COVID-19 Clinical Update

January 25, 2022

Information Current as of 01/25/2022 @ 12:00 pm

Purpose

Provide timely, relevant, actionable information to keep our medical group, APP aligned and independent physicians and APCs informed and engaged in our system’s response to COVID-19 and support them in their practice.

Learning Objectives

After completing this course, you will be able to: discuss the indications, efficacy, and safety for the outpatient COVID-19 therapeutics: Nirmatrelvir with Ritonavir (Paxlovid), Sotrovimab, Remdesivir, and Molnupiravir.

CME Designation and Accreditation

Advocate Aurora Health is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Advocate Aurora Health designates this live activity for a maximum of 0.5 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclosures

The planners and speaker(s) have indicated that there are no financial relationships with any commercial interests to be disclosed.

Our Guiding Principle

"Calm over Chaos, Faith over Fear"

Reflection

Hope is being able to see that there is light despite all of the darkness.

Desmond Tutu

Agenda

- COVID-19 Current Situation Overview (Citronberg, Lineberry)
- Asymptomatic Testing Update (Lineberry)
- Laboratory Testing and Supply Update (Janicki, Runnoe)
- Pharmacy Update (Jackson, Weber-Tatarellis)
- FAQs and Discussion (All)

COVID-19 Overview and Asymptomatic Testing Update

Tim Lineberry, MD
Rob Citronberg, MD

Update | Asymptomatic Testing

Beginning Jan 25, positive asymptomatic COVID test results will be routed to PCPs for follow up calls.

Medical group clinicians: Check your InBasket for your patients' test results, as you do for other test results.

APP aligned/independent PCPs: You'll receive your patients' results in the same way you receive other test results from Advocate Aurora.

Unassigned patients will receive outreach from a centralized team.

All patients with positive results and active LiveWell accounts will be invited to enroll in our automated virtual symptom monitoring program through LiveWell.

Covid-19 Laboratory Testing Update

Glenn Janicki
Mick Runnoe

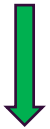
AdvocateAuroraHealth

Covid-19 Testing Week of January 16th

System positivity 24.9%

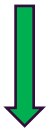
IL positivity 22.2%

WI positivity 27.1%



Testing volume 35,187 / week

System influenza positivity 1.6%



ACL Laboratories
Every Sample is a Life™

AdvocateAuroraHealth

Covid-19 & Flu Testing Options

Molecular – PCR

Cepheid Rapid PCR
Covid/Flu/RSV Panel (LAB10789)
45 minutes

Hologic Panther PCR
2019 Novel Coronavirus PCR (LAB10635)
<24 hours

Antigen

Sofia (WI) Veritor (IL)

SARS-COV2-Antigen (LAB10715)

Rapid Influenza Antigen (LAB10788)

<45 minutes

Binax / Quickvue / Sure-Vue

POCTSARS-COV2Antigen (POC265)

POCT Influenza A/B (POC214)

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Testing Conservation and Clinical Recommendations

Emergency Department

- Symptomatic –Covid/Flu Antigen
- Asymptomatic – Rapid Quad PCR

Hospital Inpatient

- Rapid Quad PCR (on-site)
- Non Rapid Covid PCR (ACL Central Lab)

Ambulatory / Urgent Care / Immediate Care

- Covid/Flu Antigen (ACL Onsite or Back Office point of care)
- Non Rapid Covid PCR (ACL Central Lab)

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Covid-19 / Flu Viral Detection Test Code Guide
Effective January 31st, 2022

