

COVID-19 Test to Treat Pathways:
Policy Options for Achieving National Implementation



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Executive Summary

The United States possesses a number of countermeasures against Covid-19—including a host of safe, effective therapeutics for mild-to-moderate disease that can be updated in response to new variants while preventing those most at-risk from progressing to severe illness. Recent actions by the Biden Administration have facilitated greater short-term availability of those treatments in conjunction with timely access to testing after symptoms or exposure. These actions include expansion of the number of Test to Treat locations, the ability of more administration sites to directly order product, and dedicated outreach to providers and patients. However, the utilization of therapeutics remains low relative to caseloads, uneven, and difficult to track.

Uneven utilization of therapeutics is due in part to: 1) gaps in public and provider awareness, with uncertainty about timely access and patient prioritization; 2) lack of clarity for continued reliable supply, with uncertainty about procurement and thus about future availability of treatments, especially during surges; and 3) inadequate and unclear policy and financial supports for coverage and access following the expiration of the public health emergency (PHE) due to a lack of clarity on reimbursement for administration and cost-sharing requirements for tests and treatments. During the PHE, health plans are required to provide access to testing, and federal procurement of treatments has lowered the cost burden for patients. With the end of the PHE looming, there is no definitive national strategy for supporting effective and equitable availability of Test to Treat pathways for Covid-19.

This issue brief outlines the gaps in existing Test to Treat pathways and describes short- and long-term actions for improving timely use and supply of Covid-19 therapeutics. It includes policy options to ensure adequate therapeutic supply, steps to expand existing public health and health care Test to Treat pathways, and opportunities to address payment barriers for access to treatment.

To implement Test to Treat pathways on a national scale, we urge federal and state health agencies work concertedly with private sector health partners to prioritize the following recommendations:

Improve Guidelines and Foster Evidence Development

1. Improve evidence and guidance on deploying antiviral treatments, including monoclonal antibody (mAb) and oral treatments, with practical and [equitable considerations](#) for access.
2. Support education and outreach efforts to health care workers and to the public to ensure that individuals at high risk of severe Covid-19 illness, and particularly those who have tested positive using at-home antigen tests, know both that they are eligible for and encouraged to receive treatment as well as where they can receive treatments.
3. Identify and, in case of future supply or access constraints, prioritize patient populations or subgroups who experience high risk of severe Covid-19 illness and would benefit most from therapeutics.
4. Communicate with state and health system leaders the anticipated allocations of therapeutic products and availability of timely testing to enable planning for reliable pathways.

Maintain Stable Financing for Predictable Access to Priority Covid-19 Therapeutics

1. Procure testing and treatments for adequate supply in advance of widespread case surges and facilitate rapid, broad distribution. Federal funding for reliable availability of tests and mAb and antiviral Covid-19 treatments will enable effective health care and public health planning around Test to Treat strategies and help protect against variants that pierce immunity or develop resistance to current therapies.

2. Provide federal funding for advanced research and development of novel infectious disease therapeutics.
3. Maintain a “warm capacity” for adequate manufacturing if a major surge requires additional therapeutics and to support future U.S. pandemic preparedness.
4. Conduct ongoing assessment of adequacy of advance purchase funding. In particular, an investment of at least \$5 billion in advance purchases and further treatment development is necessary to provide sufficient supply to support reliable availability of Test to Treat pathways for the remainder of this year. While conditions may change, continued federal funding for emergency use therapies will likely be required to ensure sufficient access to limit Covid-19 public health impacts after the PHE.

Ensure Widely-Available Test to Treat Care Pathways

1. Develop public health educational campaigns and information resources that can rapidly connect patients to testing and Test to Treat locations.
2. Implement health plan- and health care provider-driven outreach programs and reliable Test to Treat pathways for at-risk patients, and plans to expand these programs in response to surging case rates to avoid hospitalizations.
3. Prioritize sustainable funding for Test to Treat services that improve access in underserved areas and for uninsured patients.
4. Generate further evidence on best practices to implement and flexibly scale testing and treatment capacity to ensure continued availability and access for treatments during surges, and to support and coordinate their adoption at the regional and state levels.

