

Understanding Coverage Considerations for COVID-19 Vaccines and Treatments

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KEY POINTS

- COVID-19 vaccines and treatments have been important tools in the prevention of infections, hospitalizations, and deaths. Availability of these vaccines and treatments has relied in part on the Food and Drug Administration (FDA)'s Emergency Use Authorizations (EUAs), with the US Government (USG) making purchasing commitments conditional on FDA approval or authorization. To date, the USG has generally covered both the administration and ingredient costs of COVID-19 vaccines and treatments available under EUAs without individual cost-sharing, regardless of insurance status.
- In the near future, COVID-19 vaccines and treatments will need to transition to more established regulatory pathways of approval and payment by public and private payers (a process we refer to as “commercialization”). This reflects both the likely exhaustion of funds for direct government purchase of these products and the need for planning as we move beyond the acute phase of the pandemic.
- During the COVID-19 pandemic, it has taken 5 to 18 months from EUA issuance to FDA approval of COVID-19 vaccines and treatments; the timing depends on many factors, including activity against currently circulating variants and continued data collection.
- Coverage and payment considerations and policies needed to transition to commercialization vary by payer and the product in question. One key approach that may prevent potential gaps in coverage is for payers to expedite and begin coverage and payment decision-making well before the USG-provided supply runs out, potentially concurrently with FDA regulatory review.
- Coverage of COVID-19 vaccines and treatments could lead to savings to payers by reducing hospitalization costs. Our estimates indicate that COVID-19 vaccines result in large savings in direct health care costs. The savings from the initial vaccination series far exceed the costs of the vaccines. Savings from vaccine boosters essentially cover the full cost for older adults. COVID-19 treatments also generate savings by lowering hospitalization costs, and these savings partially offset the costs of these treatments.
- These estimated health care savings are in addition to the lives saved and health improved by these vaccines and treatments, which are their most important benefits.

INTRODUCTION

COVID-19 vaccines have been an important tool in the prevention of COVID-19, including preventing hospitalization or death. Similarly, COVID-19 treatments have been used to treat those infected, including for early treatment to prevent hospitalization, severe illness, or death. COVID-19 treatments like Paxlovid have demonstrated effectiveness of nearly 90 percent in preventing hospitalizations.^{1,2} Prevention or early treatment can help improve patients' health outcomes, reduce stress on health care facilities, and reduce costs by preventing hospitalizations, intensive care unit stays, and other related health care costs. To date, the US Government (USG) has provided funding for the purchase of at least 500 million doses of COVID-19 vaccines and more than 3.9 million courses of treatments such as antivirals.^{3,4}

The availability of COVID-19 vaccines and treatments has relied in part on Emergency Use Authorizations (EUAs) by the Food and Drug Administration (FDA), with the USG making commitment purchases conditional on FDA marketing authorization or approval. The USG has made these vaccines and treatments available to individuals without any cost-sharing, regardless of their insurance status. The development of COVID-19 vaccines and treatments was also partly funded by the USG through the Department of Health and Human Services (HHS)'s Biomedical Advanced Research and Development Authority's (BARDA) COVID-19 Medical Countermeasures portfolio.⁵ The USG invested in the development of six COVID-19 vaccines (with two approved by the FDA, two authorized under an EUA and two more still in phase 3 development), as well as 18 COVID-19 treatments (including monoclonal antibodies and oral antiviral medications), many of which have been approved or authorized by FDA.⁶

This approach was a response to the unprecedented nature of the COVID-19 pandemic combined with the need to expedite the development, production, and access to COVID-19 vaccines and treatments. Ultimately, availability and access of these COVID-19 vaccines and treatments will need to transition to the traditional market approach for payment and coverage using established regulatory pathways because of both the likely exhaustion of funds for direct government purchase of these products and the need for planning to support the transition out of the acute phase of the pandemic. During this transition from USG-supplied products, there may also be some circumstances where some products under an EUA could be covered by payers, while others may depend upon FDA approval for coverage and payment. In addition, this may include implications from potentially ending the PHE⁷ and the end of EUA declarations by the HHS Secretary that facilitate the issuance of EUAs for COVID-19 vaccines and treatments. The timing of these two actions – ending the PHE and the issuance of EUAs – are independent. Because the EUA declaration is allowed under a different authority than the general PHE, EUAs can continue to be issued even if the general PHE ends.

Given these possibilities, Federal and state agencies, medical product manufacturers, and payers need to prepare to transition from relying on USG-supplied COVID-19 vaccines and treatments to payer coverage and payment for COVID-19 vaccines and treatments, or "commercialization." Understanding the potential costs, as well as cost-savings, associated with COVID-19 vaccines and treatments can also inform planning, payment, and coverage decisions.

Understanding the implications of these changes is important for multiple reasons. First, each payer's coverage and payment processes and decision-making considerations may vary. Second, coverage and payment decisions may vary by product and payers based on whether a medical product has FDA

approval, or is FDA authorized under an EUA and whether there is a PHE in place. For example, COVID-19 vaccines have an established coverage pathway for most payers. If the CDC's Advisory Committee on Immunization Practices (ACIP) recommends COVID-19 vaccines and treatments, they are required to be covered by Medicaid for certain populations and non-grandfathered group health plans, and health insurance issuers offering non-grandfathered group or individual health insurance coverage. Third, the extent to which vaccination and treatment may reduce downstream medical spending can be an important factor in coverage decision-making by payers.

As we prepare for the potential end of the PHE, this report: 1) provides an overview of the current coverage and payment of COVID-19 vaccines and treatments across payers; 2) identifies expected gaps in coverage after the end of USG-provided supply and key considerations for coverage determinations post-PHE; and 3) presents estimates on expected savings and spending offsets for a select set of COVID-19 products that have been demonstrated to reduce COVID-19-related hospitalizations. This report concludes with potential next steps for payers as they navigate the coverage and payment process to prevent gaps in availability of lifesaving COVID-19 vaccines and treatments. In the course of preparing this report, Secretary Xavier Becerra, other HHS officials, and HHS staff convened a stakeholder meeting with payers, manufacturers, providers, pharmacies, state and local officials, and other organizations from across the health care system whose input and partnership on these issues is critical.

PART I. BACKGROUND: COVID-19 VACCINES AND TREATMENTS

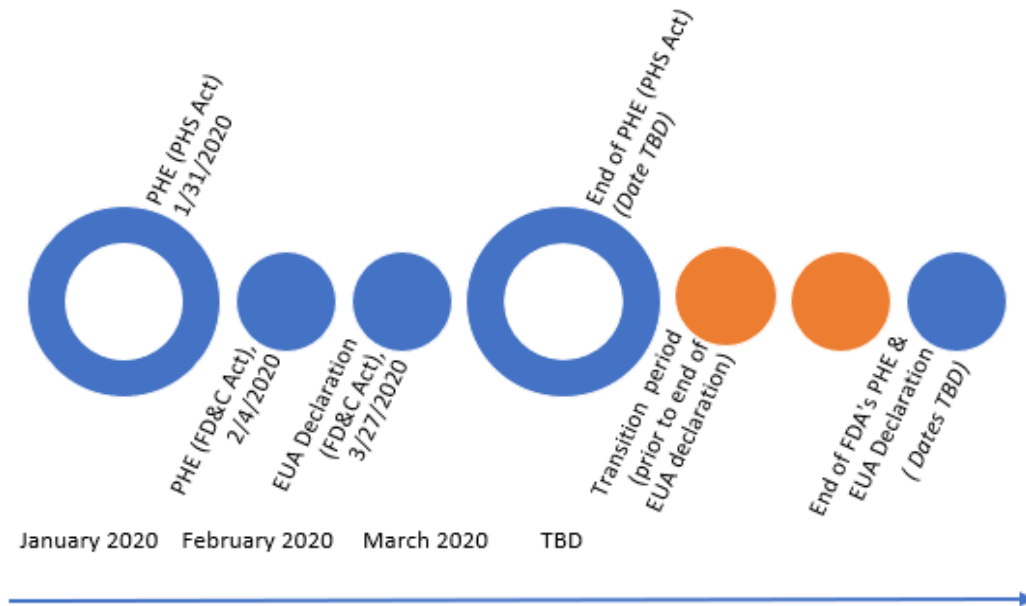
Overview of FDA EUA vs. Approval of COVID-19 Vaccines and Treatments