Test Type	Rapid Covid/FLU/RSV	Covid PCR Only (Central Labs)	Covid / Flu PCR (Central Labs) Starting Feb 1st	ACL Covid Antigen	ACL FLU A,B Antigen	Back Office Ambulatory Covid	Back Office Ambulatory FLU A,B	Emergency Dept Binax Now / Quidel Quickvue Covid	Emergency Dept Binax Now / Quidel Quickvue FLU
Test Code	COVID/Flu/RSV Panel (LAB10789)	2019 Novel Coronavirus (SARS-CoV2) PCR (LAB10635)	Non-rapid COVID/Flu Panel (LAB11071)	SARS-COV2-Antigen (LAB10715)	RAPID INFLUENZA A/B ANTIGEN (LAB10788)	POCT SARS-COV-2 ANTIGEN (POC259)	POCT INFLUENZA A/B (POC214)	POCT SARS-COV-2 ANTIGEN (POC265)	POCT INFLUENZA A/B (POC214)
Turn Around Time	<60 minutes	24 - 48 hours	24 - 48 hours	<45 minutes	<45 minutes	<45 minutes	<45 minutes	~15 minutes	~15 minutes
Patient Population									
ED Symptomatic		XXX	XXX					XXX	XXX
ED Asymptomatic	XXX								
Hospital Inpatient	XXX	XXX	XXX						
WI Urgent Care		XXX	XXX	XXX	XXX				
WI Ambulatory		XXX	XXX	XXX	XXX	XXX	XXX		
IL Urgent Care		XXX	XXX			XXX	XXX		
IL Ambulatory		XXX	XXX			XXX	XXX		
Exempt / Deferred TM		XXX							
Employee Health								XXX	XXX

New Covid/FLU test offering Feb 1st 2022

Hologic Panther (ACL Central Labs)

Combo test SARS-COV-2 and Influenza by PCR (LAB11071).
<24 hours

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AdvocateAuroraHealth

Outpatient COVID-19 EUA Medications

High-Level Summary

Vincent Jackson
Kersten Weber Tatarelis

AdvocateAuroraHealth

Objectives

- Discuss current supplies and utilization
- Discuss sites of administration for the monoclonal antibody therapies
- Review the five medications with an EUA for the **treatment or prevention** of COVID-19, specifically their:
  - Indication
  - Criteria for use (internal and the EUA)
  - General ordering/scheduling
  - Other considerations

EUA COVID Medications

For non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression, the NIH recommends using 1 of the following therapeutics (listed in order of preference):

- Nirmatrelvir with Ritonavir (Paxlovid)
- Sotrovimab
- Remdesivir
- Molnupiravir

EVUSHELD (tixagevimab/cilgavimab)

- EUA approval as pre-exposure prophylaxis against SARS-CoV-2 for those unexpected to mount sufficient immune response to a SARS-CoV-2 vaccine and/or those unable to receive a SARS-CoV-2 Vaccine.

Supplies and Usage

- **Paxlovid/Molnupiravir**
  - >60 courses of therapy have been dispensed from our API retail pharmacies
  - API Retail pharmacies have over 1,000 courses available

- **Sotrovimab**
  - >500 doses administered across AAH
  - Inventory WI = 381, IL = 288

- **Remdesivir**
  - Only being administered at Advocate Good Samaritan Immediate Care Center in Lemont, IL
  - Adequate supplies on-hand

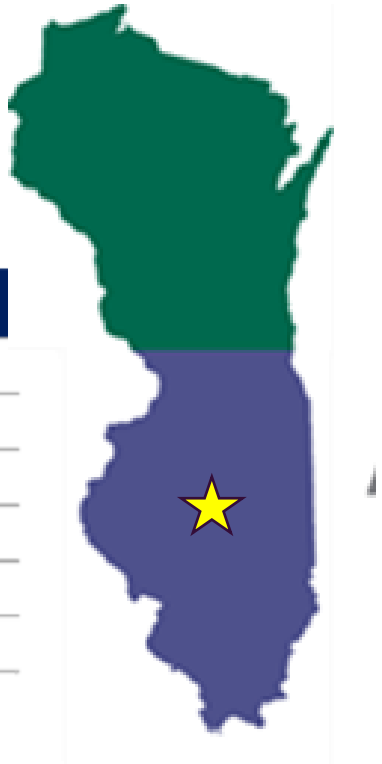
- **Evusheld**
  - SRAT is finalizing appropriate use criteria for this limited resource
  - Inventory WI = 408, IL = 800

