CDC/IDSA COVID-19 Clinician Call

February 13, 2021

Welcome & Introductions

Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs & Guidelines
IDSA

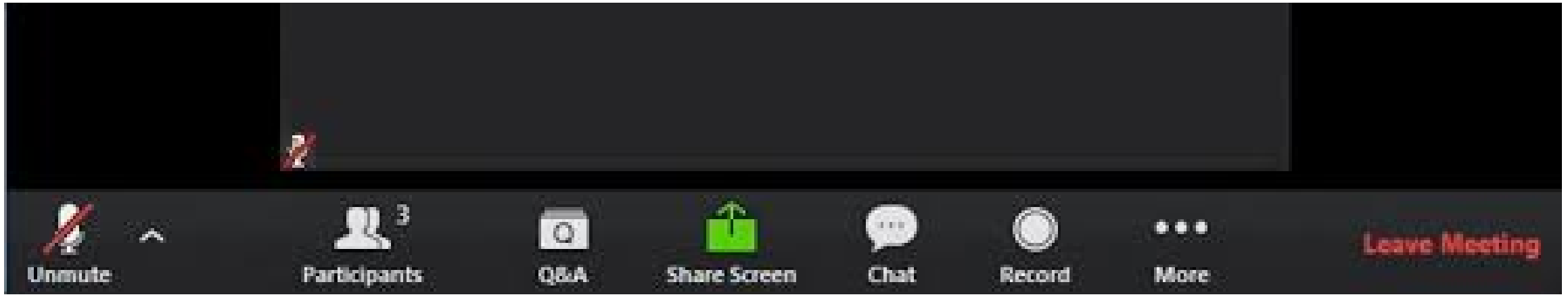
- 54th in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

TODAY'S TOPICS

- Assessment of Outpatient Dispensing of Products Proposed for Treatment or Prevention of COVID-19 by U.S. Retail Pharmacies During the Pandemic
- New Monoclonal Antibody EUA of Bamlanivimab and Etesevimab Administered Together
- COVID-19 Vaccine Q&A

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Assessment of Outpatient Dispensing of Products Proposed for Treatment or Prevention of COVID-19 by U.S. Retail Pharmacies During the Pandemic

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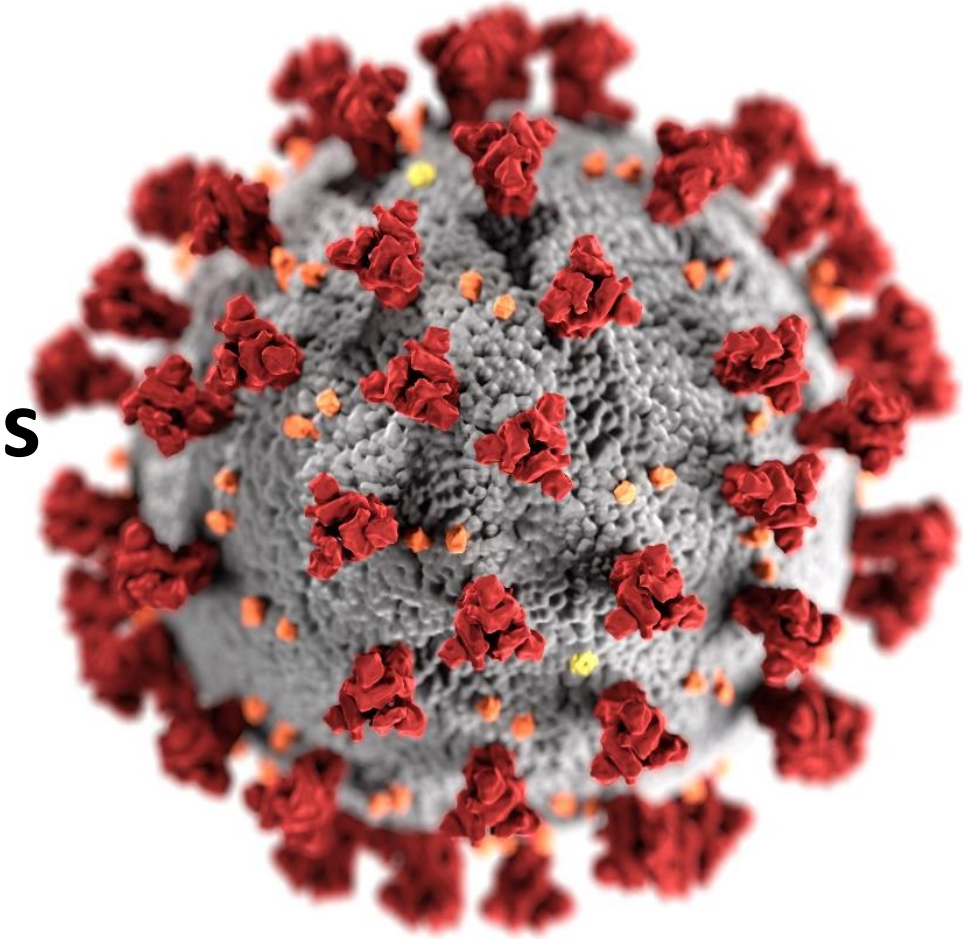
Lead, Adverse Event Monitoring Unit
CDC COVID-19 Health Systems and Worker Safety Task Force

