Special Assessment of Outpatient Treatments for COVID-19

Public Meeting — April 12, 2022

Meeting materials available at: https://icer.org/assessment/covid-19-2022/#timeline

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Clinical and Patient Experts

Adarsh Bhimraj, MD, Chair, Infectious Diseases Society of America COVID-19 Treatment and Management Guidelines

- *No conflicts of interest to disclose.*

Linda Goler Blount, MPH, President and Chief Executive Officer, Black Women's Health Imperative

- *Black Women's Health Imperative receives funding from Hologic Inc., and Gilead Sciences.*

Edward Mills, PhD, Professor of Health Sciences, McMaster University

- *Edward Mills has stock ownership and employee status at Cytel. He received funding from Eiger Biosciences for the TOGETHER trial.*

Why Are We Here Today?

I was very scared. I have diabetes, COPD, and asthma. But I didn't want to go to the hospital – I'd seen bills as high as a down payment on a house. I tried to do research at home but it [COVID-19] isn't like a cold or the flu, where I could drive to CVS and get cough syrup. I felt helpless and really like my only choice was to go to the emergency room, and I eventually did. They gave me an infusion and that helped, but I was nervous the whole time because I'm allergic to a lot of medicines. What if it didn't work and I got worse?

COVID-19 Patient

Why Are We Here Today?

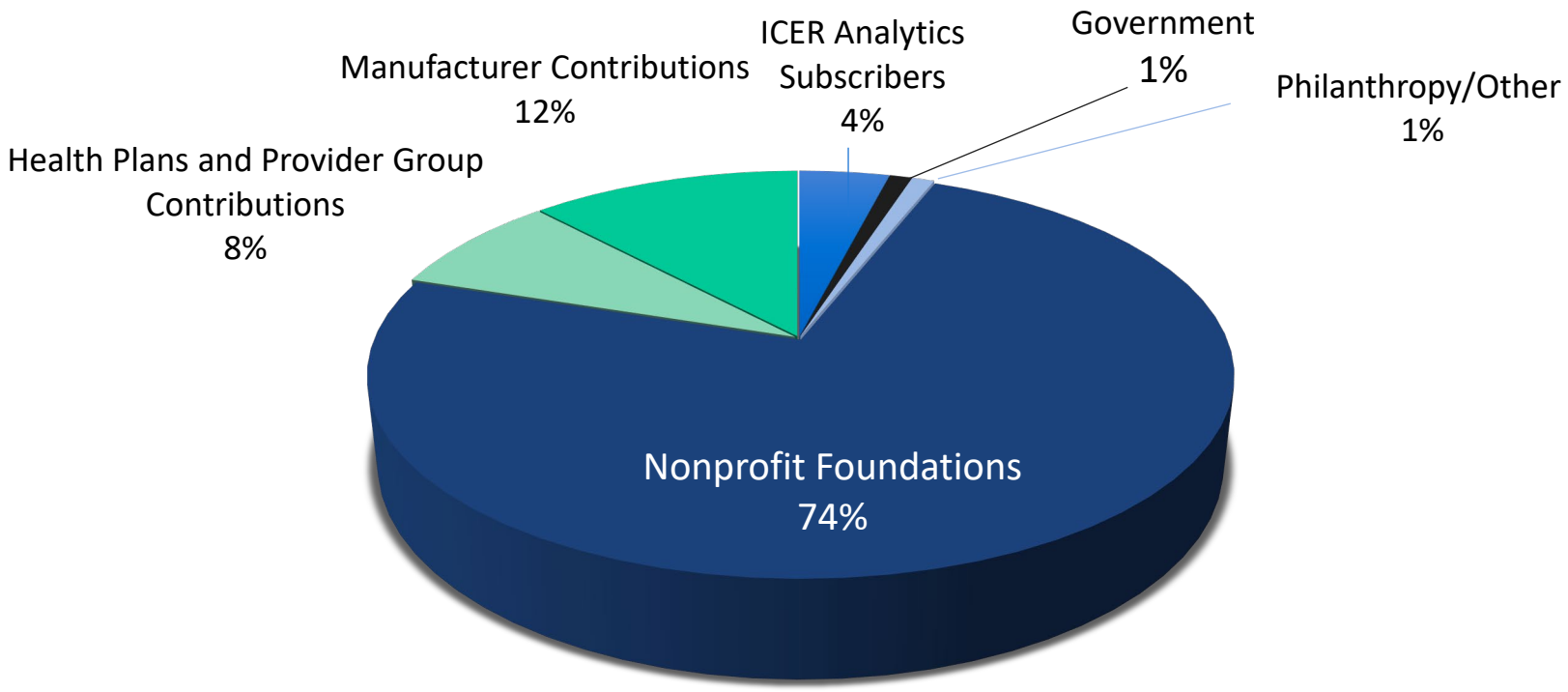
- What happens the day these treatments receive FDA approval?
- Questions about:
  - Evidence – what are the risks and benefits?
  - How do new treatments fit into the evolving landscape?
  - What are reasonable prices and costs to patients, the health system, and the government?
  - What lessons are being learned to guide our actions in the future?