mAB Administration Sites

Illinois Sites

NEW: Emergency Departments are not to be used as referral sites

AAH Monoclonal Antibody Infusion Site	PSA	Classification	Within Hospital Campus	Hours of Operation	Contact Phone Number (Infusion Hub & Ambulatory Only)	Logistics / Referral Process
Advocate Condell Vernon Hills	North Illinois	Infusion Hub - Hospital Based	No	M - F 8am - 5pm	847-990-2202	Therapy Plan
Advocate Good Shepherd Hospital	North Illinois	Infusion Hub - Hospital Based	Yes	M,T, W, F, Sat 7:30am-3:30pm	847-842-3160	Therapy Plan
Advocate Good Samaritan Hospital	Central Chicagoland	ICC	No	T, W, Th, F 8a-8p	630-275-8400	Order Set
Advocate Christ Hospital	South Chicagoland	Infusion Hub - Hospital Based	Yes	M, W, F 4:30pm - 8:30pm	708-684-2680	Therapy Plan
Advocate Children's Hospital - Park Ridge	Pediatrics	Infusion Hub - Hospital Based	Yes			Therapy Plan
Advocate Children's Hospital - Oak Lawn	Pediatrics	Infusion Hub - Hospital Based	Yes			Therapy Plan



Full list available: Monoclonal Antibody Playbook

Wisconsin Sites

NEW: Emergency Departments are not to be used as referral sites

AAH Monoclonal Antibody Infusion Site	PSA	Classification	Within Hospital Campus	Hours of Operation	Contact Phone Number (Infusion Hub & Ambulatory Only)	Logistics / Referral Process
Aurora Medical Center - Bay Area	North Wisconsin	ED	Yes	-	-	Order Set
Aurora Medical Center - Bay Area	North Wisconsin	Infusion Hub - Hospital Based	Yes	7a-3p M-F	715-735-4200 ext 6491	Therapy Plan
Aurora BayCare Medical Center	North Wisconsin	ED/Urgent Care	Yes			Order Set
Aurora BayCare Health Center - Kaukauna	North Wisconsin	Urgent Care	No	0700 - 1930	920-766-3200	Order Set
Aurora Health Center - Oshkosh West	North Wisconsin	Urgent Care - Clinic Based Site	Yes	Tu, Th, Sa 0800-1700	-	SmartSet
Aurora Urgent Care - Manitowoc	North Wisconsin	Urgent Care	No	•M-F o0800-1100 o1100-1400 o1600-1900 •Saturday o0800-1100 o1100-1400	920-686-5731	SmartSet
Aurora Sheboygan Memorial Medical Center	Central Wisconsin	ED	Yes	-	-	Order Set
Aurora Urgent Care - Plymouth	Central Wisconsin	Urgent Care	No	M-F: 8 am - 8 pm Sat-Sun: 8am - 4pm		SmartSet
Aurora Medical Center - Summit	Central Wisconsin	Infusion Hub - Hospital Based	Yes		262-434-1970	Therapy Plan
Aurora Medical Center - Washington County	Central Wisconsin	Infusion Hub - Hospital Based	Yes	M-F 0800-1400 S, S, Holidays 1100-1400	262-670-7265	Therapy Plan
Aurora St. Luke's Medical Center	Greater Milwaukee	ED	Yes	-	-	Order Set
Aurora St. Luke's South Shore	Greater Milwaukee	Infusion Hub - Hospital Based	Yes	M-F, S, S 0830-1600, No Holidays	414-489-4052	Therapy Plan
Aurora Medical Center - Grafton	Greater Milwaukee	Infusion Hub - Hospital Based	Yes	M-F 9a-4p	262-329-1950	Therapy Plan
Aurora Medical Center - Grafton	Greater Milwaukee	ED	Yes	-	-	Order Set
Aurora Sinai Medical Center	Greater Milwaukee	ED	Yes	-	-	Order Set
Aurora West Allis Medical Center	Greater Milwaukee	ED	Yes	-	-	Order Set
Aurora Medical Center - Kenosha	South Wisconsin	ED	Yes	-	-	Order Set
Aurora Medical Center - Kenosha	South Wisconsin	Infusion Hub - Hospital Based; 2 areas: DTC and after hours Infusions in the Wound Care Clinic	Yes	DTC: 0800 to 1800 After hours infusion clinic: 1600 to 2000	(262) 948-6834	Therapy Plan
Aurora Lakeland Medical Center	South Wisconsin	Infusion Hub - Hospital Based	Yes	-	-	Therapy Plan
Aurora Medical Center - Burlington	South Wisconsin	Infusion Hub - Hospital Based	Yes	Accepts referrals from ALMC during the week	(262) 767-6860	Therapy Plan