CAPT Daniel Budnitz, MD, MPH
Director, Medication Safety Program
Division of Healthcare Quality Promotion, CDC

Assessment of Outpatient Dispensing of Products Proposed for Treatment or Prevention of COVID-19 by U.S. Retail Pharmacies During the Pandemic



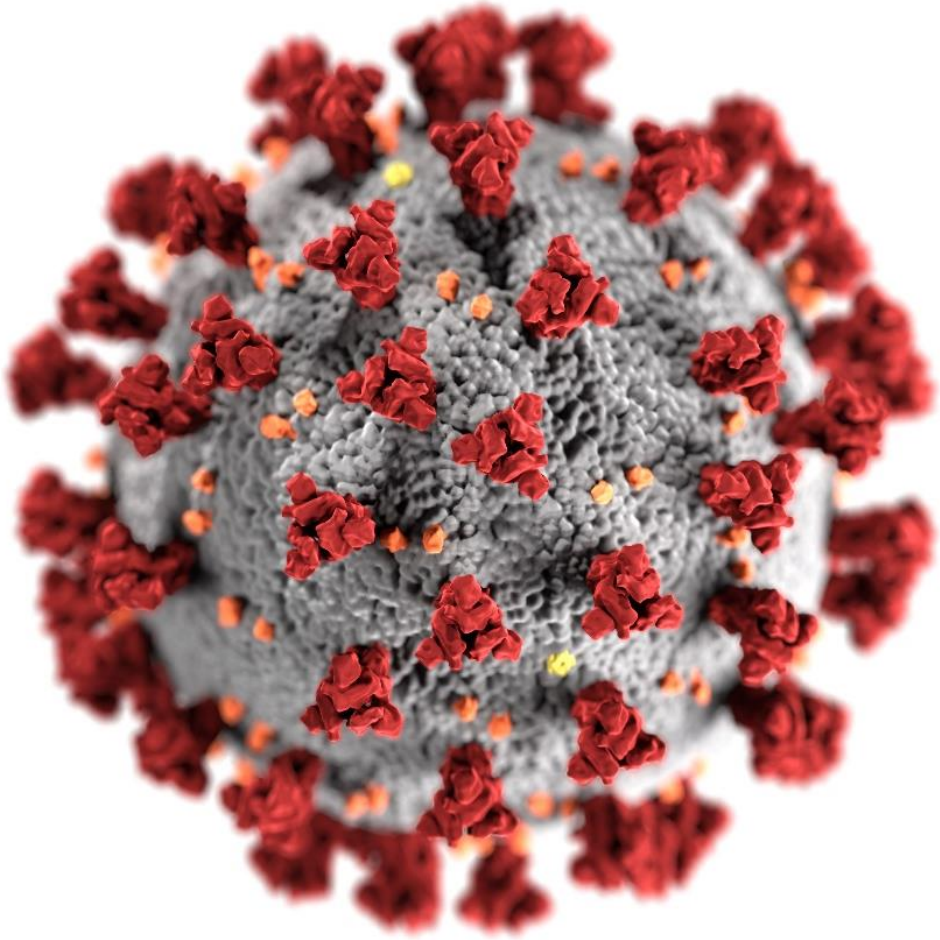
Jennifer N. Lind, PharmD, MPH

February 13, 2021

cdc.gov/coronavirus

Disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC).



cdc.gov/coronavirus

Outpatient Treatment and Prevention of COVID-19

- Prior to November 2020, no FDA-authorized products for outpatient COVID-19 treatment or prevention

- **Objective:** Determine if outpatient retail dispensing frequency or proposed treatments for COVID-19 increased since the declaration of a national emergency due to COVID-19

Geller A, Lovegrove M, Lind J, Datta S, Budnitz D. Assessment of Outpatient Dispensing of Products Proposed for Treatment or Prevention of COVID-19 by US Retail Pharmacies During the Pandemic. JAMA Intern Med. 2021 Feb 11;doi:10.1001/jamainternmed.2021.0299.

Assessment of Outpatient Dispensing of Products Proposed for COVID-19

- **Methods**
  - Potential treatments selected (n=17)
    - NIH *COVID-19 Treatment Guidelines*
    - ASHP *Assessment of Evidence for COVID-19-Related Treatments*
  - IQVIA National Prescription Audit Weekly dispensing estimates
    - Sample of 48,900 retail pharmacies; represents ~92% of all retail prescription activity
    - Compared period March 14-December 18, 2020 to pre-pandemic baseline dispensing
  - Piecewise (segmented) regression for treatments with dispensed prescriptions ≥50% above baseline

- **Limitations**
  - Lack of prescribing indication
  - Purchases of over-the-counter products (e.g., famotidine, vitamin C, zinc) not captured

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Table. Estimated Increases in Dispensed Retail Prescriptions for Selected Products Proposed to Treat or Prevent COVID-19—United States, March-December 2020 vs 2019[a]