Organizational Overview

- Midwest Comparative Effectiveness Public Advisory Council (CEPAC)
- The Institute for Clinical and Economic Review (ICER)

Sources of Funding, 2022

https://icer.org/who-we-are/independent-funding/



*Individual / matching contributions and speech stipends

How Was the ICER Report Developed?

- Scoping with guidance from patients, clinical experts, manufacturers, and other stakeholders
- Internal ICER staff evidence analysis and cost-effectiveness modeling
- Public comment and revision
- Expert reviewers
  - **Andrew D. Badley, MD**, Professor of Infectious Diseases; Professor and Chair, Department of Molecular Medicine; Chair, SARS-CoV-2 COVID-19 Task Force, Mayo Clinic
  - **Rajesh Gandhi, MD**, Professor of Medicine, Harvard Medical School; Director, HIV Clinical Services and Education, Massachusetts General Hospital; Co-Director and Principal Investigator, Harvard University Center for AIDS Research
  - **Shivanjali Shankaran, MD**, Assistant Professor; Director, General Inpatient Infectious Diseases; Associate Director, Adult Antimicrobial Stewardship Program Division of Infectious Diseases, Rush University Medical Center
- How is the evidence report structured to support CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Agenda

Time (CT)	Activity
10:00 am – 10:20 am	Meeting Convened and Opening Remarks
10:20 am – 11:00 am	Presentation of the Clinical Evidence
11:00 am – 11:40 am	Presentation of the Economic Model
11:40 am – 12:00 pm	Public Comments and Discussion
12:00 pm – 12:45 pm	Lunch Break
12:45 pm – 1:45 pm	Midwest CEPAC Vote on Clinical Effectiveness and Value
1:45 pm – 2:00 pm	Break
2:00 pm – 3:30 pm	Policy Roundtable
3:30 pm – 4:00 pm	Reflections from Midwest CEPAC
4:00 pm	Meeting Adjourned

Presentation of the Clinical Evidence

Kai Yeung, PharmD, PhD

Assistant Scientific Investigator

Kaiser Permanente Washington Health Research Institute

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Key Collaborators

- **Molly Beinfeld, MPH**, Senior Research Lead, Evidence Synthesis, ICER
- **Rasheed Mohammed, PharmD, MPH**, Health Technology Assessment Fellow, ICER
- **Abigail Wright, PhD, MSc**, Senior Research Lead, Evidence Synthesis, ICER
- **Emily Nhan**, Research Assistant, ICER

Disclosures:

We have no conflicts of interest relevant to this report.