An EUA by the FDA is a mechanism intended to facilitate the availability and use of medical countermeasures, including vaccines and treatments, in order to prepare for and respond to certain types of emergencies. On January 31, 2020, the HHS Secretary first announced that a PHE from the novel coronavirus (2019-nCoV) existed since January 27, 2020. This PHE was declared under section 319 of the Public Health Service Act (PHS).⁸ This allowed the adoption of certain regulatory flexibilities by Federal and state governments as well as implementation of public health mitigation measures, such as wearing masks, stay-at-home orders, and suspending elective procedures. To date, this PHE has been renewed every 90 days, with the most recent renewal announced on July 15, 2022.⁹

A section 319 PHE declaration, however, does not enable the FDA to issue EUAs. A separate declaration, referred to as an EUA declaration, must also be issued by the HHS Secretary under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Following the section 319 PHE declaration, on February 4, 2020, the HHS Secretary determined, pursuant to this authority under section 564 of the FD&C Act, that there was an emergency with significant potential to affect national security.¹⁰ On March 27, 2020, the HHS Secretary issued an EUA declaration for drugs and biologic products,¹¹ which continues until the HHS Secretary declares an end to the EUA declaration. This difference in the declaration of a PHE under the PHS Act and an EUA declaration means that even if the section 319 or general PHE ends and the HHS Secretary no longer renews the general PHE, new medical products authorized under an EUA may continue to be made available while manufacturers seek FDA approval, if certain statutory conditions are met. Figure 1 illustrates the steps in a potential transition period between the end of section 319 PHE under the PHS Act and the end of the EUA declaration.

Figure 1. Timeline of Public Health Emergency Declarations and Potential Transition Period



Available COVID-19 Vaccines and Treatments

As of August 15, 2022, there are four COVID-19 vaccines in the United States authorized for emergency use or FDA-approved (each vaccine may have different dose or formulations by age or for boosters). All of these vaccines first became available under an EUA for use in certain populations.¹² Two of the four vaccines have obtained FDA approval for the prevention of COVID-19 for certain patient populations – Pfizer’s Comirnaty (ages 12 and up),¹³ and Moderna’s Spikevax (ages 18+)^{14,15} – and also remain under an EUA for certain populations. Janssen’s and Novavax’s COVID-19 vaccines are available under EUA for individuals ages 12 and up.^{16,17} Veklury (remdesivir) and Olumiant (baricitinib) are the two drugs that have obtained FDA approval for treatment of COVID-19 in certain patients, after first being made available under EUAs.¹⁸ Veklury and Oluminant also remain available under EUA for some populations. In addition, other treatments that have been authorized under EUA include monoclonal antibodies (bebtelovimab), oral antiviral therapies [Lagevrio (molnupiravir) and Paxlovid (nirmatrelvir co-packaged with ritonavir)], and a pre-exposure prophylaxis for prevention (PrEP) therapy [Evusheld (tixagevimab and cilgavimab)] are available under an EUA.¹⁹ Furthermore, additional COVID-19 vaccines and treatments are under development that may be more effective against future variants.^{20,21}

Comparing EUA versus New Drug or Biologics License Application Process

Under an EUA declaration, the FDA may consider issuing EUAs allowing the use of unapproved medical products or unapproved uses (such as new strength or form or population) of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or

conditions when certain statutory criteria are met.²² The FDA evaluates the evidence submitted by manufacturers and assesses the risks and benefits and whether certain criteria have been met to determine whether an EUA can be issued.

Overall, development of vaccines or drugs under the established regulatory pathways to FDA approval can be summarized into four distinct phases.^{23,24,25,26}

- *Research and Development, pre-clinical and pre-Investigational New Drug:* For vaccines, this includes the development of the rationale based on disease, immunogen identification, development of manufacturing process, and conduct of non-clinical studies. For drugs, this includes the exploratory stage that includes identification and validation of a potentially treatable target for a specific disease, identifying a candidate compound, investigating interactions or potential effects, and animal testing.
- *Clinical Stage - pre-licensure/pre-marketing:* This includes submission of an Investigational New Drug (IND) application to the FDA before beginning human trials, and conducting phase 1, phase 2, and phase 3 clinical studies.²⁷
- *Regulatory Review:* This includes submission of a biologics license application (BLA) to the FDA for review by the FDA's Center for Biologics Evaluation and Research (CBER) for vaccines, or a New Drug Application (NDA) to the FDA's Center for Drug Evaluation and Research (CDER) for drugs. The sponsor of the BLA or NDA must demonstrate that its drug or biological product is safe and effective for the intended use, and that it can manufacture the product to Federal quality standards.
- *Post-marketing:* This includes conducting phase 4 studies to further investigate the duration of immune response to the vaccine or to collect additional safety data.

For an EUA, the FDA and manufacturers actively engage to expedite all stages of the development process, which may include conducting certain steps in parallel rather than in sequential order; prioritizing inspections, reviews, or other related assessments; and requiring essential information to be provided to providers and recipients to address risks and benefits.^{28,29} (Appendix B Table A1 provides an illustrative example for vaccines.) For instance, to expedite review of COVID-19 treatments and vaccines, the FDA created the new Coronavirus Treatment Acceleration Program in April 2020.²⁰ Another example is the creation of the *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)* partnership between Federal agencies and industry partners to coordinate the response to the COVID-19 pandemic. The ACTIV partnership included activities such as developing a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, and coordinating regulatory processes.³⁰

In addition, for FDA approval of INDs, BLAs, and NDAs, FDA has a number of expedited programs manufacturers may request as part of the application review process, including *Fast Track*, *Accelerated Approval*, *Priority Review*, *Breakthrough*, and *Regenerative Medicine Advanced Therapy*, if certain conditions are met.³¹ For example, *Fast Track* means the FDA will meet and communicate more frequently with the applicant and allow rolling submission of parts of the BLA/NDA application. *Accelerated Approval* allows developers to use a surrogate or intermediate clinical endpoint while confirming clinical benefit post-approval. *Priority Review* means the FDA acts on an application within six months, compared to 10 months under standard review timelines. It is important to note that a priority review designation does not shorten the clinical trial length or alter the regulatory standard for approval

or the quality of evidence necessary for approval of a product.^{32,33,34,35} Where applicable, these regulatory review pathways or designations can expedite the review of COVID-19 treatments and vaccines under consideration for FDA approval through the FDA’s BLA/NDA application processes.³⁶

Table 1 illustrates the variation in the time it may take to get FDA approval after FDA has issued an EUA for some COVID-19 vaccines and treatments. As Table 1 shows, based on experience in the last two years, it may take as few as 5 months (remdesivir) from EUA issuance to BLA/NDA submission and FDA approval of COVID-19 vaccines and treatments, or as many as 14 months (Moderna’s COVID-19 vaccines primary series) or 18 months (Baricitinib for hospitalized COVID-19 patients needing ventilation). The estimated time from EUA to FDA approval reflects time for the FDA to review an application, time for companies to recruit sufficient number of study participants in clinical trials to assess and demonstrate effectiveness and safety, time to prepare an application, time for FDA to review an application, and at least 6 months follow-up data on potential adverse events to address FDA requirements. The timing may also vary by patient subgroups, which reflects varying benefit/risk considerations and challenges recruiting certain patient populations, such as children. In addition, manufacturers may use an approach where clinical trials may begin in adults or adolescents and proceed downward in age as safety and effectiveness data are gathered. Timing may also vary if additional information is required in order for the FDA to initiate or complete its review.