Treatment[b]	Baseline No. of prescriptions dispensed per week[c]	Peak week, 2020 (end date)[d]	Peak No. of prescriptions dispensed per week, 2020[d]	No. of prescriptions dispensed above baseline in peak week, 2020	Increase in prescriptions dispensed above baseline in peak week, 2020, %	Weeks >50% above baseline, 2020, No.
Ivermectin	3589	Dec 18, 2020	24 528	20 939	583.4	12
Chloroquine	499	Mar 20, 2020	2966	2467	494.4	2
Zinc[e]	1810	Dec 11, 2020	9110	7300	403.3	32
Hydroxychloroquine	93 640	Mar 20, 2020	267 308	173 668	185.5	4
Vitamin C[f]	9331	Dec 11, 2020	21 020	11 689	125.3	30
Dexamethasone	57 178	Dec 18, 2020	123 829	66 651	116.6	6
Lopinavir/ritonavir	492	Mar 20, 2020	954	462	93.8	1
Famotidine[g]	253 684	Dec 18, 2020	365 699	112 015	44.2	0
Tocilizumab	293	Dec 4, 2020	400	107	36.4	0
Sarilumab	123	Aug 14, 2020	154	31	25.2	0
Janus kinase inhibitors	2171	Dec 4, 2020	2960	789	36.4	0
Tyrosine kinase inhibitors	1770	Mar 20, 2020	1966	196	11.1	0
Azithromycin[h]	860 605	Mar 20, 2020	953 074	92 469	10.7	0
Colchicine	54 564	Mar 20, 2020	60 294	5730	10.5	0
Vitamin D[i]	568 481	Mar 20, 2020	624 726	56 245	9.9	0
Interferons	703	Mar 20, 2020	742	39	5.5	0
Nitazoxanide	577	Mar 20, 2020	593	16	2.8	0

**See article for complete footnotes:*

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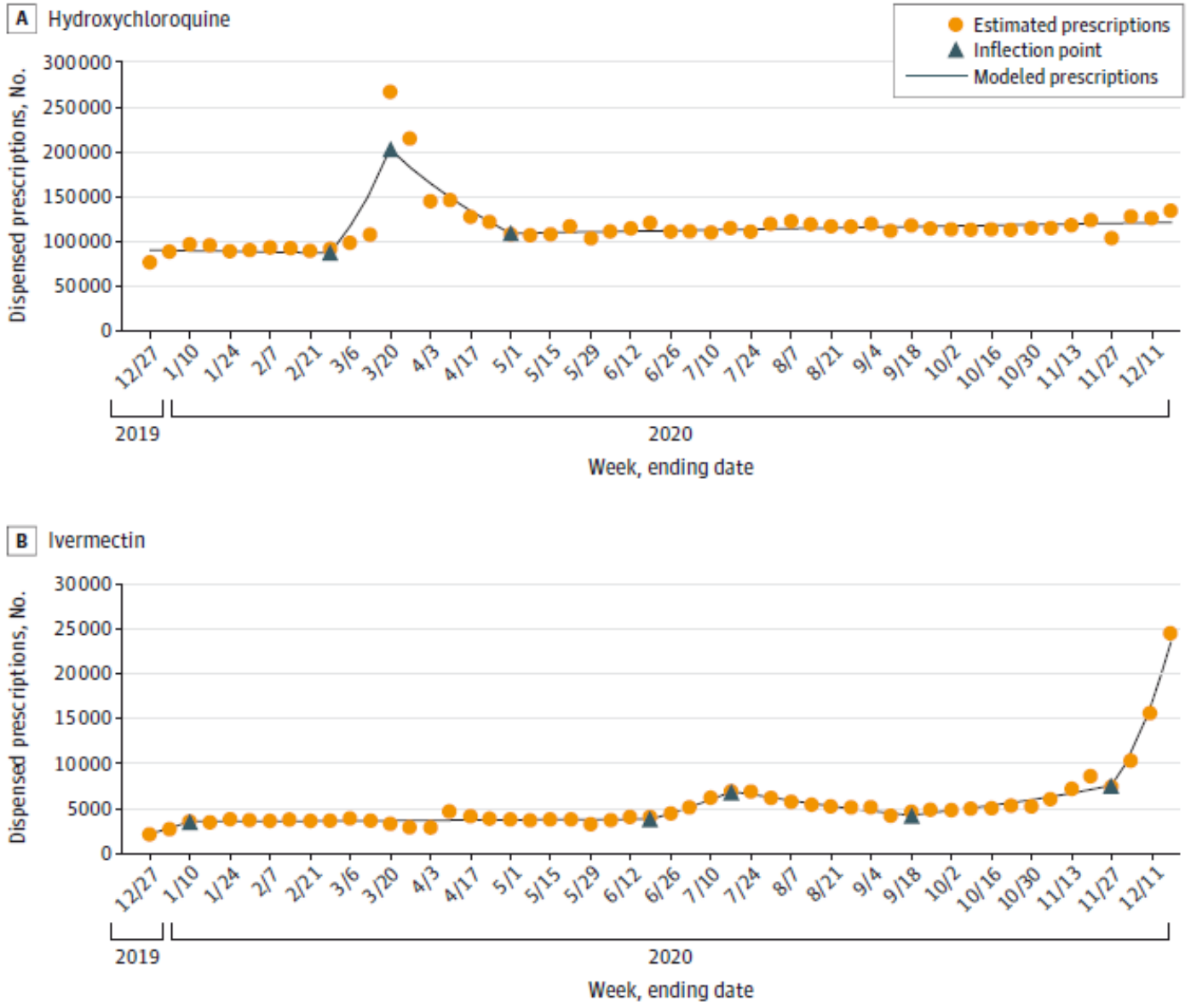
Outpatient Retail Dispensing Trends for Selected Products