Clarify Insurer Coverage and Payment for Test to Treat Beyond the PHE

1. Clarify coverage and payment for Test to Treat in Medicare to promote affordability, availability, and equitable access of treatments and testing for patients at elevated risk of severe Covid-19 illness. These include requiring Medicare to cover Test to Treat care pathway services after the PHE.
2. Require Medicare and private health insurance plans to cover and limit cost-sharing for evidence-based Test to Treat care pathway services—to promote affordability, availability, and equitable access for authorized testing and treatment for patients at elevated risk of severe Covid-19 illness.
3. Establish payment incentives for coordination of testing, assessment, and treatment services that encourage the development and sustainability of Test to Treat pathways.
4. Provide incentive payments for timely use of Covid-19 therapeutics in patients at high risk of severe Covid-19 illness.
5. Provide funding for testing and treatments for patients without insurance.

Background

In the third year of the Covid-19 pandemic, the US has a growing array of effective medical and public health response measures to control the impact of the virus, both to limit spread and to reduce substantially the risks of severe health outcomes related to infection. These countermeasures include highly effective vaccines and boosters, rapid at-home testing options for monitoring exposure, and effective therapeutic options for both pre-exposure prevention and treatment of mild-to-moderate disease, all of which can potentially be updated efficiently as concerning new variants emerge. As of early 2022, the increasingly broad array of therapeutics available to prevent serious consequences of Covid-19 infections includes:

1. The monoclonal antibody (mAb) bebtelovimab (presently the only mAb [effective](#) at treating Covid-19 caused by some Omicron variants), the oral antivirals Paxlovid (nirmatrelvir/ritonavir) and Lagevrio (molnupiravir), and the intravenous antiviral Veklury (remdesivir) – all for the early treatment of mild-to-moderate Covid-19 following a positive test result
2. The mAb Evusheld (tixagevimab/cilgavimab) for pre-exposure prevention

However, this increasingly broad array of therapeutics has been underutilized and unevenly distributed.

The Biden Administration has taken a series of actions to address this underuse and uneven distribution of Covid-19 treatments. The President's State of the Union [address](#), the Administration's updated [National Covid-19 Preparedness Plan](#), and an [April 2022 announcement](#) of expanded pathways for therapeutic access all described elements **of a national Test to Treat initiative for ongoing control of Covid-19 and mitigation of its impacts**. This includes a number of promising approaches, including:

- Expanding the number of Test to Treat locations where patients can easily receive both Covid-19 testing and rapid access to treatments. The Administration has to-date established 2,200 of these sites nationwide with federal support.

- Allowing a broad range of health care settings and providers to directly order and receive shipments of oral antiviral treatments from the government, beyond the exclusive state-based allocation and distribution channels that existed between September 2021 and [April 2022](#). These include pharmacies, community health centers, hospitals, urgent care centers, Federally Qualified Health Centers (FQHCs), long-term care facilities (LTCs), and Veteran's Affairs or military facilities— increasing the number of sites where oral antivirals are readily available from the current estimated 20,000 locations to a goal of 40,000 in the near future.
- Increasing the type and frequency of educational, scientific, and public messaging campaigns aimed at all types of providers, pharmacists, community health workers, caregivers, and everyday Americans— consistently informing as many people as possible about the availability of lifesaving Covid-19 treatments and where and when to seek them out in the course of a newly-symptomatic or -confirmed case of Covid-19.

Despite incremental increases in use, current uptake of these treatment options falls far short of their potential benefits, increasing the risk of serious health consequences, hospitalizations, health system impacts, and inequitable outcomes, especially with surges in cases. Clear data on the use of Covid-19 therapeutics has been inaccessible. Demand for oral antiviral use has soared, with the Biden Administration stating [20,000 courses](#) of Paxlovid have been prescribed per day in mid-May of 2022. Furthermore, between April 10 and May 14, there were increases of [315 percent and 200 percent](#) in prescribed courses of Paxlovid and Lagevrio, respectively. Data from Pfizer, the manufacturer of Paxlovid, demonstrated a [ten-fold rise](#)—from 8,000 to 79,000—in weekly courses administered of the oral antiviral from late February to mid-April. At the same time, US case rates were rising above [100,000 reported cases](#) per day, with actual cases potentially [multiple times higher](#), suggesting that only a fraction of Covid-19 patients at high risk of severe illness were receiving

treatment while hospitalizations were rising. At the same time, reported courses administered of Evusheld and bebtelovimab are only approximately [20 percent and 15 percent](#), respectively, of the number made available for distribution—signifying use has remained flat. Substantial numbers of treatment courses for both oral antivirals, Evusheld, and bebtelovimab [remain available](#). **These top-line numbers represent the best available data for tracking therapeutic utilization—accurate data collection and transparent exchange of collected data still present challenges.** Despite [ASPR guidance](#) mandating sites report Covid-19 therapeutics utilization and supply records, readily accessible utilization data available on effective therapeutics is incomplete.