Table 1. FDA EUA and Approvals of Select COVID-19 Vaccines and Treatments

Product (tradename)	Age Group (years)	EUA Issuance Date	FDA Approval	Estimated Time from EUA to FDA Approval
Pfizer/BioNTech COVID-19 mRNA Vaccine ³⁷ (Comirnaty)	16+ (primary)	12/11/2020	8/23/2021 ³⁸	8 months
	18+ (first booster)	11/19/2021		
	16-17 (first booster)	12/09/2021		
	65+ or 18-64 high-risk (first booster)	09/22/2021		
	50+ or 12+ immunocompromised (second booster)	03/29/2022		
	12-15 (primary)	05/10/2021	7/08/2022 ³⁹	14 months
	12-15 (booster)	01/03/2022		
	5-11 (primary)	10/29/2021		
	5-11 (booster)	05/17/2022		
	6 months – 4 (primary)	06/17/2022		
Moderna COVID-19 mRNA Vaccine ⁴⁰ (Spikevax)	6 months – 5, 6-11 (primary)	06/17/2022		
	6-11 years (booster)	Not authorized		
	12-17 (primary)	06/17/2022		
	12-17 (booster)	Not authorized		
	18+ (primary)	12/18/2020	1/31/2022	13 months
	65+ or 18-64 high risk (first booster)	10/20/2021		
	18+ (first booster)	12/9/2021		

Product (tradename)	Age Group (years)	EUA Issuance Date	FDA Approval	Estimated Time from EUA to FDA Approval
	18+ immune-compromised (second booster)			
Janssen COVID-19 Vaccine ⁴¹	18+ (single primary dose) EUA limited to individuals 18+ not appropriate for other vaccines (single primary or booster dose)	2/27/2021 5/05/2022		
Novavax COVID-19 Vaccine, Adjuvanted ⁴²	18+ (primary)	07/13/2022		
Remdesivir (Veklury) ^{43, 44}	12+ hospitalized	05/01/2020	10/22/2020	5 months
	12+ outpatient		1/21/2022	
	Infants/children		4/25/2022 ⁴⁵	
Baricitinib (Olumiant) ⁴⁶	18+	11/19/2020	5/10/2022 ⁴⁷	18 months
	2-17	11/19/2020		
Ritonavir-Boosted Nirmatrelvir (Paxlovid) ^{48,49}	12+ high-risk with mild-to-moderate symptoms	12/22/2021		
AstraZeneca -Evusheld	12+ as pre-exposure prophylaxis for immunocompromised	12/08/2021		
Molnupiravir (Lagevrio) ⁵⁰	18+ high-risk with mild-to-moderate symptoms	12/23/2021		



Notes: Blanks indicate FDA approval not yet secured

Figure 2 outlines potential timelines for commercialization based on the time needed to bring a drug authorized under EUA to FDA approval. Figure 2 assumes manufacturers have the necessary data to submit an application for full approval, and subsequently receive full approval without requests for additional data. However, for some products or payers, commercialization may take place with an EUA.

It is important to note that as more data are collected on potential adverse events or other risk-benefit information, EUAs may also be revoked, revised, or approvals may be limited for certain use or in specific populations, as seen with the revised EUA for the Janssen COVID-19 vaccine.⁵¹

Figure 2. Potential Timeline* of FDA Approval of New COVID-19 Vaccines and Treatments by EUA Issuance Quarter Based on Recent Product Approvals

Quarter EUA First Issued	Potential FDA Approval of New COVID-19 Vaccines & Treatments*						
	2022 Q2	2022 Q3	2022 Q4	2023 Q1	2023 Q2	2023 Q3	2023 Q4
2021 Q1							
2021 Q2							
2021 Q3							
2021 Q4							
2022 Q1							
2022 Q2							
2022 Q3							

 Assumes 6-14 months
 Assumes up to 18 months

Notes: * Each row indicates the quarter an EUA was first issued for a COVID-19 vaccine or treatment, each column denotes the quarter in which FDA approval may occur. Shaded cells indicate the likely timing of FDA approval, assuming either a 6-14 timeline (light green) or up to 18 months (dark green) based on product approval timelines observed during the COVID-19 pandemic. For example, an EUA for a COVID-19 vaccine issued in Q3 of 2021 (third row) may receive FDA approval by Q2-Q3 of 2022 if the approval takes 6-14 months, but it may receive approval in Q4 of 2022 if it takes up to 18 months. These scenarios are presented for illustrative purposes and are based on select cases that may not be representative. The timeline assumes that applicants already have the data necessary to submit an application that would be accepted for FDA review or that applicants have already submitted the application for FDA review. Additional time may be required to gather the necessary data to initiate or complete review.

PART II. GAPS IN COVERAGE AND CONSIDERATIONS AFTER THE PHE

COVID-19 Vaccine and Treatment Coverage Considerations by Payer

Payers will need to consider statutory and regulatory restrictions in their decisions to cover and pay for COVID-19 vaccines and treatments under an EUA and whether FDA approval is required for coverage and payment. Some of these products are available through procurement and distribution efforts led by the USG. With the potential end of the PHE and depletion of COVID-19 funds, payment and coverage of COVID-19 vaccines and treatments will need to shift to regular coverage pathways public programs like Medicare and Medicaid/CHIP, private insurance, and programs for uninsured and underinsured individuals. This section reviews coverage and payment considerations for each type of payer for COVID-19 vaccines and treatment.

Table 2 summarizes these considerations across payers.

MEDICARE

Vaccines and Monoclonal Antibody Treatments

Vaccines and drugs are typically covered and paid for by Medicare Part A, B, and/or D upon FDA approval based on the approved label and do not need to undergo a National Coverage Determination (NCD) process. However, there may be a potential gap in coverage for some COVID-19 treatments under an EUA prior to FDA approval and Medicare coverage if USG supplies run out. During the transition, there may be in circulation at the same time both USG-procured products authorized under EUA as well as FDA-approved commercial products.

Coverage of COVID-19 Vaccines and COVID-19 Monoclonal Antibodies under Part B

Any FDA-approved COVID-19 vaccination is covered under Medicare Part B by statute (see section 1861(s)(10)(A) of the Social Security Act). Furthermore, Medicare is statutorily required to cover COVID-19 vaccines without cost-sharing under the Coronavirus Aid, Relief and Economic Security (CARES) Act,⁵² and CMS has proposed via rulemaking⁵³ to treat a COVID-19 vaccine's EUA by the FDA to be tantamount to being "licensed under section 351 of the PHS Act," as required by the CARES Act.⁵⁴ This would avoid a potential gap in coverage for COVID-19 vaccines under EUA, if USG supplies are depleted.