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Key Takeaways

- Increased dispensing of ivermectin, zinc, and dexamethasone coincided with national increase in COVID-19 cases
  - NIH COVID-19 Treatment Guidelines Panel has not recommended outpatient use of these products for treatment or prevention of COVID-19
- Clinicians should consider the most recent recommendations from NIH and FDA before prescribing unproven therapies for COVID-19 to outpatients outside of clinical trials
- National monitoring of outpatient dispensing of proposed products for treatment of COVID-19 should continue

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DEPARTMENT OF HEALTH & HUMAN SERVICES USA
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

New Monoclonal Antibody EUA

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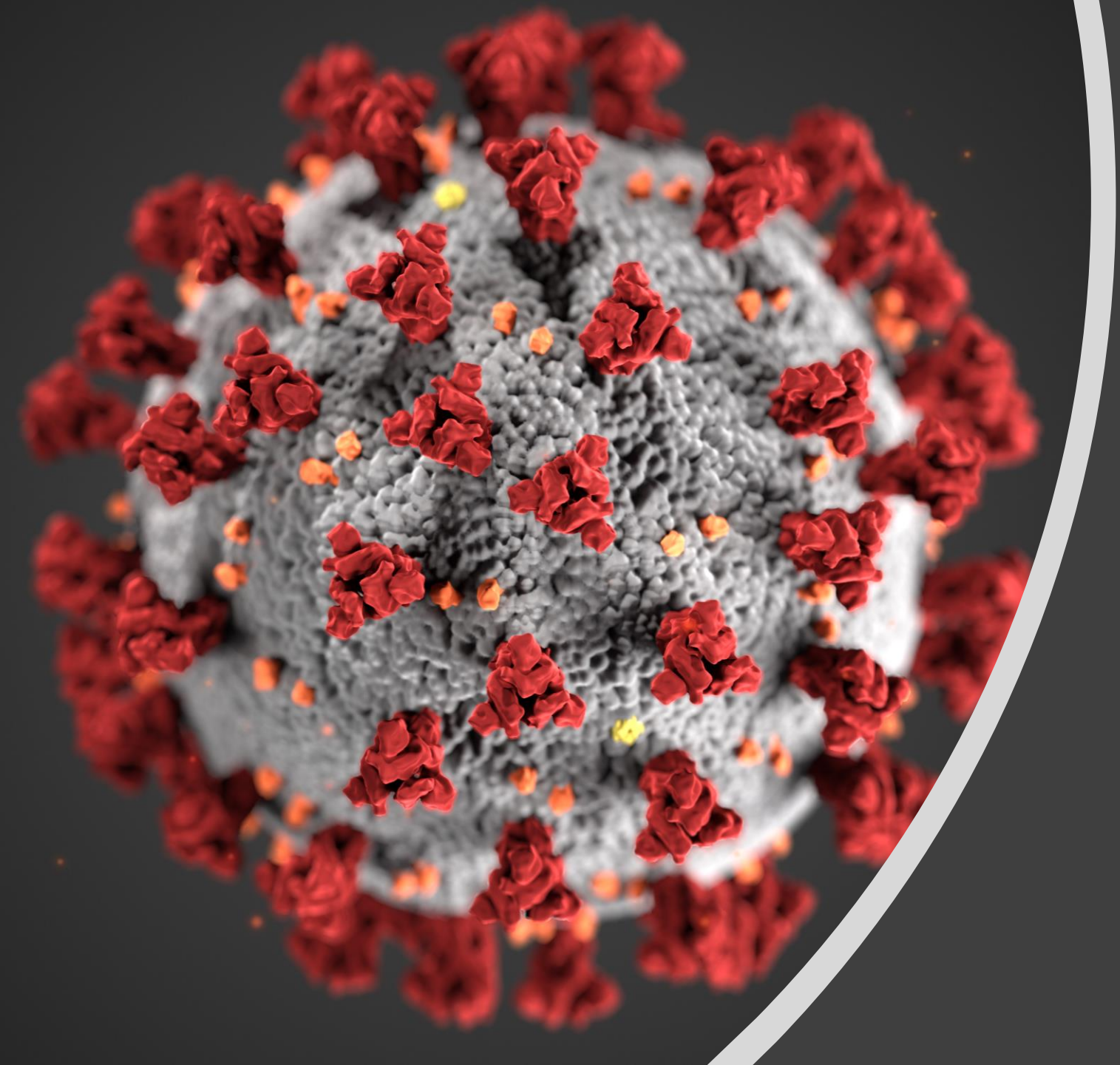