Full list available: [Monoclonal Antibody Playbook]

Paxlovid

88% relative risk reduction

- Dosing/Criteria: Nirmatrelvir 300mg (two tabs) + **Ritonavir** 100mg PO BID within 5d of symptoms
  - ≥12 years and ≥40 kg
  - EUA and AAH criteria for use are the same
- Ordering: Can be prescribed in EPIC with order comments indicating EUA criteria the patient meets (intent: *to minimize call backs)*
  - WI: API; IL: other retail pharmacies
- Other considerations:
  - Renal dose adjustment, CrCl 30 to <60mL/min
    - Nirmatrelvir 150 (1 tab) + Ritonavir 100mg PO BID
      - *Must remove Nirmatrelvir tabs from blister pack*
  - Drug interactions with Ritonavir component
  - Supply adequate; demand lower than anticipated

Sotrovimab

85% relative risk reduction

- Dosing/Criteria: Sotrovimab 500mg ONCE as a single IV infusion, within 10d of symptoms
  - ≥12 years and ≥40 kg
  - AAH criteria consistent with EUA *(expanded this week)*
- Ordering: Can be prescribed in EPIC to outpatients and inpatient who meet internal use criteria.
- Other considerations:
  - **Retains activity against the Omicron variant**
  - Supply adequate; Demand lower than anticipated

The following medical conditions or other factors may place adults and pediatric patients (12 to 17 years of age weighing at least 40 kg) at higher risk for progression to severe COVID-19:
• Older age (for example ≥65 years of age)
• Obesity or being overweight (for example, adults with BMI >25 kg/m2 , or if 12 to 17 years of age, have BMI ≥85th percentile for their age and gender based on CDC growth charts
• Pregnancy • Chronic kidney disease • Diabetes • Immunosuppressive disease or immunosuppressive treatment
• Cardiovascular disease (including congenital heart disease) or hypertension
• Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension) • Sickle cell disease
• Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
• Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID 19])

87% relative risk reduction

Remdesivir

- <u>Dosing/Criteria:</u> Remdesivir 200mg IV on day one then 100mg IV on days 2 and 3 within 7d of symptoms
  - ≥12 years and ≥40 kg
- <u>Other Considerations</u>:
  - Familiar anti-viral, used inpatient for most of pandemic but x 5-10d
    - NO routine renal nor hepatic monitoring
    - One-hour post-infusion observation required
  - **Only available at** Advocate Good Samaritan Immediate Care Center in Lemont, IL.
    - 3 consecutive days of treatment is operationally challenging
  - Supply adequate

30% relative risk reduction

Molnupiravir

- Dosing/Criteria: Molnupiravir 800mg PO BID x 5 days, started within 5d of symptoms
  - ≥ 18 years
  - EUA and AAH criteria for use are the same
- Ordering: Can be prescribed in EPIC with order comments indicating EUA criteria the patient meets (Intent : *to minimize call backs)*
  - WI: API; IL: other retail pharmacies
- Other considerations:
  - Bone/cartilage toxicity concerns (WHY limited to adults only)
  - Pregnancy: not recommended due to embryo-fetal toxicity risk
  - **Less effective than the other three EUA medications**
  - Supply adequate

