u>



New CDC Quarantine and Isolation Guidelines



New CDC Quarantine and Isolation Guidelines

If You Test Positive for COVID-19 (Isolation)

Everyone, regardless of vaccination status:

- Stay home for 5 days
- If asymptomatic after 5 days, you can leave your house
- Continue to wear a mask around others for 5 additional days
- You may test at day 5 and without symptoms:
 - If positive, continue to isolate to day 10
 - If negative, end isolation and continue to wear a mask around others until day 10

If you have a fever or other symptoms, continue to stay home until symptoms resolve

(Quarantine guidelines on next slide)



New CDC Quarantine and Isolation Guidelines

If You Were Exposed to Someone with COVID-19 (Quarantine)

If you are unvaccinated or overdue for a booster:

- Stay home for 5 days. After that continue to wear a mask around others for 5 additional days.
- If you can't quarantine you must wear a mask for 10 days.
- Test on day 5 if possible.

If you develop symptoms, get a test and stay home.

If you are vaccinated and boosted:

- Wear a mask around others for 10 days.
- Test on day 5, if possible.

If you develop symptoms, get a test and stay home Source: <u>CDC</u>

Takeaways: Triple Play Strategy



Triple Play and Takeaways for Primary Care

Covid isn't over

- Unlike this time last year, we now have baseball bats, a better pitch, and protective gear
- The <u>Triple Play</u> will lead us through Omicron and the Winter season
 - Vaccines including boosters
 - Testing test at your practice
 - Therapeutics prescribe antivirals and mAb referrals



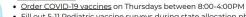


The COVID-19 Triple Play: Three Keys to COVID Mitigation in Primary Care



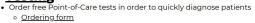
There are many strategies and a lot of information out there related to COVID-19. With the winter holidays around the corner, focus on three essential areas for primary care to mitigate COVID-19 -- primary care's triple play. Below you will find the three essential focus areas and related links to guide your practice.

Vaccines



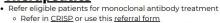
- Fill out 5-11 Pediatric vaccine surveys during state allocation phase
 Outreach to patients to get them in for initial vaccines and <u>booster</u> dose appointments
- Refer patients to a <u>vaccinating site</u> or request a <u>mobile vaccination</u> <u>clinic</u> via this <u>form</u>

Testing



- Consider PCR testing for asymptomatic patients
- Review <u>this webinar</u> (beginning at 51:00) for PCR testing options
 Use this toolkit to guide testing protocols and communication

Therapeutics



 Prepare for the roll out of Molnupiravir, which will be <u>reviewed by the</u> <u>EDA</u> on 11/30, by ordering Point-of-Care tests to rapidly diagnose



With this triple play, we can send COVID-19 to the dugout!



Take Care of Yourself and Your Staff

- It is not selfish to take breaks and you cannot work nonstop
- Check in on your team and talk about your feelings and experiences
- Connect with family and friends

You have been an essential part of the Covid response and have saved countless lives

Thank you for all that you do!



Pandemic End Game 2022

- We will not eradicate this virus
- The virus will continue to mutate with selective advantage being higher transmission rate
- Population will have some level of virus recognition
- Variants such as Omicron will be less virulent
- Additional therapies will reduce death and hospitalizations
- The pandemic will fade into a manageable status
- We will be better prepared for the next global threat



Questions From Last Webinar



Questions from Last Webinar

Q: What is the comparison between natural immunity to individuals with the Covid vaccine primary series and individuals with the Covid vaccine primary series + a booster dose?

- Individual levels of immunity vary
- Data indicates that natural immunity from having recovered from a Covid infection can allow around <u>90 days</u> of some level of immunity
- Data indicates the Covid vaccine primary series can allow around <u>6 months</u> of immunity and wanes over time
- Data indicates that the Covid vaccine booster provides additional immunity beyond the initial vaccine series

The best way to be protected from COVID-19 is to obtain the Covid vaccine and booster dose when eligible

Source: CDC, JHU

Questions from Last Webinar

Q: Is there a cost of the oral antivirals to patients?