In short, with tens of thousands of Covid-19 cases reported daily involving patients likely to benefit from timely access to therapeutics, and many more cases unreported, only a fraction of the available therapeutics are actually helping patients. Lack of transparency can make understanding supply numbers more difficult and inhibit identification of developing therapeutic shortages. Supply shortages may present locally in places with greater use of testing and awareness of effective treatments. **Covid-19 remains a leading cause of death, and continued therapeutic underuse and uneven use is likely driving health disparities across and between different patient communities based on geographic location, insurance and socioeconomic status, and other well-documented barriers to treatment for underserved populations.**

In the face of continuing gaps in treatment, there remain a number of addressable evidence, coordination, resourcing, and other policy challenges to standing up Test to Treat pathways as a reliable, ongoing, and key element of Covid-19 response efforts through three potentially reinforcing avenues.

First, there are continued gaps in clinicians' ready understanding of availability and appropriate use of Covid-19 treatments across different patient characteristics and care settings, and persistent gaps in public awareness of their availability to patients. While many

organizations are taking steps to provide patients and their providers with tools, evidence summaries, and in some cases even flowchart-like guides to enable Test to Treat pathways to operate more efficiently and equitably, information gaps and uncoordinated messaging will continue to hamper widespread viability of Test to Treat options.

Second, while the administration is using some PHE funding to increase availability of Test to Treat capabilities—sites co-locating testing, assessment, and treatment at FQHCs, Health Information Services, VA clinics, Rural Health Clinics, and federal retail chain pharmacy partner clinics—**additional funding for these approaches is likely to be limited beyond the PHE, or even in the shorter term.** Limited funding creates challenges to ensuring continued staffing, space, and supplies of tests and treatments to sustain these specially dedicated sites.

Third, clinicians, pharmacies, and other health care providers are expanding access to reliable Test to Treat pathways through their own means. Such health system- and payer-mediated pathways for routine management of Covid-19 patients at high risk of severe illness will likely predominate in a post-PHE setting. However, the federal government has provided limited guidance in Medicare or other federal programs about expectations for strengthening and sustaining such care pathways, especially beyond the PHE. Medicare and public and private health plans are providing free access to tests (including rapid at-home tests and molecular tests) during the PHE, and health plans are required to cover many of the Covid-19 therapeutics with no or limited copays, but requirements after the PHE are unclear. Nor are health plans or providers who could support Test to Treat initiatives reporting data consistently on how these pathways are being implemented.

Uncertainty about adoption of Test to Treat pathways is compounded by uncertainty about the continued availability of federally supported procurement and distribution of therapeutics, vaccines, and testing supplies during and beyond the PHE, including for potential surges. Congress has debated whether, and at what level, to approve these additional funds, which are instrumental to maintaining our current Covid-19 therapeutic

armamentarium. Recent bipartisan legislative activities have focused on \$5 billion in domestic supplemental funding for therapeutics pending further action. Without reliable access to federal funding for continued procurement, access to these treatments will depend on the limited and uneven capacity of individual state public health procurement and public and private payers to fill the gaps and ensure sustainability.

Perhaps the most precarious aspect of Test to Treat initiatives is a lack of clarity for what happens when the federal PHE is no longer in effect. States, health systems, and health plans need ample time and clarity to prepare for what will potentially be a major change in authorities

and supports for Test to Treat. **Post-PHE procurement and payment policies across Medicare, Medicaid, and the private sector are not clear.**

This issue brief describes priorities for a US therapeutic strategy to contain Covid-19, including clear policy guidance to: ensure an adequate supply of therapeutics to respond to demand surges; maximize the use of effective care pathways; and address payment challenges and other barriers to the long-term sustainability of Test to Treat approaches, during and especially beyond the PHE.