Background

- >80 million COVID-19 cases and 966,000 COVID-19 deaths in US[1]
- Rapidly shifting public health landscape
  - Variants of concern
  - Population vaccination rates
- Most COVID-19 cases are mild to moderate
- Risk factors for severe disease: older age, obesity, cardiovascular disease, and chronic lung diseases

1. Center for Systems Science and Engineering at Johns Hopkins University, 2021

Scope of Review

- **Population:** Non-hospitalized patients with mild-to-moderate COVID-19 at high risk for progression to severe disease
- **Interventions**
  - Oral: Molnupiravir, Paxlovid, fluvoxamine
- **Other Treatments**
  - EUA revised: not currently authorized in any U.S. region
    - REGEN-COV (IV): EUA revised January 2022
    - Sotrovimab (IV): EUA revised April 2022
    - Bamlanivimab and etesevimab (IV): EUA revised January 2022
  - Recent EUA
    - Remdesivir (IV) granted EUA, January 2022
    - Bebtelovimab (IV) granted EUA, February 2022
    - Peginterferon lambda (IV) manufacturer currently pursuing EUA

Interventions of Interest

Intervention	Mechanism of Action	Dosage and Administration	FDA EUA Status
Molnupiravir	Promotes RNA replication error	4 pills twice daily for 5 days	• Issued 12/21: ≥18 age, not recommended during pregnancy • Revised 2/22: Limit usage to individuals without alternative FDA-authorized COVID-19 treatment options
Paxlovid	Protease inhibitor	2 pills nirmatrelvir and 1 pill ritonavir twice daily for 5 days	• Issued 12/21
Fluvoxamine	Unknown, potentially σ-1 receptor agonist	1 pill twice daily for 10 days	• Approved for obsessive compulsive disorder • EUA for COVID-19 being pursued by university-based researchers as of 12/21

Outcomes of Interest

- Primary outcome: Relative risk reduction in hospitalization or all-cause death within 28 or 29 days as compared to placebo
- Secondary outcomes
  - Mortality
  - Serious adverse events
  - Discontinuation of treatment

Insights from Discussions with Patients

- Caregivers were heavily involved with supporting activities of daily living
- Concerned about substantial financial burden of COVID-19
- Concerned about limited access to diagnostic testing
- Open to trying new treatments

Clinical Evidence

Overview of RCTs

Key Trials	Dates of Enrollment	US Enrollment	Primary Outcome	Baseline Characteristics
Molnupiravir MOVe-OUT N=1,433	5/21-10/21	6%	COVID-19 hospitalization or death from any cause through day 29	-Obese: 74% -Vaccinated: 0% -Variant: 32% Delta
Paxlovid Epic-HR N=2,246	7/21-11/21	41%	COVID-19 hospitalization or death from any cause through day 28	-Obese: 36% -Vaccinated: 0% -Variant: NR
Fluvoxamine TOGETHER N=1,497	1/21-9/21	0%	COVID-19 related admission to an emergency setting >6 hrs or transfer to hospital by day 28	-Obese: 31% -Vaccinated: 6% -Variant: NR

Key Study Results: Primary Outcome

Key Trials	Intervention	Hospitalization or Death from Any Cause	Relative Risk Reduction % (95% CI)
MOVe-OUT	**Molnupiravir**	48/709 **(6.8%)**	Interim RRR: **48% (NR)** Final RRR: **30% (NR)**
	Placebo	68/699 **(9.7%)**	
Epic-HR	**Paxlovid**	8/1,039 **(0.8%)**	RRR: **88% (NR)**
	Placebo	66/1,046 **(6.3%)**	
TOGETHER	**Fluvoxamine**	79/741 **(11%)**	ITT RRR: **32% (12 to 48%)** >80% adherent RRR: **66% (46% to 79%)**
	Placebo	119/756 **(16%)**	

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	Placebo	119/756 **(16%)**	

Key Study Results: Secondary Outcome

Key Trials	Intervention	Mortality
MOVe-OUT	**Molnupiravir**	1/709 **(0.1%)**
	Placebo	9/699 **(1.3%)**
Epic-HR	**Paxlovid**	0/1,039 **(0%)**
	Placebo	12/1,046 **(1.1%)**
TOGETHER	**Fluvoxamine**	17/741 **(2.3%)**
	Placebo	25/756 **(3.3%)**