However, CARES Act coverage of COVID-19 vaccines does not apply to COVID-19 treatments. In order to ensure beneficiary access to COVID-19 monoclonal antibodies under an EUA, CMS announced via rulemaking that it will cover COVID-19 monoclonal antibodies under the Part B preventive vaccine benefit through the end of the calendar year in which the PHE ends. CMS has recently proposed to end that vaccine benefit-based coverage instead at the end of the calendar year in which the FDA's EUA declaration for drugs and biologicals ends with respect to COVID-19 (*rule to be published July 29, 2022*)^{55,56} (See Appendix B. Table A2). If the rule is finalized (*also refer to Tables 71-72 of the proposed rule*), CMS will stop paying for COVID-19 monoclonal antibodies and their administration under the Part B preventive benefit after the end of the EUA declarations, and then shift coverage of COVID-19 monoclonal antibodies and their administration back under the applicable payment system of the setting in which the product is administered (i.e., Part A for inpatient, Part B for outpatient). Once COVID-19 monoclonal antibodies and their administration are no longer covered under the Part B preventive vaccine benefit, Medicare beneficiaries may be subject to the standard Part B cost-sharing (20 percent of the cost of the drug, though approximately 84 percent of Medicare beneficiaries have supplemental coverage that may reduce these out-of-pocket costs).⁵⁷

For pre-exposure prophylactic COVID-19 monoclonal antibodies, CMS's policy is slightly different. CMS recently proposed to continue coverage and payment of pre-exposure prophylactic COVID-19 monoclonal antibodies and their administration under the Part B vaccine benefit even after the applicable EUA declaration ends.

Coverage of COVID-19 Antiviral Treatments

Once a drug receives FDA approval, the type of coverage under Medicare depends on whether the antiviral treatment is administered via an infusion by a physician in the hospital or outpatient clinic and therefore paid for under Medicare Part A or B, or if it is an oral antiviral prescription medication available at the pharmacy and therefore a Medicare Part D covered drug. However, under current law (Social Security Act, Sections 1860D-2(e)(1) and 1927(k)(2)), Medicare cannot cover prescription medications under Part D while they are authorized under an EUA and have not yet received FDA

approval. While Part D plans cannot cover EUA products, currently, they can bill for and report dispensing fees for USG-procured oral antivirals authorized under EUA.⁵⁸ Part D plans may also waive cost-sharing and prior authorization for Part D-covered drugs indicated for treatment or prevention of COVID-19.⁵⁹ During the PHE, CMS exercised enforcement discretion to allow plans to pay pharmacy dispensing claims for oral antivirals under EUA while the drug cost is being covered by USG procurement,⁶⁰ such as Paxlovid, a highly effective COVID-19 oral antiviral treatment. If USG supplies run out prior to FDA approval of a COVID-19 antiviral treatment, there may be gaps in beneficiary access to COVID-19 treatments under an EUA. This gap in coverage is likely to present a substantial barrier for Medicare beneficiaries, which is concerning given that Paxlovid's largest clinical benefit to prevent severe outcomes is seen in those ages 65 years and older.

Oral antivirals for COVID-19 that otherwise meet the statutory requirements for Part D coverage at section 1860D-2(e) of the Social Security Act⁶¹ must be covered by Part D plans, as a formulary product or through the formulary exception process. However, even after FDA approval, there may be gaps in coverage of COVID-19 antiviral treatments by Part D plans. Medicare statute requires drugs be approved by the FDA for coverage under Part D, but Part D plans may take up to 180 days after FDA approval or the next plan year to determine whether they add a drug to the formulary, subject to requirements that they cover all drugs in protected classes (which does not currently apply to any COVID-19 treatments) and at least two drugs in each non-protected class.

While oral antivirals for COVID-19 are not a protected drug class under Part D, given patients' ongoing need to access COVID-19 treatments, Part D sponsors could consider expediting approval of any newly approved oral antivirals by their Pharmacy and Therapeutics (P&T) committees review within the same expedited timeframe for protected class drugs. Drugs within the six protected classes are subject to an expedited review process and a decision within 90 days of release on the market. Part D sponsors could also consider adding at least one FDA-approved oral antiviral for COVID-19 to their Part D formularies on a preferred or \$0 cost-sharing tier to increase access to these life-saving treatments, because there currently are no formulary alternatives and USG supplies will eventually run out.

Prior to Part D plans adding a COVID-19 treatment to their formularies, beneficiaries (or their representative or prescriber on their behalf) can also request that the treatment be available to the individual through the Part D plan's "exception process" with standard coverage determination required within 72 hours or within 24 hours for expedited exceptions requests.⁶² That means it is possible to access antivirals under Part D after FDA approval, but prior to a coverage decision by a Part D plan. Plan D plans may need to consider expediting their exceptions process for individual coverage determinations of oral antivirals to ensure beneficiaries' requests are granted in the timeframe indicated for the treatment. For example, currently available oral antivirals require treatment initiation within five days of symptom onset. Beneficiaries will also be subject to Part D cost-sharing for COVID-19 treatments.

Coverage Decisions in Medicare Advantage under Part C

Medicare Advantage plans are required to cover the same benefits covered by Medicare Parts A and B. Furthermore, if the estimated cost of a Part A or B national coverage decision or legislative change represents at least 0.1 percent of the national average per capita costs (e.g. \$13 per beneficiary per year), it is considered a significant cost and the FFS Medicare program provides coverage for the service until the costs are factored into Medicare Advantage payments, thus preventing gaps in coverage

between plan bid cycles. CMS determined that the legislative change in benefits to add Part B coverage of a COVID-19 vaccine and its administration met the significant cost threshold. Therefore, the FFS Medicare program provided this coverage for MA plan enrollees through 2021. MA organizations began paying for the COVID-19 vaccine and its administration (including approved booster doses), without cost sharing, as of January 1, 2022, for beneficiaries enrolled in their plans. This coverage will continue during and beyond the expiration of the PHE.

Medicare Advantage plans that include Part D prescription drug coverage are subject to the same Part D coverage rules and requirements as standalone Medicare Part D plans.

MEDICAID/CHIP

COVID-19 Vaccines

For COVID-19 vaccines, currently the USG is paying for the vaccine costs while the Medicaid program provides reimbursement for vaccine administration. If the USG supply runs out, the costs of vaccines would be borne by CDC's Vaccines for Children (VFC) program, which covers 100% of the costs for all ACIP-recommended vaccines and their administration for children in Medicaid and CHIP without cost-sharing. For the adult and other remaining populations, states would be responsible for vaccine costs, while vaccine administration would be fully federally funded up until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period (the ARP coverage period). After that period, vaccine administration services would be reimbursed at the applicable state federal medical assistance percentage (FMAP). To receive the 1% FMAP bump authorized by section 4106 of the Affordable Care Act (ACA), states must also include all USPSTF A and B recommended preventive services without cost sharing, but this is not required.