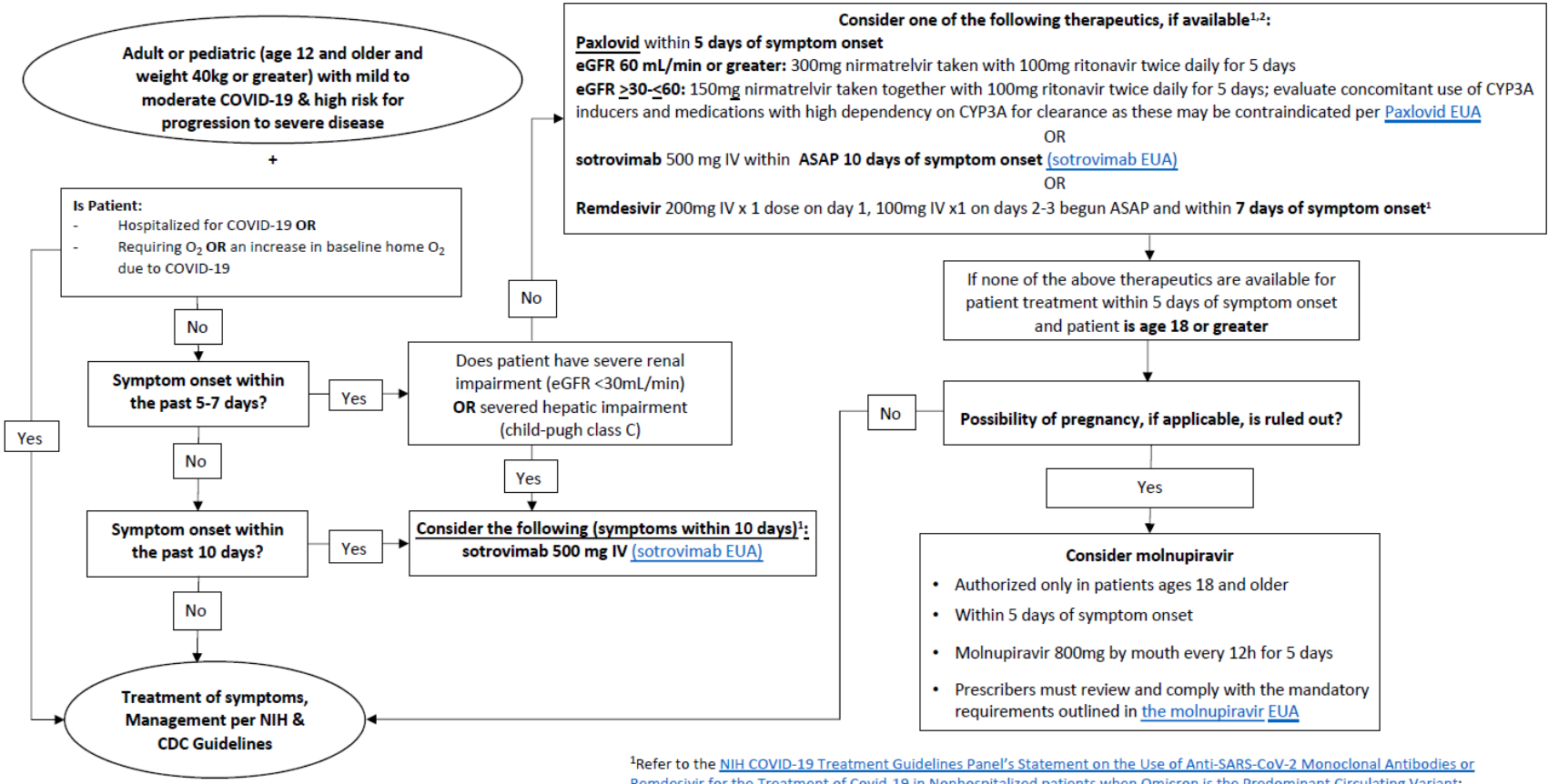
EVUSHELD

69% relative risk reduction

- Dosing/Criteria:
  - Tixagevimab 150mg and cilgavimab 150mg administered as two separate consecutive **intramuscular** injections
  - Pre-exposure prophylaxis against SARS-CoV-2 for those **not expected to mount a sufficient immune response** to and/or unable to received a COVID-19 vaccine ≥12 years and ≥40 kg
- Ordering: Will be available end of week in EPIC with order comments validating EUA criteria the patient meets
  - Internal ethical framework criteria in development: utilization of category 1 and ADI criteria to identify AAH patients
  - Due to limited initial resources and demand>> supply, the drug will be allocated to patients via lottery.
  - List of outpatient clinics in by PSA to be selected/communicated this week to begin ASAP.
- Other considerations:
  - **Note: Category 1 patients comprised <5% of clinical trial leading to EUA*

Category 1 Proposed (highest risk):

- Lung transplant recipient (any time frame) or Small bowel transplant recipient (any time frame).
- Receipt of the following immunosuppressive medication within the past 12 months (including for solid organ transplant).
  Anti-thymocyte globulin (ATG), Alemtuzumab, Anti-B-cell therapy (e.g., rituximab)
- B-cell malignancies, on active treatment Multiple myeloma, on active treatment with two or more agents.
- Allogeneic stem cell transplant, within 12 months of transplant.
- Autologous stem cell transplant, within six months of transplant.
- Receipt of anti-CD19 or anti-BCMA (CAR)-T-cell immunotherapy, within six months of treatment.
- Primary or secondary T-cell immunodeficiency, including severe combined immunodeficiency.
- Recipient of more than one active transplant, different organs (any time frame).
- Acute myeloid leukemia under active treatment.
- Additional pediatric conditions to be considered as Category 1 (age 12-17):