FDA U.S. FOOD & DRUG ADMINISTRATION

Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab Administered Together

CDC/IDSA COVID-19 Clinician Call

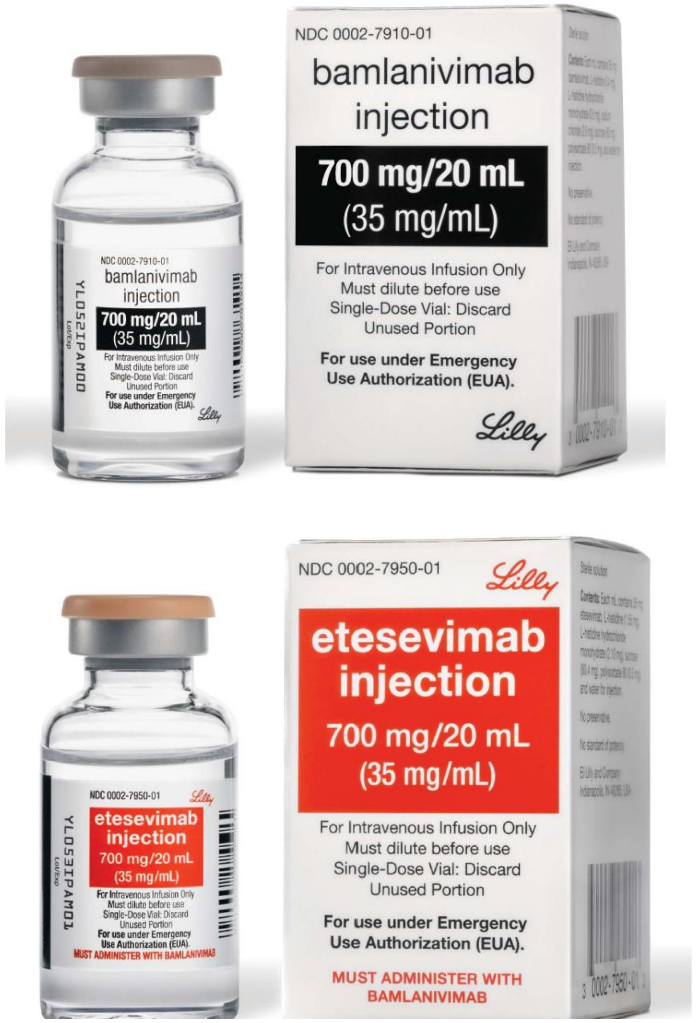
February 13, 2021

Wendy Carter, DO

Clinical Team Leader, Division of Antiviral Products, CDER, FDA

Introduction

- **Product:** Bamlanivimab and etesevimab administered together
- **Neutralizing monoclonal antibodies**: Bamlanivimab and etesevimab are designed to block SARS-CoV-2 viral attachment and entry into human cells, thus neutralizing the virus
- **Authorized use:** treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg), with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization
- **Dose:** bamlanivimab 700 mg and etesevimab 1400 mg administered together in a single IV infusion
  - **Etesevimab MUST be administered with bamlanivimab**



Abbreviations: BAM= bamlanivimab, ETE= etesevimab

Limitations of Authorized Use

- Bamlanivimab and etesevimab are not authorized for use in patients:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy due to COVID-19, OR
  - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

- Treatment with bamlanivimab and etesevimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

Definition of High Risk for COVID-19 Disease Progression

- High risk is defined as patients who meet at least one of the following criteria:
  - Have a body mass index (BMI) ≥35
  - Have chronic kidney disease
  - Have diabetes
  - Have immunosuppressive disease
  - Are currently receiving immunosuppressive treatment
  - Are ≥65 years of age
  - Are ≥55 years of age AND have
    - o cardiovascular disease, OR
    - o hypertension, OR
    - o chronic obstructive pulmonary disease/other chronic respiratory disease
  - Are 12 – 17 years of age AND have
    - o BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
    - o sickle cell disease, OR
    - o congenital or acquired heart disease, OR
    - o neurodevelopmental disorders OR
    - o a medical-related technological dependence OR
    - o asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Preparation and Administration

Table 1: Recommended Dilution and Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion[a] in Patients Weighing 50 kg or More

Drug[a]: Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as instructed below		
Size of Prefilled 0.9% Sodium Chloride Infusion Bag	**Maximum Infusion Rate**	**Minimum Infusion Time**
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes
250 mL	310 mL/hr	60 minutes

[a] 700 mg of bamlanivimab and 1,400 mg of etesevimab are added to the same infusion bag and administered together as a single intravenous infusion.