As included in the American Rescue Plan (ARP),⁶³ mandatory coverage of COVID-19 vaccines and vaccine administration for nearly all Medicaid beneficiaries expires at the end of the ARP coverage period. Once the provisions of the ARP expire, coverage of ACIP-recommended vaccinations without cost sharing will only be mandatory for adults enrolled in an Alternative Benefit Plan (ABP) and children eligible for Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. Coverage of vaccines and vaccine administration is optional for other Medicaid beneficiaries. In general, states could choose to cover COVID-19 vaccines and their administration for non-mandatory populations, including non-expansion adults. Most state Medicaid programs cover at least some of the ACIP-recommended vaccines and the administration of those vaccines for adults.⁶⁴

Children would continue to qualify for COVID-19 vaccine coverage without cost-sharing under separate state CHIP programs after the expiration of the ARP provisions, but Federal law would no longer require COVID-19 vaccine coverage without cost-sharing for pregnant women, who qualify for separate state CHIP programs in six states.⁶⁵

COVID-19 Treatments

Manufacturers wishing to have state Medicaid programs cover their FDA-approved covered outpatient drugs (CODs) must participate in the Medicaid Drug Rebate Program (MDRP). With limited exceptions, states must in turn cover FDA-approved CODs from manufacturers with a rebate agreement. The MDRP, however, does not apply to prescription drugs only available under EUs. A series of COVID-19 related laws (most recently, ARP) addressed this gap by requiring that Medicaid cover all COVID-19 vaccines,

administration fees, and treatments without enrollee cost-sharing, and requires that all outpatient drugs for COVID-19 be covered, regardless of whether they were included in the MDRP. These provisions apply through the last day of the first calendar quarter that begins one year after the end of the COVID-19 PHE.⁶⁶ The ARP also requires similar coverage under CHIP, with the same timeline, although separate state CHIP programs are not part of the MDRP.⁶⁷ Currently the USG is paying for the costs of all COVID-19 treatments until supplies run out.

After the ARP provisions expire, Medicaid programs would remain responsible for coverage of COVID-19 CODs. Federal matching and rebates would be available, but enrollees could be responsible for cost-sharing, which is generally lower in Medicaid than in other types of coverage. Coverage of COVID-19 treatments in separate state CHIP programs would be subject to the same rules as other prescription drugs are in those programs.

PRIVATE INSURANCE

COVID-19 Vaccines

Private insurance includes employer-sponsored plans, Marketplace plans, and other individual market coverage. Private health plans that are compliant with the ACA, including all Marketplace plans, are required to cover vaccines recommended by the ACIP without patient cost-sharing, including those for COVID-19 under either EUAs or FDA approval. However, plans such as grandfathered and Short-Term Limited-Duration Insurance (STLDI) may not cover COVID-19-required vaccines or may require cost-sharing.

COVID-19 Treatments - Monoclonal Antibodies and Oral Antivirals

Federal law does not require private plans to cover COVID-19 treatment or put any limits on patient cost-sharing if they do. Plans generally have discretion to cover medicines under EUAs, and to set cost-sharing rules for them as they do for FDA-approved drugs. In the early period of the pandemic, when the only available COVID-19 treatments were for hospitalized patients, most fully-insured employer plans covered these treatments without patient cost-sharing.⁶⁸ By August 2021, however, 72 percent of the largest fully-insured plans in the employer and individual markets were requiring cost-sharing for COVID-19 treatment. The Kaiser Family Foundation Employer Health Benefits Survey found similar results for self-insured employer plans in the first half of 2021.⁴⁴ These findings suggest that most employer and individual market plans will cover the COVID-19 treatments currently procured by the USG after the supply ends, but that enrollees will be responsible for some of the costs related to treatments and their administration. Evidence about the effectiveness of these treatments in preventing serious and expensive illness may influence plans' coverage and cost-sharing decisions.

UNINSURED AND UNDERINSURED INDIVIDUALS

Access to COVID-19 vaccinations and treatments after the transition to commercialization may be most limited for the 26.4 million people who lack health insurance (as of early 2022), as well as millions more whose insurance may not include adequate coverage for these products (whom we refer to in this context as "underinsured").⁶⁹ With Federal procurement of vaccines and treatments, and the Health Resources and Services Administration (HRSA) COVID-19 Uninsured Program to cover administration costs, uninsured individuals have been able to get vaccinated and treated for COVID-19 as needed with no out-of-pocket costs. The HRSA program also covered the costs of COVID-19 testing for the uninsured.

In the absence of additional funding, however, the HRSA program stopped accepting provider claims for testing and treatment of COVID-19 on March 22, 2022, and stopped accepting claims for vaccine administration on April 5, 2022.⁷⁰

Fifteen states have adopted a new Medicaid option created by the Families First Coronavirus Response Act (FFCRA) to provide COVID-19 testing, vaccines, and treatment to uninsured patients, but this option will no longer be available after the end of the month in which the PHE ends.⁷¹ As with most health care services, uninsured individuals may be able to obtain COVID-19 vaccines and treatments without charge, or on a sliding scale based on income, from Federally Qualified Health Centers or other safety-net providers – though it is unlikely that there will be adequate supply to meet the full need without additional dedicated funding. This means many uninsured or underinsured individuals will have to pay full cost for COVID-19 vaccination or treatment, or else not receive these lifesaving services.

Section 317 of the PHS Act authorizes the federal purchase of vaccines for certain populations; this is known as the Section 317 Vaccine Program. COVID-19 vaccines have also been made available through CDC's Section 317 Vaccine Program, which covers uninsured children not covered by VFC and uninsured adults. Section 317 is dependent on available funding and if CDC makes a determination to include COVID-19 vaccines as part of the program. State, local, tribal, and territorial governments have been active in administering COVID-19 vaccines under USG procurement and some may continue to do so with funding from Section 317 or other sources.

The FY2023 President's Budget includes a proposal to create a mandatory Vaccines for Adults (VFA) program to provide uninsured individuals access to ACIP-recommended routine and outbreak vaccines at no cost.⁷² This would include COVID-19 vaccines. The VFA program would be modeled CDC's VFC program and tailored to adults. The VFA program would provide funding for the purchase of ACIP-recommended vaccines for eligible adults, provider fees, and program operations. Ultimately, the program aims to reduce vaccination coverage disparities, improve outbreak control of vaccine-preventable diseases, and enhance and maintain the infrastructure needed for responding to future pandemics.

Table 2. Overview of Coverage of COVID-19 Vaccines and Select Treatments by Payer and FDA Status

COVID Vaccine or Treatment Payer Coverage	COVID-19 Vaccines ⁷³		COVID-19 Antiviral Treatments		
	Vaccines (FDA approved)	Vaccines including Boosters ⁷⁴ (EUA)	Oral Antivirals – Paxlovid or Lagevrio (EUA)	Intravenous Antiviral – Veklury (FDA approved)	Pre-Exposure Prophylaxis for Immunocompromised Patients – Evusheld ⁽¹⁾ (EUA)
USG supplied	Yes	Yes	Yes	No (ended October 2020) ⁷⁵	Yes
Medicare					
Part A	NA (See Part B)	NA (See Part B)	NA (See Part D)	Yes (5 day IV treatment if hospitalized)	NA (See Part B)
Part B	Yes without cost sharing	Yes without cost sharing ⁷⁶	NA (See Part D)	Yes if outpatient	Yes, without cost sharing (proposed rulemaking to continue this coverage without beneficiary cost sharing after the EUA ends)
Part C (Medicare Advantage)	Same as Part A (inpatient) and Part B ⁵⁸ (outpatient); however if a new benefit is added through a National Coverage Determination by FFS Medicare or a legislative change and is determined to be a “significant” cost, the FFS Medicare program provides coverage for the service until the costs are factored into Medicare Advantage payments. MA plans began covering the COVID-19 vaccine as of Jan. 1, 2022				
Part D	NA (See Part B)	NA (See Part B)	No – coverage requires FDA approval	NA (See Part B)	No – coverage requires FDA approval
Medicaid & CHIP: Children					
During PHE & Up to One Year After PHE	Yes	Yes	Yes	Yes	Yes
> 1 Year After PHE Ends	Yes, covered by VFC program	Yes	Yes – EUA drugs can be covered as prescribed drugs if included in the state plan	Yes with cost sharing	Yes – EUA drugs can be covered as prescribed drugs if included in the state plan
Medicaid: Adults⁽²⁾					
During PHE & About One Year After PHE	Yes without cost sharing	Yes without cost sharing	Yes	Yes	Yes
> 1 Year After PHE Ends	Possibly (depends on eligibility group; may be cost-sharing for some)	Possibly (depends on eligibility group and state ⁽³⁾ ; may be cost-sharing for some)	Possibly (EUA drugs depends on eligibility group and state ⁽³⁾ ; subject to cost-sharing)	Yes, may be subject to cost-sharing	Possibly (depends on eligibility group and state ⁽³⁾ ; may be subject to cost-sharing)