Key Study Results: Harms

Key Trials	Intervention	Serious Adverse Events, n/N (%)	Discontinuation Due to Adverse Event, n/N (%)
MOVe-OUT	**Molnupiravir**	49/710 **(7%)**	10/710 **(1%)**
	Placebo	67/701 **(10%)**	20/701 **(3%)**
Epic-HR	**Paxlovid**	18/1,109 **(2%)**	23/1,109 **(2%)**
	Placebo	74/1,115 **(7%)**	47/1,115 **(4%)**
TOGETHER	**Fluvoxamine**	59/741 **(8%)**	84/741 **(26%)**
	Placebo	70/756 **(9%)**	64/756 **(18%)**

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TOGETHER	**Fluvoxamine**	59/741 **(8%)**	84/741 **(26%)**
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Uncertainties that Apply to All Interventions

- Only one Phase III trial for each intervention
- Generalizability
  - Rapid evolution of SARS-CoV-2 leading to variants with treatment resistance and different morbidity and mortality impacts
  - Enrollment of generally healthier and lower risk and predominately unvaccinated populations in clinical trials
  - Hospitalization rates from pre-omicron variant and based predominately or exclusively in countries outside of US
- Access: Funding of treatments, test to treat

Intervention-Specific Uncertainties and Concerns

- Molnupiravir
  - Drop in efficacy from interim to final study results
  - Mutagenicity, teratogenicity, and toxicity to growing bone and cartilage
  - Viral mutation
- Paxlovid
  - Many known drug-drug interactions
  - Potential resistance
- Fluvoxamine
  - Primary outcome definition
  - Effects on secondary outcomes
  - Treatment discontinuation

Potential Other Benefits and Contextual Considerations

- Society's goal of reducing health inequities
- Preventing spread of COVID-19
- Providing support for policies to manage the pandemic with fewer restriction on schools and businesses

Summary

- “Special” evidence assessment in the context of data limitations
  - Changing prevalence of SARS-CoV-2 variants
  - Changing national vaccination rate
  - Single pivotal trials in population of interest
  - Trials conducted at different times and in different countries, with different outcome definitions
- The drugs of interest reduce hospitalizations among the population of interest
- Important limitations to use of each drug

ICER Evidence Ratings

Treatment	Comparator	Evidence Rating
Molnupiravir	Usual care	C+
Paxlovid	Usual care	B+
Fluvoxamine	Usual care	C+

B+: Incremental or Better – moderate certainty of a small or substantial net health benefit with high certainty of at least a small net health benefit
C+: Comparable or Incremental – moderate certainty of a comparable or small net health benefit, with high certainty of at least a comparable net health benefit

Questions

COVID-19: Effectiveness and Value

Melanie D. Whittington, PhD, MS

Director of Health Economics

Institute for Clinical and Economic Review

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Key Review Team Members

- **Noemi Fluetsch, MSc, MPH**, ICER
- **Marina Richardson, MSc**, ICER

Disclosures:

We have no conflicts of interest relevant to this report.