  - Combined immune deficiencies with or without immune dysregulation (e.g., APDS, STAT3 GOF, ALPS).
  - Primary immune regulatory disorders with or without immune deficiency (e.g., APECED, XIAP).
  - High-risk or relapsed acute lymphoblastic leukemia/lymphoblastic lymphoma on intensive therapy (not maintenance therapy).



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

December 30, 2021

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2] COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)

CME Credit Claiming

Claim your attendance instantly by texting **DOMQOB** to **414-219-1219**.

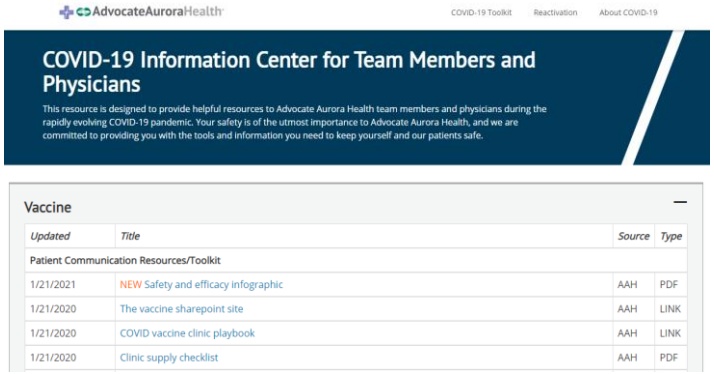
- You will receive a confirmation text once it goes through.
- **CME Credit will be available until December 31, 2022**
- Credits will be stored in your account on https://cme.advocateaurorahealth.org
- If you have any questions regarding CME credit, please contact the CME Office at cme@aah.org.

*Remember your mobile number will need to be updated on the CME Learning Platform in order to claim credit via texting.

Staying informed

COVID-19 Info Center: advocatehealth.com/covid-19-info

- **Single resource for COVID-19 and vaccine information**
- ***Plus! Timely updates in This Week, Medical Group Update, APP Key Messages, Medical Staff News and The Leader***



Wrap-up and Discussion

COVID-19 Information Center for Team Members and Physicians

This resource is designed to provide helpful resources to Advocate Aurora Health team members and physicians during the rapidly evolving COVID-19 pandemic. Your safety is of the utmost importance to Advocate Aurora Health and we are committed to providing you with the tools and information you need to keep yourself and our patients safe.

https://www.advocatehealth.com/covid-19-info/

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