	COVID-19 Vaccines ⁷³		COVID-19 Antiviral Treatments		
COVID Vaccine or Treatment Payer Coverage	Vaccines (FDA approved)	Vaccines including Boosters ⁷⁴ (EUA)	Oral Antivirals – Paxlovid or Lagevrio (EUA)	Intravenous Antiviral – Veklury (FDA approved)	Pre-Exposure Prophylaxis for Immunocompromised Patients – Evusheld ⁽¹⁾ (EUA)
	beneficiaries)	some beneficiaries)			
Private Insurance					
Plans subject to the ACA’s preventive service requirements	Yes	Yes	May not be covered or may require cost-sharing		
Plans not subject to the ACA’s preventive service requirements	May not be covered or may require cost-sharing				

Notes: NA = Not Applicable. Green – covered, no cost sharing; Light green – covered, may include cost-sharing; Orange – Possibly not required to be covered, or covered with limitations; Red – Not covered. Status as of August 27, 2022.

(1) Evusheld is authorized for use in immunocompromised patients or those unable to be vaccinated, who do not have COVID-19 and no known exposure to someone infected. It is administered via two separate consecutive intramuscular injections and repeated every six months.

(2) Medicaid coverage of ACIP-recommended vaccines depends on eligibility category. Coverage is mandatory for beneficiaries eligible for EPSDT and those enrolled in ABPs for ACIP-recommended vaccines.

(3) States may continue to cover EUA drugs after the end of the ARP PHE period if their state plan specifies such coverage.

PART III. ANALYSIS OF POTENTIAL COST SAVINGS FROM VACCINES AND TREATMENTS

As discussed in the previous section, some payers have the authority to cover COVID-19 vaccines and treatments but are not required to do so. Thus, another important consideration is understanding the costs as well as potential cost-savings from covering COVID-19 vaccines and treatments. In this section, we estimate potential cost-savings associated with averted hospitalizations for COVID-19 vaccines and select COVID-19 treatments.

DATA

We utilized multiple data sources, including infection rates and information on the effectiveness of COVID-19 vaccines (separately for primary doses and boosters) and treatments, and the probability of hospitalization among different populations. These data were analyzed separately for those ages 19-64 and adults 65 and over. For simplicity, individuals 65 and over are assumed to be covered by Medicare and those 19-64 by other payers.⁷⁷ We also used data on vaccination from the Centers for Disease Control and Prevention (CDC). The estimated cost of the vaccines or treatments was informed by publicly available sources^{78,79} and are meant to be for *illustrative purposes only*. Given the multiple

factors involved in commercial negotiations, there is uncertainty regarding what the costs will be after negotiations.

METHODS

We estimated cost savings as a result of reductions in hospitalizations in two steps. First, we calculated the expected per-person hospitalization cost with and without intervention (receiving a COVID-19 vaccine or treatment). The per-person cost of hospitalization is calculated using the cost per hospital stay, the probability of infection, and the probability of being hospitalized, based on historical data. Second, for each scenario we compared the anticipated costs of the vaccine or treatment and expected hospitalization cost with and without the vaccine or treatment. Specifically, we calculated the difference between the per-person cost of the vaccine or treatment and the per-person expected hospitalization cost. When cost savings from reduced hospitalizations exceed the cost of the vaccine or treatment, this means the vaccine or treatment is cost-saving on net; when the hospitalization cost savings are less than the costs of the vaccine or treatment, this results in a partial cost offset.

We note that for purposes of this analysis we focus on inpatient hospitalizations. Cost-related benefits associated with reduction in emergency department or ambulatory visits are not considered in this analysis. We make the simplifying assumption that the cost of the treatment or the hospital stay does not vary by health insurance coverage status. We also make simplifying assumptions with respect to the timing of vaccine and booster efficacy. This methodology also does not consider reduced future spending from reduced prevalence or intensity of future infections due to vaccination or treatments. This methodology is limited in that it does not examine benefits by more disaggregated age groups, vaccination status, or health history. As such, the average estimates may not fully reflect the potential for cost savings of these treatments when targeted specifically toward individuals with very high-risk profiles.

Most importantly, this analysis only examines savings related to health care costs. These estimates do not measure presumably the most important benefit of these vaccines and treatments – their reduction in illness and death. Previous research by ASPE quantifies some of those non-financial benefits, finding for instance that COVID-19 vaccinations accounted for nearly \$3 trillion in benefits to the US through mid-2021, primarily through vaccine-related reductions in mortality.⁸⁰

See Appendix A methodology for additional details on the data and related assumptions.

RESULTS

Projected Cost Savings from COVID-19 Vaccines and Treatments

Table 3 shows projected cost savings for COVID-19 vaccines and treatments related to reductions in hospital spending separately for all payers (population under 65) and Medicare (population 65 and older). We note that our estimates rely on assumptions and publicly available data sources that may not fully reflect the information or other factors, including commercial negotiations, involved in actual coverage decisions.

Adults Under 65: Table 3 shows the results for the adult population ages 19 to 64. Overall, we find that the *initial vaccination series is cost-saving with roughly \$110 in reduced hospital costs per person on*

average compared to remaining unvaccinated. Other boosters and treatments result in smaller hospital cost savings, which reflects the low probability of hospitalization in this younger population, but still offset a significant portion of the costs of treatment in some cases. Specifically, reduced hospital spending offsets 23 percent of Paxlovid’s treatment cost (\$181 out of \$800) and 6 percent (\$122 out of \$2,100) of the cost of a monoclonal antibody treatment, assuming infection with an Omicron-like variant.

Population 65 and Older: Table 3 shows the results for the population age 65 years and older. Overall, we find that the *initial vaccination series is cost-saving, with nearly \$1,000 per person in reduced hospital costs on average compared to remaining unvaccinated;* this is more than enough to offset the vaccine cost even with significant levels of wasted doses. The cost savings for Medicare are largely driven by a reduced probability of infection and reduced probability of hospitalization after vaccination among adults aged 65 years and older.

Boosters, compared to full vaccination, show smaller savings, but still enough that *hospital savings from booster shots nearly or fully cover the cost of additional doses at \$20 per dose.*

KEY FINDINGS
<ul style="list-style-type: none">• COVID-19 vaccines reduce hospitalization costs<ul style="list-style-type: none">➤ by \$110 per person in adults under 65➤ and nearly \$1,000 per person among seniors• Hospital savings from boosters nearly cover the full cost of booster doses

For treatments, cost savings increase as the probability of hospitalization increases. Under our current assumptions, reduced hospital spending offsets 51 percent of Paxlovid costs (\$410 out of \$800) and 13 percent of the cost of a monoclonal antibody treatment (\$277 out of \$2,100), assuming infection with an Omicron variant.