Similar to monoclonal antibodies, the federal government has purchased the antivirals and there will be no cost to the patient for the treatment. There may be a delivery fee from the pharmacy.

Q: Can primary care refer immunocompromised patients for Evusheld?

Currently with limited supply, Evusheld is being allocated to hospitals. Primary care can contact a local hospital to determine if referral is possible. As supply increases, MDH will notify you of other referral pathways.



Questions from Last Webinar

Q: Which antivirals can be prescribed for pregnant or breastfeeding patients?

- Molnupiravir: not recommended during pregnancy; breastfeeding is not recommended during treatment but can be stopped for the course of treatment
- Paxlovid: see <u>FDA Fact Sheet</u> for patient-specific recommendations

Q: How long after exposure should patients get tested for Covid?

- > As soon as possible if symptomatic
- > 5 days after exposure, quarantine in the meantime

Future Webinars

Thank you to all of our providers and their staff who have been true healthcare heroes throughout the pandemic

Regular Wednesday Covid-19 Updates occur every other week:

- Wednesday, 1/12, 5:00 PM 6:30 PM
 - ➢ Registration link <u>here</u>
- Wednesday, 1/26, 5:00 PM 6:30 PM
 - ➢ Registration link <u>here</u>

Announcements

- Open enrollment is live for Maryland Health Connection and closes 1/15/22- Additional information is in the Appendix of this slide deck
- COVID-19 Triple Play Strategy Guide

Guest Presentation



Guest Presentation: MDH Communications

- Deidre McCabe, Director of Communications
- David Blum, Senior Vice President of GKV
- Presentation on MDH Communications and Vaccine Outreach Efforts



Winter 2021/2022 Communications

- Vaccinating Kids 5+
 - Mix of doctors, parents and kids
 - Safe and Effective
 - Science plus emotional connection
- Getting a Booster
 - Protect yourself and your family
 - Simplify information and reach key groups



Let's end COVID, Maryland.



Message Delivery

- Statewide TV and Cable TV
- Social Media
- Radio
- Hispanic/Latino Outreach
- Movie Screens
- Pediatrician/PCP
 Waiting Rooms



GOVAX@GKV.COM

Question and Answer Session



CME



CME Accreditation and Designation

- This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of MedChi, The Maryland State Medical Society, and The Maryland Department of Health. MedChi is accredited by the ACCME to provide continuing medical education for physicians.
- ★ MedChi designates this live webinar educational activity for a maximum of 1 AMA PRA Category 1 Credits[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Contact Frank Berry at <u>fberry@medchi.org</u>



CME Disclosures and Evaluation

- Presenters and Planners: Howard Haft, MD, has reported no relevant financial relationships to disclose.
- MedChi CME Reviewers: The reviewers from the MedChi Committee On Scientific Activities (COSA) for this activity have reported no relevant financial relationships to disclose.
- Attendees can receive CME credit by completing <u>this evaluation</u> after each webinar. MedChi will then be in contact with the certificate



Appendix

Resources



CDC Updated Recommendations

- On 12/16, the CDC updated its recommendations on COVID-19 vaccines to include a clinical preference for the two mRNA vaccines (Pfizer and Moderna) over J&J
- J&J still available



60

Pfizer 'Gray Cap'

- Beginning 12/23, a new Pfizer vaccine formulation will become available (Pfizer Tris-sucrose Adult Formulation)
- For all 12+ individuals
- Changes to ordering and handling:
 - > They will have a gray cap
 - Will be available in smaller 300-dose configuration
- 00-dose

DO NOT DILUTE

- Does not require diluent
- \succ May be stored at 2-8°C(36-46°F) for up to 10 weeks

Practices should use current remaining Pfizer inventory before ordering the Tris-Adult formulation

More on 'Gray Cap'



Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years" ("Age 5y to <12y" on vial label)
Vial Cap Color	Purple	Gray	Orange
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial [*]	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)