Objective

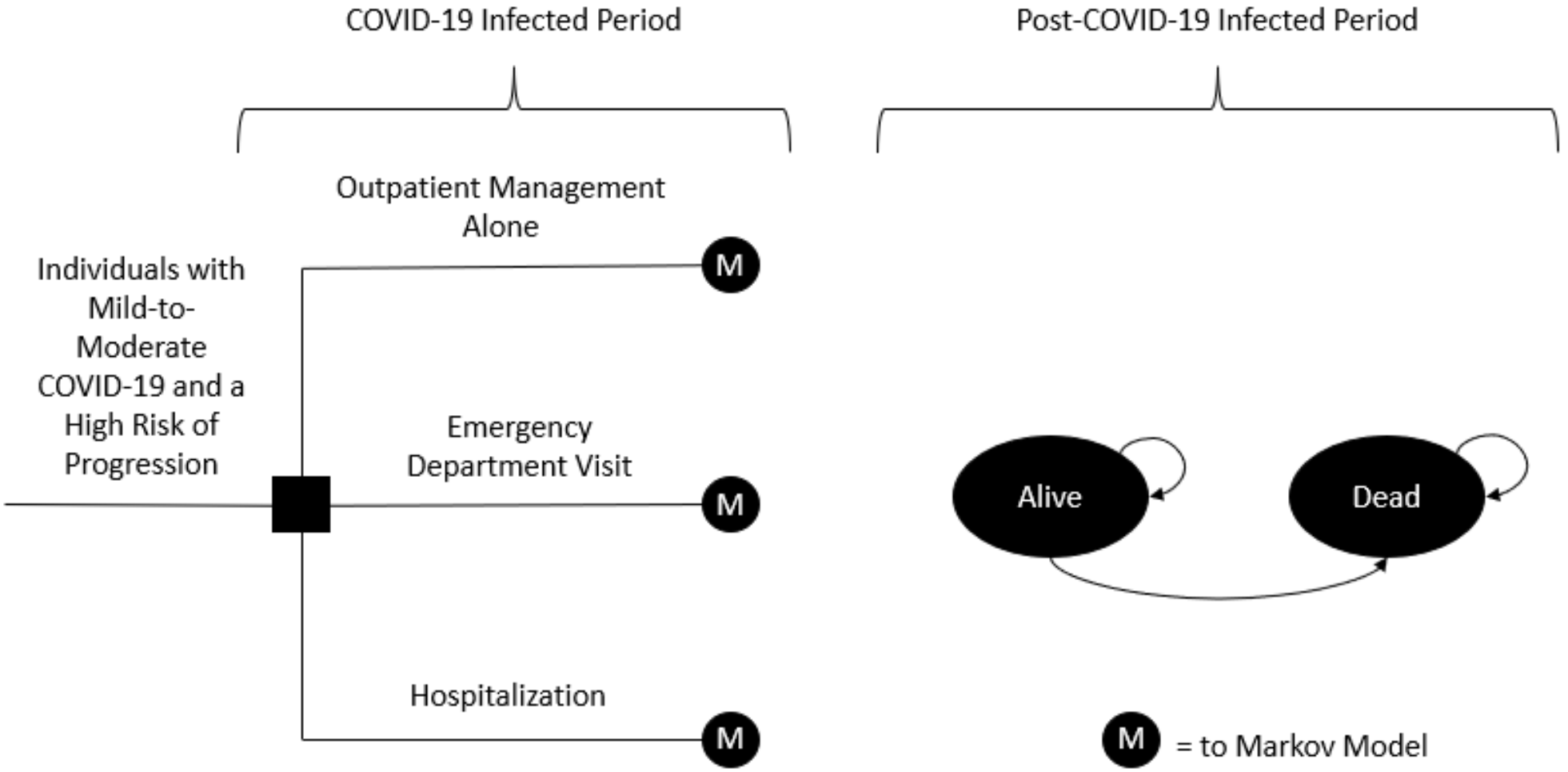
- Estimate the cost effectiveness of molnupiravir, Paxlovid, and fluvoxamine for the treatment of COVID-19

Methods in Brief

Methods Overview

- **Model**: Decision tree followed by a Markov model
- **Setting**: United States
- **Perspective**: Health care sector, modified societal perspective
- **Time Horizon**: Lifetime
- **Discount Rate**: 3% per year (costs and outcomes)
- **Primary Outcomes**: QALYs, evLYs, LYs, hospitalizations

Model Schematic



Key Model Assumptions

1. Baseline characteristics were consistent across all intervention arms and the comparator arm
2. Evidence for the comparator was based on a pooling of the usual care arms from each pivotal trial
3. Relative treatment effects from trials were applied to the outcomes from the pooled usual care evidence
4. Death was downstream of hospitalization
5. Long-term consequences were assigned for those discharged following a hospitalization that required mechanical ventilation

Population

- Individuals with mild-to-moderate COVID-19 and high risk of progression to severe disease or hospitalization
  - Both vaccinated and unvaccinated
  - Adjustments to risk of hospitalization and death observed in evidence for % of cases among vaccinated (currently 29% of all cases)

Usual Care Outcomes

- Highest setting of care
  - 94.9% outpatient management
  - 1.5% ED
  - 3.6% hospitalization
- Respiratory support required (if hospitalized)
  - 26% no oxygen support
  - 35% low-flow oxygen
  - 29% high-flow oxygen/non-invasive ventilation
  - 10% mechanical ventilation

Treatment Effectiveness

Parameter	Relative Risk of a Hospitalization
Molnupiravir	0.70
Paxlovid	0.12
Fluvoxamine	0.68*

*Using the outcome of retention in a COVID-19 emergency setting or transfer to a tertiary hospital, which was suggested by clinical experts as a reasonable proxy for hospitalization in US.