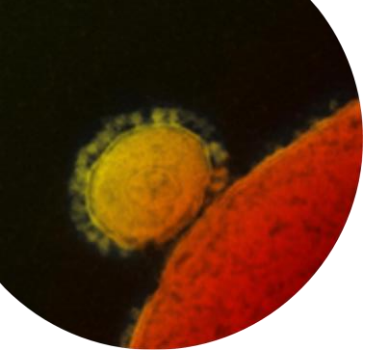
- Preparation allows for use of various volumes of prefilled 0.9% sodium chloride infusion bags, and tables are separated by weight (≥50 kg and < 50kg)
- 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL are added directly to a prefilled infusion bag and administer per Table 1 or Table 2 in the Fact Sheet
- Maximum infusion rate is the same for all except for if a patient is <50kg and the drugs are diluted in 250mL, then the rate must be slowed to keep under a safe endotoxin limit for infusion.

Table 2: Recommended Dilution and Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion[a] in Patients Weighing Less Than 50 kg

Drug[a]: Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as instructed below		
Size of Prefilled 0.9% Sodium Chloride Infusion Bag	**Maximum Infusion Rate**	**Minimum Infusion Time**
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes
250 mL[b]	266 mL/hr	70 minutes

[a] 700 mg of bamlanivimab and 1,400 mg of etesevimab are added to the same infusion bag and administered together as a single intravenous infusion.

[b] The minimum infusion time for patients weighing less than 50 kg who are administered bamlanivimab and etesevimab together using the 250 mL prefilled 0.9% Sodium Chloride infusion bag must be extended to at least 70 minutes to ensure safe use (endotoxin load).



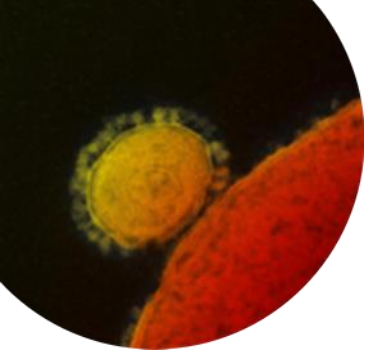
Data to Support Authorization- BLAZE-1

- Trial BLAZE-1 – ongoing, randomized, double-blind, placebo controlled P2/3 trial

- Phase 2 - Subjects with mild to moderate COVID-19 with and without high risk of disease progression :
  - Treatment arm 1: Placebo (N = 156)
  - Treatment arm 2: BAM 700 mg (N = 101)
  - Treatment arm 3: BAM 2800 mg (N = 107)
  - Treatment arm 4: BAM 7000 mg (N = 101)
  - Treatment arm 6: BAM 2800 mg + ETE 2800 mg (N = 112)

- Phase 3 - Subjects with mild to moderate COVID-19 with high risk of disease progression:
  - Treatment arm 7: BAM 2800 mg + ETE 2800 mg (N = 518)
  - Treatment arm 8: Placebo (N = 517)

Abbreviations: BAM= bamlanivimab, ETE= etesevimab



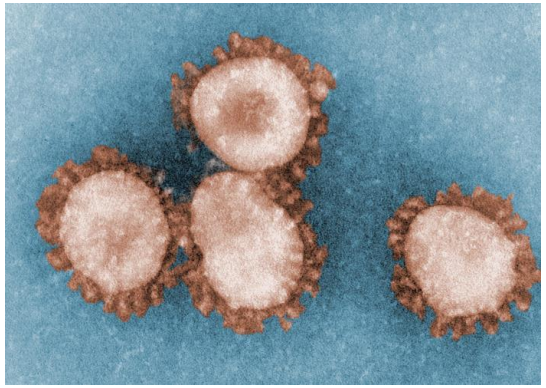
Data to Support Authorization – BLAZE-4

- Trial BLAZE-4 - ongoing P2 trial enrolling subjects with mild to moderate COVID-19 (excludes subject ≥65 years old and BMI ≥35)
  - Treatment arm 1: Placebo (N = 153)
  - Treatment arm 3: BAM 700 mg + ETE 1400 mg (N = 158)
  - Treatment arm 4: BAM 2800 mg + ETE 2800 mg (N = 101)

Abbreviations: BAM= bamlanivimab, ETE= etesevimab; Results not complete for additional arms of this trial

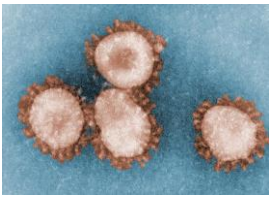
Phase 3 Data from BLAZE-1
Baseline Demographics and Disease Characteristics

- Median age 56 years (31% ≥ 65 years old)
- 52% female
- 87% White, 8% were Black or African American and 29% Hispanic or Latino
- 77% had mild and 23% had moderate COVID-19
- Mean duration of symptoms was 4 days
- Mean viral cycle threshold (CT) was 24 at baseline



Phase 3 Data BLAZE-1 Efficacy Outcomes

- Primary endpoint was the proportion of subjects with COVID-19 related hospitalization (defined as ≥24 hours of acute care) or death by any cause by Day 29.
- 70% reduction in events
  - 36 events on placebo (7%) vs. 11 events on BAM 2,800 mg and ETE 2,800 mg (2%) ($p<0.001$)
  - 10 deaths on placebo vs. 0 deaths BAM 2,800 mg and ETE 2,800 mg ($p<0.001$)
- Proportion of subjects with persistently high viral load at Day 7 (SARS-CoV-2 viral load >5.27)
  - 29% on placebo vs 10% on BAM 2,800 mg and ETE 2,800 mg ($p<0.000001$)