- Pfizer Vaccine Formulation/Presentation Guide
- Pfizer trainings are ongoing and additional information is in the announcements section of this slide deck

Heterologous Dosing - Mixing and Matching

- The CDC has now advised that booster doses can be a different vaccine type than the primary series
 - Ex: An individual that originally obtained Moderna for doses 1 and 2, can now obtain Moderna, Pfizer, or J&J for a booster if they are eligible for a booster dose
- All Moderna booster doses are a half dose, regardless of the individual's primary vaccine type



5-11 Yr Old Pediatric Pfizer Vaccine

- Two dose regimen, dose 2 can be administered 21 days after dose 1
- Different product from 12+
- Will require reconstitution
- Allocation
 - Providers will need to manage 2nd dose appointments through supply provided; no separate allocation for 2nd doses
- MDH <u>Toolkit</u> for 5-11 Pediatric Pfizer Vaccine
 - Password: 5+Vaccine



Moderate to Severe Immunocompromise

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory



Appendix

Monoclonal Antibody Treatment Information and Resources



Monoclonal Treatment Eligibility

- Who Qualifies for Treatment?
 - mAb treatment is for adults and adolescents (12 and older) who:
 - Recently tested positive for COVID-19
 - Are within 10 days of first experiencing symptoms
 - Do not need to be hospitalized for COVID-19
 - ✓ Weigh at least 88 pounds

Are in one of the following high-risk categories:

- Are age 55 to 64 AND have cardiovascular disease, hypertension, chronic respiratory diseases or COPD
- ✓ Have diabetes, obesity, kidney disease or other serious chronic conditions
- ✓ Are 65 years old or older
- ✓ Are pregnant
- For adolescents: high BMI, sickle cell disease, heart disease, neurodevelopmental disorders, a medical-related technological dependence, asthma or other chronic respiratory disease
- Or who have been determined by their healthcare provider to be at high risk for worsening and/or hospitalization



Patient Facing Resources

Website

- ➤ Landing page -- general page
- FAQ-- detailed information about mAb

Contact tracing

- Direct text message to all contacts and people with positive tests (ages 18+) linking to Landing Page (Eng. & Sp.)
- MAb information sent to Interviewed Cases & Exposed Contacts at conclusion of contact tracing interview
- Site Access and PEP status
 - Flyer with treatment location list, PEP information, and self-referral information



Self-Referral Options for Patients

- Patients should coordinate with their respective physician or care provider before contacting a location to schedule an appointment.
- Patients without a healthcare provider, contact <u>eVisit</u> to schedule a virtual appointment or complete a <u>self-referral form</u>.
 - Eligible patient(s) will be referred to an infusion site for treatment.
- For those without internet access or a healthcare provider, they may contact the MDH-supported monoclonal antibody call center at 410-649-6122 (Monday Friday from 8 a.m. to 5 p.m) and speak to a clinician to review eligibility.
 - *Odenton VFD, City of Praise Ministries, and <u>MDmAbs</u> also accept direct patient contact to determine eligibility and/or schedule treatment



Provider-Facing Resources

- Webinars over 100
- Clinician Letters
 - "Checklist" to assist providers in determining patient eligibility for mAbs.



- Ease in making referral
 - Option 1: <u>CRISP eREFERRAL for</u> **Monoclonal Antibody Infusion**
 - Option 2: <u>Maryland Referral Form for</u> **Monoclonal Antibody Infusion** <u>Treatment</u> (Updating to include sites where PEP is available)
 - Some sites allow patients to self-refer for evaluation (listed on referral materials)



Monoclonal Antibody Checklist

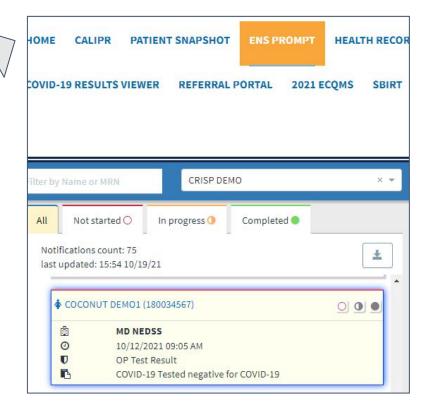
ant of Health (MDH) provides th checklist as a resource for referring or ed under Emergency Use Authorization lonal antibodies are currently indicated for two r