Treatment Costs

Treatment	Treatment Course Acquisition Cost
Molnupiravir	$707
Paxlovid	$529
Fluvoxamine	$12

COVID 19-Related Disutilities

Highest Setting of Care	Disutility
Outpatient Management Alone	-0.19
ED Visit	-0.30
Hospitalization (Without Oxygen or With Low-Flow Oxygen)	-0.30
Hospitalization (With High-Flow Oxygen or Non-Invasive Ventilation)	-0.50
Hospitalization (With Mechanical Ventilation)	-0.60

Results

Base-Case Model Outcomes

Treatment	Total Cost	Inpatient Hospitalizations	QALYs	Life Years	evLYs
Molnupiravir	$298,500	2.49%	15.94	19.47	15.94
Paxlovid	$298,500	0.43%	15.96	19.50	15.97
Fluvoxamine	$297,800	2.42%	15.94	19.48	15.94
Usual Care	$297,700	3.56%	15.92	19.46	15.92

Base-Case Incremental Results

Treatment	Cost per evLY Gained	Cost per QALY Gained	Cost per Life Year Gained	Cost per Inpatient Hospitalization Averted
Molnupiravir	$58,000	$61,000	$51,000	$76,000
Paxlovid	$20,000	$21,000	$18,000	$26,000
Fluvoxamine	$8,100	$8,400	$7,000	$10,000

One Way Sensitivity Analyses

- Key drivers
  - Relative risk of hospitalization
  - Baseline risk of hospitalization
- Molnupiravir: $30,000 to $1,000,000+ per evLY gained
- Paxlovid: $0 to $30,000 per evLY gained
- Fluvoxamine: Cost saving to $20,000 per evLY gained

Scenario Analysis: Modified Societal Perspective

- Patient productivity gains/losses during infected period
- ICU capacity considerations
  - Excess deaths averted associated with reduction in ICU capacity

Scenario Analysis: Modified Societal Perspective

Societal Perspective	Threshold Price at $100,000 per evLY Gained	Threshold Price at $150,000 per evLY Gained
Molnupiravir	$2,300	$3,800
Paxlovid	$6,900	$11,100
Fluvoxamine	$2,500	$4,000
Health Sector Perspective	**Threshold Price at $100,000 per evLY Gained**	**Threshold Price at $150,000 per evLY Gained**
Molnupiravir	$1,300	$2,000
Paxlovid	$3,800	$5,800
Fluvoxamine	$1,400	$2,100

Scenario Analysis: Lower Probability of Hospitalization

Treatment	Cost per evLY Gained	Cost per QALY Gained
Molnupiravir	$71,000	$74,000
Paxlovid	$32,000	$34,000
Fluvoxamine	$20,000	$21,000

Limitations

- The COVID-19 pandemic continues to evolve, as new variants emerge, vaccination uptake slowly increases, and the role of booster vaccinations becomes a major issue
- Our current approach to estimate the hospitalization risk, a key driver of model findings, was based on what was observed in the pooling of the pivotal trials
- The long-term consequences potentially associated with COVID-19 continues to be studied, with no evidence on whether these treatments influence the risk or severity

Comments Received

- Do not compare interventions to each other
- Compare each intervention to its respective clinical trial comparator and forego the use of the pooled analysis for the usual care arm
- Model deaths based on the deaths reported in the trial
- Exclude vaccination parameters from the base-case analysis
- Present the modified societal perspective as a co-base case

Conclusions

- Our analyses suggest that each outpatient intervention produces improved clinical outcomes
- At their current prices, each intervention is estimated to meet standard cost-effectiveness levels in the US health care system, even under a scenario with a lower hospitalization risk that may reflect the current Omicron wave
- The cost-effectiveness findings are primarily driven by a treatment's ability to reduce hospitalization and the baseline probability of hospitalization