BLAZE-4 Data in Mild to Moderate COVID-19

- Ongoing phase 2, randomized, double-blind, placebo controlled trial in mild to moderate COVID-19 (excluded ≥ 65 years old or BMI ≥ 35)*
  - BAM 700 mg and ETE 1400 mg (N=158)
  - BAM 2,800 mg and ETE 2,800 mg (N=101)
  - Placebo (N=153)
- Primary Endpoint: persistently high viral load at Day 7 (SARS-CoV-2 viral load >5.27)
  - BAM 700 mg and ETE 1400 mg – 14% (21/147, p<0.001 versus placebo)
  - BAM 2,800 mg and ETE 2,800 mg – 10% (10/99, p<0.001 versus placebo)
  - Placebo – 31% (42/135)

*Results not complete for additional arms of this trial

Rationale for Authorized Dosage

- Available data demonstrate that a dosage of 700 mg bamlanivimab and 1,400 mg etesevimab administered together has similar antiviral activity to a dosage of 2,800 mg bamlanivimab and 2,800 mg etesevimab administered together, which is also supported by in vitro data and pharmacokinetics/pharmacodynamics (PK/PD) modeling
- A dosage of 2,800 mg bamlanivimab and 2,800 mg etesevimab administered together reduced COVID-19 related hospitalizations and deaths in addition to significantly reducing viral load relative to placebo
- Bamlanivimab and etesevimab administered together resulted in fewer treatment-emergent variants relative to bamlanivimab administered alone

- Based on analyses of the available nonclinical, clinical, and virologic data, as well as supportive data from pharmacokinetic/pharmacodynamic modeling, the authorized dosage of 700 mg bamlanivimab and 1,400 mg etesevimab is expected to have similar clinical effect to a dosage of 2,800 mg bamlanivimab and 2,800 mg etesevimab

Safety Summary

- Approximately 1500 subjects have been exposed to bamlanivimab and etesevimab at doses of bamlanivimab 700 mg and etesevimab 1400 mg or higher (770 at authorized dose)
  - More than 3,900 subjects have received bamlanivimab (either alone or with etesevimab) at doses ranging from 700 to 7,000 mg

- Phase 2:
  - Nausea was the most common adverse event (4% of BAM and ETE and 4% of placebo);
  - Pruritus and pyrexia were more frequently report with BAM and ETE (2% and 1%) than placebo (1% and 0%, respectively)
  - Hypersensitivity events were mild or moderate in severity

- Phase 3:
  - Adverse Events were reported in 13% of BAM and ETE and 12% of placebo subjects
  - Most common AEs were nausea, dizziness, and rash (1% BAM and ETE and 1% placebo)
  - Hypersensitivity events were mild to moderate in severity

Warnings and Precautions

- Across ongoing, blinded clinical trials, a case of anaphylaxis and other cases of serious infusion-related reactions were reported with bamlanivimab, with and without etesevimab
  - All infusions were stopped, required treatment and all events resolved.

- Serious hypersensitivity reactions, including anaphylaxis
  - Immediately discontinue infusion and provide appropriate medications and/or supportive care
  - Monitor clinically for 1 hour post infusion

- Clinical worsening after bamlanivimab administration- (part of ongoing safety monitoring of bamlanivimab alone under EUA)
  - Signs and symptoms of fever, hypoxia/respiratory difficulty, arrythmia, fatigue, and altered mental status
  - Some events required hospitalization
  - Not known if events related to bamlanivimab use or due to progression of COVID-19