Track 1 - Active COVID-19 Infection	Track 2 - Post-Exposure Prophylaxis	
. Is the patient 12 years of age or older weighing at least 88 pounds? f NO, STOP; YES, proceed to number 2.	1. Is the patient 12 years of age or older weighing at least 88 pounds? If NO, STOP; YES, proceed to number 2.	
Does the patient have a positive COVID-19 PCR or antigen test esult? If NO, STOP; YES, proceed to number 3.	 Does the patient meet high-risk exposure criteria as defined by CDC Quarantine and Isolation guidance?² If NO, Proceed to Number 3; YES, proceed to number 4. 	
Does the COVID-19 positive patient have mild to moderate OVID-19 symptoms such as fever, cough, shortness of breath, loss f tast/smell, farigue, nausea, vomiting, diarrhea, throat pain, ongestion, myalgia, or headache? If NO, STOP; VES, proceed to umber 4.	 Is the patient at high risk of exposure to an individual infected with COVID-19 in the same institutional setting? If NO, STOP; YES, proceed to number 4. 	
. Has it been less than 10 days since symptom onset and positive COVID-19 test result? If NO, STOP; YES, proceed to number 5.	4. Is the individual <u>NOT</u> fully vaccinated? ³ If NO (individual is fully vaccinated), Proceed to Number 5; YES (individual is not fully vaccinated), proceed to number 6.	
. Is the COVID-19 positive patient at high risk ⁴ for progression to evere COVID-19, including hospitalization or death? If NO , STOP ; (ES , proceed to number 6.	 Is the individual anticipated to <u>NOT</u> mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g. immunocompromised or taking immunosuppressive medications)? If NO, STOP; YES, proceed to number 6. 	
If any of the following apply, STOP: the patient is not eligible for estimated. Observing proceed in matters proceeding matters Patient height proceeding matters of the COVID-19 Patient requires express the any due to COVID-19 Patient requires require an increase in baseline oxygen flow rate due to COVID-19 Patient is in imminent need of hospitalization due to COVID- 19	6. If exposure occurred within the past 96 hours, patient meets eligibility criteria: proceed with administration or referral. Patients who meet eligibility criteria cas he referred to facilities geographically spread arrow Maryland for equitable access. To refer a patient, please use the CRUSP platform <u>eligerical Tool</u> or the Maryland Department of Health (MDH) Maryland Beformal Ferro.	



Practice mAb Referral Workflow

- Daily, go into the CRISP ENS PROMPT to view new positive Covid-19 test results for your patients
- 2) For Covid-positive patients, assess every patient for <u>mAb</u> <u>eligibility</u>
- 3) For eligible patients, call the patient to recommend mAb treatment
 - a) See this <u>patient-facing website</u>
- 4) Refer the patient to mAb treatment through <u>CRISP</u> or
- 71 <u>externally</u>





Additional Monoclonal Information

Indications for Outpatient COVID-19 mAbs

Monoclonal Antibody Indications and Routes of Administration			
Monoclonal Antibody	TREATMENT of Mild to Moderate COVID-19 Infection within 10 days of symptom onset in patient with high risk of progression to severe disease	POST-EXPOSURE PROPHYLAXIS for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease	
bamlanivimab and etesevimab ¹ (Eli Lilly)***	Dose: 700 mg bamlanivimab and 1400 mg etesevimab*** Route: Intravenous administration Post-administration monitoring: 60 minutes	N/A	
casirivimab and imdevimab² (REGEN-COV)	Dose: casirivimab 600mg and imdevimab 600mg Route: Intravenous is preferred route, however subcutaneous injection may be utilized in situations where there would be a delay in intravenous administration Post-administration monitoring: 60 minutes	Dose: casirivimab 600mg and imdevimab 600mg Route: Intravenous or subcutaneous Post-administration monitoring: 60 minutes	
Sotrovimab ³ (Glaxo Smith Kline)	Dose: sotrovimab 500mg Route: Intravenous Post-administration monitoring: 60 minutes	N/A	