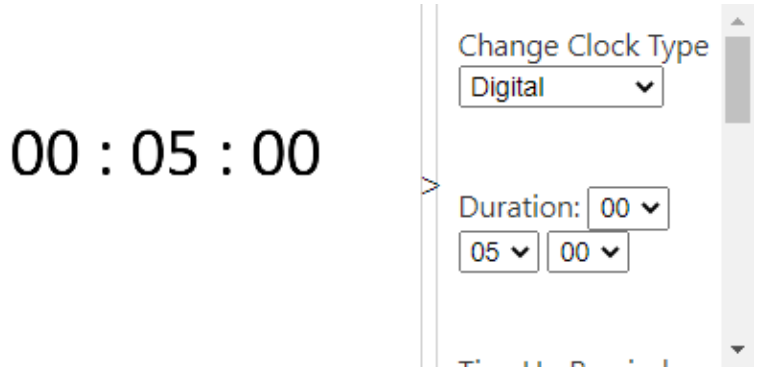
Questions

Public Comment and Discussion

Prasun Subedi, PhD, Value & Access Strategy Team Lead, Patient and Health Impact, Pfizer

Conflict of Interest:

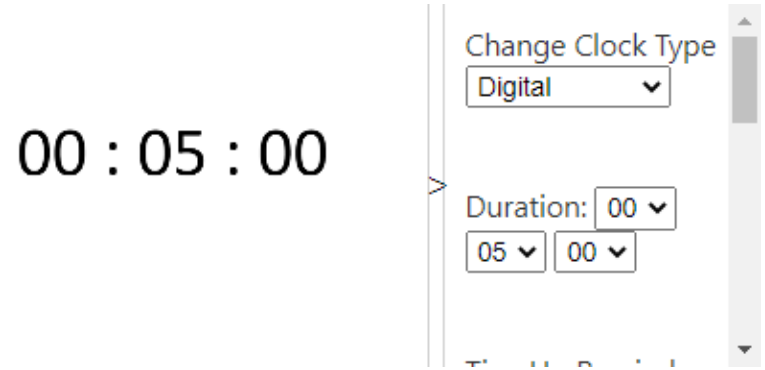
- *Dr. Subedi is a full-time employee at Pfizer.*



Oved Amitay, R.Ph., MSc, President & CEO, Solve ME/CFS Initiative

Conflict of Interest:

- *Oved Amitay owns stock in Alnylam Pharmaceuticals.*



Lunch

Meeting will resume at 12:45 pm CT

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Voting Questions

1. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of molnupiravir is superior to that provided by symptomatic care alone?

A. Yes

B. No

2. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of Paxlovid is superior to that provided by symptomatic care alone?

A. Yes

B. No

3. Given the currently available evidence, is the evidence adequate to demonstrate that the net health benefit of fluvoxamine is superior to that provided by symptomatic care alone?

A. Yes

B. No

Potential Other Benefits and Disadvantages & Contextual Considerations

Please vote on the following contextual considerations:
When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for COVID-19, on the basis of the following contextual considerations:

4. Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability

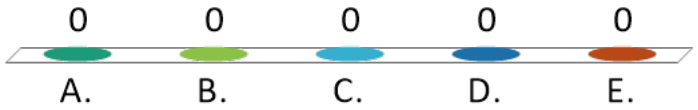
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



Please vote on the following contextual considerations:
When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for COVID-19, on the basis of the following contextual considerations:

5. Magnitude of the lifetime impact on individual patients of the condition being treated

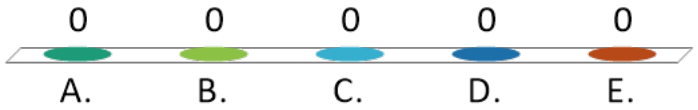
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