This analysis only examines savings related to health care costs. These estimates do not measure the most important benefit of COVID-19 vaccines and treatments – their reduction in illness and death.

Table 3. Projected Cost Savings from COVID-19 Vaccines and Treatments

Scenario	Added Per Person Cost of Vaccine or Treatment	Per Person Savings from Reduced Hospitalizations	Per-Person Net Cost or Savings from Vaccination or Treatment (%)
	(A)	(B)	(A - B)
Adults under 65			
Full Vaccination (2 shots) vs. non-Vaccinated (0 shots)	\$40	\$150	\$110 (275%)
1 Booster (3 shots) vs. No Booster (2 shots)	\$20	\$4	\$16 (20%)
2 Booster (4 shots) vs. 1 Booster (3 shots)	\$20	\$3	\$17 (15%)
Paxlovid vs. No Treatment, Among COVID-19 Infected individuals	\$800	\$181	\$619 (23%)
Monoclonal Abs vs. No Treatment, Among COVID-19 Infected individuals	\$2,100	\$122	\$1,978 (6%)
Adults 65 and Older			
Full Vaccination (2 shots) vs. non-Vaccinated (0 shots)	\$40	\$956	\$916 (2,290%)
1 Booster (3 shots) vs. No Booster (2 shots)	\$20	\$26	\$6 (30%)
2 Booster (4 shots) vs. 1 Booster (3 shots)	\$20	\$19	\$1 (95%)
Paxlovid vs. No Treatment, Among COVID-19 Infected individuals	\$800	\$410	\$390 (51%)
Monoclonal Abs vs. No Treatment, Among COVID-19 Infected individuals	\$2,100	\$277	\$1,823 (13%)

Notes: **Red** font denotes cost-savings.

DISCUSSION

This report provides a comprehensive summary of how COVID-19 vaccines and treatments have been made available to the public through the USG's purchase and via EUAs and approvals by the FDA.

This report identifies gaps in current payer coverage of COVID-19 vaccines and treatments authorized under an EUA and describes how USG-provided supplies have temporarily covered and made available these life-saving vaccines and treatments during the PHE. However, these USG-provided supplies are expected to run out sometime in late 2022 based on current COVID-19 funding (and depending on the product in question). Payers need to begin preparing for coverage of these COVID-19 vaccines and treatments in the transition to the end of the PHE and FDA approval of these life-saving medical products.

One key factor that may expedite commercialization and minimize the risk of gaps in access is for payers to expedite and begin coverage decision-making well before the USG-provided supply runs out. Other payers can start their own coverage determination processes prior to FDA approval to prevent potential gaps in coverage.

Our estimates of potential costs and savings demonstrate the benefits to payers of covering COVID-19 vaccines and treatments, which not only can save lives but also reduce costs by preventing hospitalizations in the US. Our analysis demonstrates that the initial COVID-19 vaccination series is cost-saving for all payers and remains cost-saving or essentially cost-neutral for Medicare for booster doses. COVID-19 treatments reduce the risk and cost of hospitalizations, which partially offset the costs of providing those products, with the highest offsets for Paxlovid, followed by monoclonal antibody treatments. These calculations will vary based on stratification by patients' risk factors such as comorbid conditions, occupational exposure, and community environmental risks. This analysis only included age stratification for populations below and above 65 years and only considered savings from inpatient costs. Reduced infections and severity of illness also likely reduce follow-up outpatient care and related costs, further improving the return on investment for payers covering these services.

Our results underscore the importance of primary vaccination as a population-based prevention strategy across all payers and geographic areas. Reduced hospitalization costs associated with the use of oral antivirals also partially offset the costs of these treatments to varying degrees among payers, with higher offsets for seniors. Studies suggest hospitalization costs for COVID-19 are higher than the average hospitalization. For example, the average cost of a Medicare hospitalization for COVID-19 was just under \$22,000 and more than \$49,000 if the patient needed a ventilator,⁸¹ whereas it was less than \$20,000 for a Medicare non-COVID-19 hospitalization prior to the pandemic, and approximately 145 times the cost of vaccinating a Medicare beneficiary. Other studies have estimated the average cost of a COVID-19 non-complex inpatient stay to be approximately \$34,000, up to \$98,000 for a complex inpatient stay.⁸² Given that private insurers are the primary payers for working adults, these estimated cost savings underscore the economic benefits of continued coverage of COVID-19 vaccines and treatments, especially among higher-risk populations. While this analysis did not break out hospitalization costs or estimate cost savings for specific groups other than older or younger than 65, previous studies have shown COVID-19 and severe outcomes from COVID-19 disproportionately impact Black, Latino, and American Indian/Alaska Native individuals,⁸³ people with low income, people working in high-risk public-facing occupations,⁸⁴ and those with one or more chronic conditions.⁸⁵ Higher cost savings can therefore

be expected in these higher risk groups from continued access to COVID-19 vaccines and treatments. Cost savings are also likely to differ by payer—where those with a large share of high risk groups expected to experience higher cost savings.

Our analysis has important limitations. The COVID-19 pandemic is an evolving situation, with new variants and ongoing research about the effectiveness of current treatments and vaccines. Accordingly, changes in recommended treatments may occur over time. In response, vaccine manufacturers are now developing COVID-19 vaccines that can be more effective against multiple strains of SARS-CoV-2, the virus that causes COVID-19. Our estimates reflect the state of knowledge as of August 2022, and with new variants, vaccines, and treatments, potential cost savings may change. Finally, the costs for vaccines and treatments that will be paid by different insurers are unknown at this time; we provide estimates of potential savings here that can be compared as needed to whatever specific prices are ultimately adopted or negotiated by different payers.

CONCLUSION

Current coverage for many of the COVID-19 vaccines and treatments available in the US rely in part on EUAs. Continued coverage after USG-provided supplies run out and the end of EUA declarations will require payers to work through coverage determinations in an expedited manner. The public will expect coverage of these lifesaving vaccines and treatments without gaps and ensuring broad and equitable access to these services is a key priority for the Federal government.

APPENDIX A. METHODOLOGY

COVID-19 Vaccines: Our projections were based on current infection rates combined with information on mRNA vaccine and booster effectiveness in individuals who are not immunocompromised. We assume the fourth shot has the same incremental effect as the third, and that the same percentage of individuals who went from 2 shots to 3 would go from 3 shots to 4. This percentage was 70 percent in the Medicare population⁸⁶ and 43 percent in the 18-64 population.⁸⁷ We then compared costs for 2 shots vs. 0 (fully vaccinated vs. unvaccinated); 3 shots (first booster) vs. 2 shots; and 4 shots (second booster) vs. 3 shots. These estimates do not incorporate the varying levels of effectiveness resulting from the timing of vaccination. Future variants could result in different probabilities of infection and associated costs.

Paxlovid and Monoclonal Antibodies: We considered the infection and hospitalization risks of the Delta and Omicron variants. Omicron risks are calculated by updating the vaccine effectiveness in reducing infection and treatment effectiveness in reducing hospitalization⁸⁸ relative to baseline hospitalization risk of the Delta variant.⁸⁹ We assume 89 percent effectiveness for Paxlovid⁹⁰ and 60 percent effectiveness for monoclonal antibodies in reducing hospitalizations. While we do separately model the risk of hospitalization for vaccinated (completed primary series) vs. unvaccinated individuals receiving treatment, the estimates do not incorporate changes in vaccine effectiveness based on the timing of doses or number of boosters each individual has received. As was the case for vaccines, future variants could result in different probabilities of infection and associated costs.