*** Based on the most currently available data, <u>bamlanivimab and etesevimab are now authorized</u> in all U.S. states, territories, and jurisdictions (9/2/21) [https://www.fda.gov/media/151719/download]

Refer to product Emergency Use Authorizations for detail on indications and administration

¹ Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (https://www.fda.gov/media/145802/download)

² Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COVTM (casirivimab and imdevimab) (https://www.fda.gov/media/145611/download)

³ Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab (https://www.fda.gov/media/149534/download)

Appendix

Maryland's Official Health Insurance Marketplace: Open Enrollment Information



What's New with Maryland Health Connection

November 2021



Maryland's Official Health Insurance Marketplace

Open Enrollment November 1, 2021

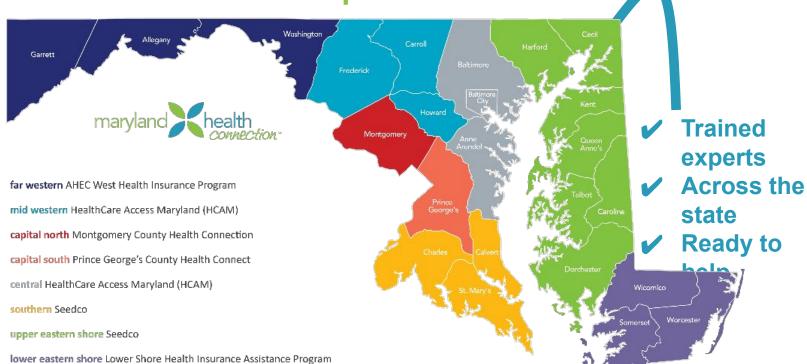
January 15, 2022, to be covered for 2022





www.MarylandHealthConnecti on.gov www.MarylandHealthConnecti on.gov/es

Where to Find Help





The Only Place to Get Financial Help

Maryland Health Connection is the only place Marylanders can get financial help to pay for their health plan. In fact, **9 out of 10 who enroll get savings.**



More Savings for More Marylanders

Did you know the **American Rescue Plan** includes big savings for health insurance?

- For the uninsured, it's worth checking out the 2022 health plan options – there are now new, bigger savings.
- If someone didn't qualify for savings before they should take another look because, for the first time, there are savings available for Marylanders with higher incomes.

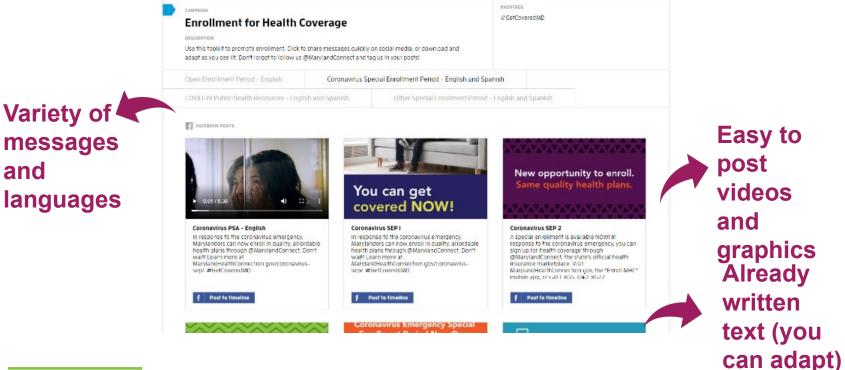
Did you know Maryland has **new discounts for young adults** ages 19-34? They're new for 2022 health plans!





TheSocialPressKit.com/MarylandConne ct

Visit our **Social Press Kit** for ready-to-post graphics to share on your social media channels, messaging to share with your community, and more.





Enrollment ends January 15.