Potential Other Benefits and Disadvantages

Effective outpatient treatments for mild-moderate COVID-19 may help reduce population spread of COVID-19.
Effective outpatient treatments for mild-moderate COVID-19 may reduce the number of hospitalized patients enough to increase capacity to treat non-COVID-19-related conditions.
Effective outpatient treatments for mild-moderate COVID-19 will help address the disparate burden of the pandemic in disadvantaged communities.
Effective outpatient treatments for mild-moderate COVID-19 may help provide psychological reassurance allowing for broader opening of schools and workplaces.
Molnupiravir cannot be used in people who are attempting to conceive or who are pregnant.
Paxlovid has many drug-drug interactions that may limit the number of patients who can use it.
Fluvoxamine affects a different phase in COVID-19 pathophysiology and therefore it may be possible to combine its use with other agents.
Other: TBD

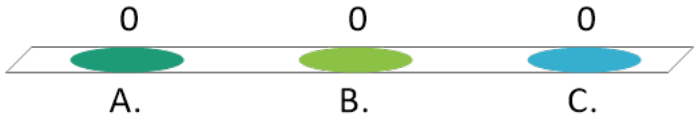
Long-Term Value for Money

6. Given the available evidence on comparative effectiveness, incremental cost effectiveness, and potential other benefits or disadvantages, what is the long-term value for money of treatment at current pricing with molnupiravir versus usual symptomatic care?

A. Low long-term value for money at current pricing

B. Intermediate long-term value for money at current pricing

C. High long-term value for money at current pricing

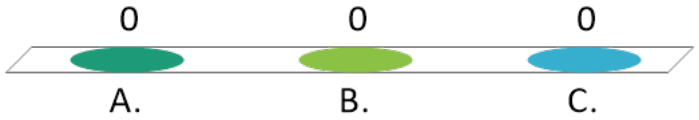


7. Given the available evidence on comparative effectiveness, incremental cost effectiveness, and potential other benefits or disadvantages, what is the long-term value for money of treatment at current pricing with Paxlovid versus usual symptomatic care?

A. Low long-term value for money at current pricing

B. Intermediate long-term value for money at current pricing

C. High long-term value for money at current pricing

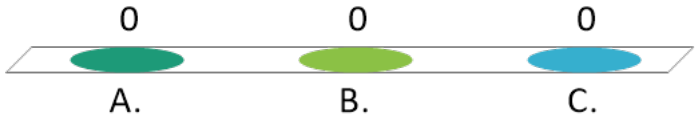


8. Given the available evidence on comparative effectiveness, incremental cost effectiveness, and potential other benefits or disadvantages, what is the long-term value for money of treatment at current pricing with fluvoxamine versus usual symptomatic care?

A. Low long-term value for money at current pricing

B. Intermediate long-term value for money at current pricing

C. High long-term value for money at current pricing



Break

Meeting will resume at 2 pm CT

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Policy Roundtable

Policy Roundtable

Participant	Title and Affiliation	Conflict of Interest
Adarsh Bhimraj, MD	Chair, Infectious Diseases Society of America COVID-19 Treatment and Management Guidelines	No financial conflicts to disclose
Linda Goler Blount, MPH	President and Chief Executive Officer, Black Women's Health Imperative	Receives funding from Hologic Inc. and Gilead Sciences
Sree Chaguturu, MD	Chief Medical Officer, CVS Caremark	Full-time employee of CVS Caremark
Jim Curotto	Vice President, Integrated Account Management, Merck	Full-time employee of Merck
Mohammad Dar, MD	Senior Medical Director, MassHealth	Full-time employee of MassHealth
Mohamed Hussein, PhD	Senior Director, HEOR General Medicine, Regeneron	Full-time employee of Regeneron.
Edward Mills, PhD	Professor of Health Sciences, McMaster University	Has stock and employee status at Cytel and received funding from Eiger Biosciences for the TOGETHER trial
Mary Roberts, MPH	Vice President, United States Market Access Strategy, GlaxoSmithKline	Full-time employee of GlaxoSmithKline

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around May 10
    - Includes description of Midwest CEPAC votes, deliberation, policy roundtable discussion
- Materials available at https://icer.org/assessment/covid-19-2022/

Adjourn

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