Calculating Savings from COVID-19 Vaccines and Treatments: We first calculate the estimated per-person costs of those who receive a COVID-19 vaccine or treatment (C^t) and those who do not (C^c), which are denoted by equations (1) and (2) below.

$$(1) C^t = c^i + h^i$$

$$(2) C^c = c^i + h^i$$

In equation (1), c^i denotes the cost of receiving a COVID-19 vaccine or COVID-19 treatment (e.g., \$40) and h^i is the expected cost of hospitalization with receipt of vaccine or treatment (\$200). h^i is the cost of a hospital stay (e.g., \$20,000) which is multiplied by the probability of being hospitalized for those who receive a vaccine or treatment (e.g., probability equal to 0.01). In equation (2) c^i is zero, and h^i is the expected cost of hospitalization (e.g., \$2,000) which is calculated using the cost of a hospital stay (\$20,000) times the probability of being hospitalized (e.g., probability equal to 0.1) if the person does not receive a vaccine or treatment at-home, at the hospital or as outpatient. We assume that the cost of a hospital stay is the same in (1) and (2).

Second, to determine whether the estimated reduction in hospitalization costs would cover the entire cost of the treatment or not, we calculate the difference in costs between those who received the vaccine or treatment and those who did not. In other words, we calculate C , or equation (3):

$$(3) C = C^t - C^c$$

Equation (3) could also be calculated as $c^i + h^i - h^i$, which in the example provided would be, -\$1760 (\$40+\$200-\$2000). Estimated per person cost-savings are determined when the costs of COVID-19

vaccines or treatments are less than the costs of COVID-19 hospitalizations compared with the counterfactual scenario when no vaccines or treatments are available ($C < 0$), which indicates that the reduction in the per-person expected hospitalization cost was greater than the per-person cost of the treatment or vaccine. Estimates where $C > 0$ denote indicate that the estimated reduction in hospitalization does not cover the cost of the treatment. That is, cost-offsets reflect the reduction in hospital spending associated with vaccination or receipt of a COVID-19 therapeutic.

APPENDIX B. TABLES

Table 1. FDA New Drug Application Approval Process vs. Emergency Use Authorization for Vaccines: Example - Pfizer/BioNTech Comirnaty COVID-19 Vaccine

Stage	I. Research & Discovery II. Pre-Clinical	Clinical Development				Application for FDA NDA or BLA Vaccine Approval	Ongoing Post-Market Surveillance
		Phase 1 - safety	Phase 2	Phase 3 - efficacy	Phase 4 - monitoring	FDA Decision	Ongoing Monitoring
New Vaccine Development	Animal testing	FDA reviews manufacturing process for reliable and consistent production of the vaccine				Submit application for FDA approval Review by VRBPAC	Ongoing safety monitoring via Vaccine Adverse Event Reporting System and FDA Adverse Event Reporting System
EUA Process	Animal testing	20-100 participants; safety assessed	Hundreds of participants Various dosage tested in different demographic groups	> 3,000 vaccine recipients tested in RCT for efficacy Review by VRBPAC.	> 6 months to continue evaluation of safety and effectiveness		
				RCT Review by Safety Board to assess if study met desired clinical endpoint	> 2 months with half of trial participants Application for EUA VRBPAC public meeting	> 6 months data	

Stage	I. Research & Discovery II. Pre-Clinical	Clinical Development				Application for FDA NDA or BLA Vaccine Approval	Ongoing Post-Market Surveillance	
		Phase 1 - safety		Phase 2	Phase 3 - efficacy	Phase 4 - monitoring	FDA Decision	Ongoing Monitoring
Example: Pfizer/BioNTech COVID-19 mRNA Vaccine Approval (Comirnaty)	1/27/2020 HHS Secretary declares PHE from 2019-nCoV 2/4/2020 HHS Secretary makes a determination of PHE ⁹¹ under section 564 of the FD&C Act 3/27/2020 HHS Secretary issues EUA declaration ⁹²				12/11/20 EUA for Pfizer BioNTech COVID-19 vaccine in population 16+ (based on 2month follow-up data on approx. 18,000 vaccine recipients and approx. 18,000 placebo recipients) 5/10/21 EUA for 12-15 year-olds 10/29/2021 EUA for 5-11 year-olds	> 6 months data	8/23/21 FDA approval of Pfizer/BioNTech Comirnaty vaccine in population 16+ (based on 6month follow-up in approx. 12,000 recipients, safety data on approx. 22,000 and effectiveness data on approx. 20,000 vaccine recipients and similar number of placebo recipients)	

Notes: Vaccines and Related Biological Products Advisory Committee: VRBPAC; randomized clinical trial: RTC. The FDA approval process and the EUA process are largely the same except for phase 3 during clinical development. EUA authorization only requires at least two months of data, whereas more than six months is needed for approval by the FDA. Color scheme: Blue – regular FDA New Drug or New Biologics License Application Process; Orange – EUA review process; Green – FDA approval stage; Light green – ongoing post marketing surveillance by FDA

Sources: US Food and Drug Administration (FDA). Emergency Use Authorization for Vaccines Explained, <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>.

Table 2. Medicare Coverage and Payment of COVID-19 Treatments during and after PHE*

Treatment	EUA Authorization or FDA Approval	Calendar year that contains PHE*	Calendar years after PHE* ends
COVID-19 Monoclonal antibodies for immunocompromised patients, e.g., Evusheld (Medicare Part B)	EUA**	Covered without cost-sharing because CMS is paying for them under the Part B vaccine benefit.	No coverage at this time without final rulemaking. CMS has recently proposed to cover and pay for pre-exposure prophylactic COVID-19 monoclonal antibodies and their administration under the Part B vaccine benefit even after the applicable EUA declaration ends.
	Approval	Covered without cost-sharing because CMS is covering them under the Part B vaccine benefit	No coverage at this time without final rulemaking. Potential coverage after PHE/EUA declaration ends if proposed rule is finalized. CMS has recently proposed to cover and pay for pre-exposure prophylactic COVID-19 monoclonal antibodies and their administration under the Part B vaccine benefit even after the applicable EUA declaration ends.
Oral antivirals, e.g., Paxlovid (Medicare Part D)	EUA**	No coverage	No coverage
	Approval	Review within 90 days and determination within 180 days but Part D plans not required to place drug on formulary until next plan year. Part D plans must cover 2 drugs per class (or 1 drug under some circumstances) on formulary. Any drug not on the formulary will be available to an individual on a one-off basis through the formulary exception process.	Same as during PHE
Physician-administered antivirals (Part B)	EUA**	No coverage	No coverage
	Approval	Regular coverage under Part B with cost-sharing.	Regular coverage under Part B with cost-sharing.

Notes: *Public Health Emergency under section 319 of the Public Health Service Act; ** EUA authorization of treatments is made pursuant to a declaration under section 564 of the FD&C Act also referred to as 564 declaration. The end of the EUA declaration may be after the end of the COVID-19 PHE under the PHS Act (currently in rulemaking to instead cover through the end of the EUA declaration). Some coverage of treatments is through the end of the calendar year of the COVID-19 PHE under the PHS Act. Until FDA approval is received, some treatments may not be covered after the COVID-19 PHE ends (after the EUA declaration ends if rulemaking is finalized as proposed). Color scheme: Green – regular coverage; Red – no coverage; Yellow – potential coverage under certain circumstances.

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