#GetCoveredMD



Appendix

Resources and Links



General Vaccine Resources

CDC Covid-19 Vaccination Communication Toolkit - ready made

materials, how to build vaccine confidence, social media messages

New York Times Vaccine Tracker - information on every Covid vaccine in development

New York Times Vaccine Distribution Tracker – information on the

distribution of Covid vaccines in the United States

MDH Covidlink Vaccine Page - information on vaccine priority groups in Maryland

CDC Vaccine Storage and Handling Toolkit

Project ECHO Webinar - webinar on vaccines and Long Term Care

Facilities, relevant for primary care

CDC <u>Moderna vaccine storage</u>



Covid-19 mAb Treatment Criteria



Patient Criteria

- Use clinical judgment
- □ Have BMI >= 35
- □ Have chronic kidney disease
- □ Have diabetes
- □ Are currently receiving immunosuppressive treatment
- □ Are >= 65 years old
- \Box Are >=55 years old and have
 - ✔ Cardiovascular disease, or
 - ✔ Hypertension, or
 - ✔ Chronic obstructive pulmonary disease/other chronic respiratory disease
- \Box Are 12 17 years old AND have
 - ✔ BMI >=85th percentile for their age and gender based on CDC growth charts, or
 - ✔ Sickle cell disease, or
 - Congenital or acquired heart disease, or
 - ✓ Neurodevelopmental disorders, or
 - ✔ A medical-related technological dependence, or
 - 🖌 Asthma



Scheduling In-Office Appointments

Patient calls in for an appointment

- □ Reception screens patient on the phone using the <u>pre-visit screening template</u>
- Schedule in-office visits for different groups: At-risk and vulnerable patients on certain days, healthier patients on other days
- Schedule telehealth and non-office-based care for other patients including follow-ups and patients uncomfortable with office visits

Check In

- Practice remote check in and limited front-desk contact
- □ Consider using a triage zone outside of office or main area;
- Or use a barrier at the front desk
- Design your office to accommodate patients who come in specifically for Covid testing and triage, separate from patients who arrive for non-Covid related and elective procedures
 - Ensure patients and staff do not cross between Covid and non-Covid areas
 - Set aside a specific area for patients who come in for testing to wait and be triaged



Scheduling In-Office Appointments

Checking out

- Practice remote check out, limit front desk exposure;
- Or use a barrier at the front desk



If patient is paying co-pays, etc., set up credit card reader outside of the barrier



Other workflow resources



- Care management workflows
- BMJ telemedicine workflow graphics
- CDC flowchart to identify and assess 2019 novel Coronavirus
- <u>CDC telephone evaluation flow chart for flu</u>
 - CDC guidance for potential Covid-19 exposure associated Maryland international or domestic travel

CDC Guidelines for Covid Patient Management

- Healthy people can be monitored, self-isolated at home
- People at higher risk should contact healthcare providers early, even if illness is mild
- Older adults and people with severe underlying chronic medical conditions are at higher risk, need closer contact
- Emergency Department and hospitals only when needed not for screening or low risk/minimal disease
- Guidelines are important and powerful tools, but remember providers' clinical experience and judgment are key to care



Personal Protective Equipment (PPE) Sources and Requests

- Practices should initially request PPE through their usual vendors
- Practices should make their PPE requests through their local health departments
- Maryland PPE Manufacturers List next slide
- National and international PPE supplier list
- PPE request form



Personal Protective Equipment (PPE) Sources and Requests

- Increasing Maryland's supply of PPE one of the 4 building blocks on the Road to Recovery
- Maryland has launched the <u>Maryland Manufacturing</u> <u>Network Supplier Portal</u>, an online platform that helps connect Maryland suppliers with buyers in need of critical resources
- For additional business resources during Covid-19, visit <u>businessexpress.maryland.gov/coronavirus</u>
- Providers may also request PPE from the non-profit <u>'Get Us PPE'</u>