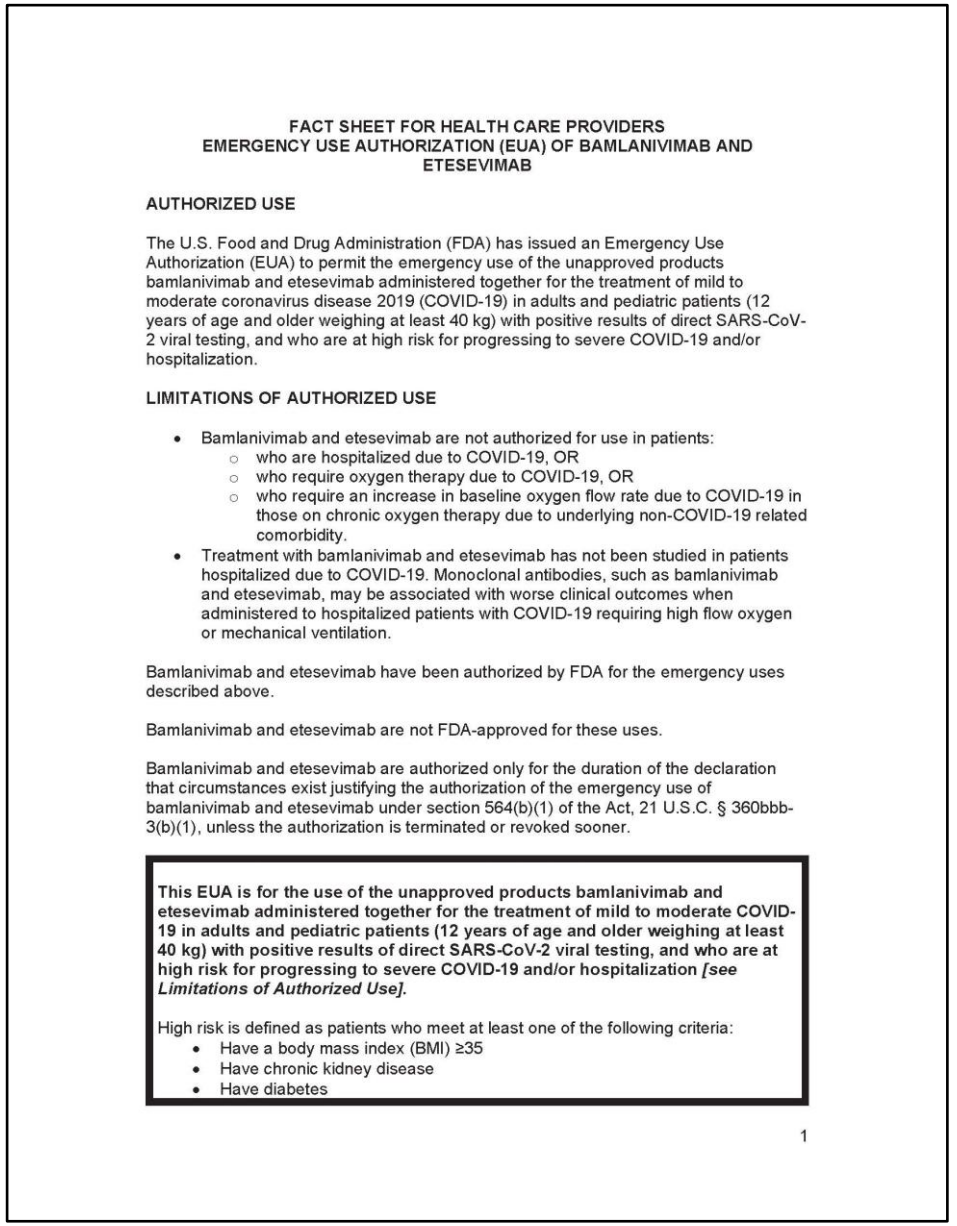
Resistant Variants

- Treatment emergent resistant variants were less frequently detected in patients who received BAM and ETE together compared to BAM alone vs placebo in phase 2 of BLAZE-1
- Preliminary data related to known variants from pseudovirus assays
  - BAM alone and BAM and ETE retained neutralizing activity against pseudovirus expressing del69-70 + N501Y found in the B.1.1.7 variant (UK origin)
  - Pseudovirus harboring spike substitutions K417N + E484K + N501Y together had reduced susceptibility to BAM alone and BAM and ETE together, suggesting reduced activity to variants with these substitutions, such as B.1.351 (South African origin)
  - Studies to be performed to assess susceptibility of pseudoviruses that harbor substitutions from P.1 (Brazilian origin)

Health Care Provider Fact Sheet

- February 9, 2021 EUA HCP Fact Sheet Available at:

https://www.fda.gov/media/145802/download



FACT SHEET FOR HEALTH CARE PROVIDERS
EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETESEVIMAB

AUTHORIZED USE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products bamlanivimab and etesevimab administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

LIMITATIONS OF AUTHORIZED USE

- Bamlanivimab and etesevimab are not authorized for use in patients:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy due to COVID-19, OR
  - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Treatment with bamlanivimab and etesevimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Bamlanivimab and etesevimab have been authorized by FDA for the emergency uses described above.

Bamlanivimab and etesevimab are not FDA-approved for these uses.

Bamlanivimab and etesevimab are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bamlanivimab and etesevimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

This EUA is for the use of the unapproved products bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization *[see Limitations of Authorized Use]*.

High risk is defined as patients who meet at least one of the following criteria:
- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes

1

Other Resources

- FDA Emergency Use Authorization page: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
  - Provides most recent FDA links to fact sheets (Health Care Providers and Patients, Parents and Caregivers), as well as any other documents such as Dear Healthcare Provider Letter, and Frequently Asked Questions for the EUA
- Eli Lilly and Company's website:
  - www.BAMandETE.com


FDA
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Vaccine Q&A

Sara Oliver, MD, MSPH
ACIP Work Group Co-Lead
CDC

Now Available: COVID-19 Vaccine FAQs

Go to www.COVID19LearningNetwork.org and click on “Vaccines FAQ”

Continue the conversation on Twitter

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We want to hear from you! Please complete the post-call survey.

Next Call: **Saturday, Feb. 20th**

A recording of this call will be posted at **www.idsociety.org/cliniciancalls**

-- library of all past calls now available --

Contact Us:

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