Provider/Patient Mental Health Resources

Providers

- "Helping the Helpers and Those They Serve," a <u>webinar series</u> from the Maryland Department of Health Behavioral Health Administration and MedChi
- Heroes Health Initiative
- Patients
 - Ask Suicide-Screening Questions toolkit
 - □ CDC <u>list of resources</u> for coping with stress



Health Equity Resources



Maryland Department of Health Office of Minority Health and Health Disparities (MHHD)



Maryland Department of Health Minority Outreach and Technical Assistance Program overview



- MHHD fiscal year 2020 minority outreach and technical assistance program information
- Description of the term "health disparity"

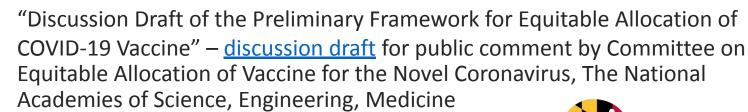


*

Implicit bias test



"Hundreds of Days of Action as a Start to Address Hundreds of Years of Inequality" – New England Journal of Medicine <u>article</u> by Maulik Joshi, DrPH





Telehealth Resources

- Maryland Health Care Commission Telehealth \mathbf{x}
- Maryland Health Care Commission Telehealth Readiness Assessment Tool



U.S. Department of Health and Human Services Health Insurance Portability and Accountability Act (HIPAA) for **Professionals**



- **American Telehealth Association**
- Maryland Telehealth Alliance
- National Consortium of Telehealth Resource Centers



Support for Patients at Home

Food

□ Meals on Wheels

Caregivers

□ Visiting nurses and caregivers

Emotional support

□ Support from family

Phone calls and videochat to fight loneliness

□ MD Department of Aging <u>Senior Call Check Program</u>



Food Resources

- Nutrition: Inform patients that children can receive three free meals/day at sites listed on:
 - <u>Maryland Summer Meals</u>
 <u>Howard County</u>
 - <u>Montgomery County</u>
 - Prince Georges County
 - □ <u>Charles County</u>

Frederick County

Anne Arundel County

- St. Mary's County
- Harford County
- Calvert County
- Free meals available from 42 rec centers in Baltimore
 - □ Call 311 for locations and to schedule pickup time



Resources for Specific Groups

- Community- and Faith-Based Organizations (<u>https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-community-faith-organizations.html</u>)
- Mass Gatherings and Large Community Events (<u>https://www.cdc.gov/coronavirus/2019-ncov/community/mass-gatherings-ready-for-covid-19.html</u>)
- Non-Pharmaceutical Interventions for Specific Groups (<u>https://www.cdc.gov/nonpharmaceutical-interventions/index.html</u>)



Resources and References

- Maryland Department of Health Coronavirus Website (<u>https://coronavirus.maryland.gov</u>)
- CDC Coronavirus Website (<u>https://www.cdc.gov/coronavirus/2019-nCoV/index.html</u>)
- CDC National data on Covid-19 infection and mortality (<u>https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html</u>)
- CDC Interim Guidance for Homes and Communities (<u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html</u>)
- CDC Interim Guidance for Businesses (<u>https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-busine</u> <u>ss-response.html</u>)
- CDC Interim Guidance for Childcare and Schools (<u>https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-for-schools.html</u>)
- CDC Travel Website (<u>https://wwwnc.cdc.gov/travel/</u>)



Articles

- <u>"Effectiveness of Mask Wearing to Control Community Spread of SARS-CoV-2</u>"
- COVID-19 Vaccines vs Variants—Determining How Much Immunity Is <u>Enough</u>
- SARS-CoV-2–Specific Antibodies in Breast Milk After COVID-19 Vaccination of Breastfeeding Women"
- <u>
 "Maternal and Neonatal Morbidity and Mortality Among Pregnant</u> <u>
 Women With and Without COVID-19 Infection: The INTERCOVID</u> <u>
 Multinational Cohort Study</u>
- <u>"Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in</u> <u>a Population in Lombardy, Italy"</u>
- "Sequelae in Adults at 6 Months After COVID-19 Infection"
- "How COVID-19 Affects the Brain"