Improving Guidance on Covid-19 Therapeutic Deployment and Use

To support continued and effective planning for Covid-19 therapeutic distribution, states and health care organizations need clear communication about treatment guidelines for patients testing positive for Covid-19. As of May 2022, the National Institutes of Health (NIH) Covid-19 Treatment Guidelines Panel provides a [broad overview](#) of preferred treatments for non-hospitalized adults not requiring hospitalization or supplemental oxygen (see the [Appendix](#)). This guidance describes Paxlovid and Veklury as higher in the order of preferential use than bebtelovimab and Lagevrio. Additionally, the Centers for Disease Control and Prevention (CDC) maintains a [list](#) of high-risk, underlying conditions that inform eligibility, dosing, and other medication adjustments required with certain therapeutics like oral antiviral drugs. In response to confusion among providers surrounding patient eligibility for Paxlovid, FDA published a [screening checklist tool](#) for prescribers to complete with a color-coded table list of contraindicated drugs.

While such guidance from the NIH panel is helpful, it has important limitations that impact education and outreach to health care workers. For example, the treatment guidance lacks actionable steps for matching therapeutics to patients based on clinical assessment, and it does not include the updated option for use of Paxlovid

[announced](#) by the FDA in mid-April 2022, for patients with renal impairment, for whom lower doses are appropriate. Further, the guidance layout is problematic for planning a patient pathway that reflects individualized treatment criteria. The World Health Organization (WHO), for example, provides a user-friendly, centralized [webpage](#), outline, and [interactive tool](#) for patient recommendations. The Infectious Diseases Society of America (IDSA) also has developed a clear [outpatient treatment roadmap](#) giving providers step-by-step directions for treatment selection. The US Department of Health & Human Services (HHS) Therapeutics Team and Assistant Secretary for Preparedness and Response (ASPR) have compiled a [table](#) summarizing key information on therapeutics—importantly, up-to-date dosage for patients with renal impairment is included. All three of these examples are included in the Appendix to this issue brief.

While the treatment guidance resources provided by NIH, WHO, IDSA, and ASPR are helpful, significant gaps in clinical practice and treatment awareness among patients remain. A variety of educational methods is needed to reach providers, recognizing the difficulty of changing established clinical practice. The [Project ECHO model](#), professional association communications, practitioner workshops, and other practical methods to inform and support frontline clinicians could help with implementation of clinical guidance, but would need to be integrated into busy clinical practices and health systems.

In addition to refining guidance for health care workers, actions are needed for raising awareness among the public on the availability and the importance of timely use of Covid-19 treatments. Increased awareness can encourage patients who are at higher risk for severe Covid-19 illness to seek timely treatment. Some states and localities, for example New York City, have [conducted public service campaigns and provided help lines](#) to improve awareness. Another step for connecting patients with guidance about treatment would be to provide a link to or copy of the guidance with at-home antigen tests, including those provided through government and health insurers.

While Covid-19 therapeutics are in excess supply now, it is possible that with increased uptake, a future surge, or a diminution of supply, availability may be constrained relative to demand, as was the case during the winter 2021-2022 Omicron surge. In preparing for therapeutic implementation resource shortages, states and health system leaders must plan for patient prioritization strategies with HHS resources needed for further guidance. Patient prioritization for treatment has been an ongoing, contentious discussion since Covid-19

therapies became available. During previous case surges, state and health systems leaders adopted prioritization criteria influenced by the tiered [risk stratification](#) produced by the NIH Covid-19 Treatment Guidelines Panel, focusing on age, vaccination status, immune status, and clinical risk factors (**Table 1**). Such prioritization should be kept up to date with the latest evidence.

Guidance on therapeutics will benefit from the development of further evidence on factors that affect benefits and risks from oral antivirals, mAbs, intravenous antivirals, or some combination of treatments. For example, [recent evidence](#) suggests that if current guidelines are followed, approximately 18 patients for whom Paxlovid is indicated would need to be treated in order to prevent one hospitalization. However, real-world use of Paxlovid potentially could refine these estimates to assess the impact of new variants on hospitalization risk reduction and to refine understanding of the impact of patient characteristics and timing. Evidence on the appropriate use of combinations of therapies is further limited.

Table 1: Patient Prioritization for Treatment

Tier	Risk Group
1	Immunocompromised individuals—regardless of vaccination status—not expected to mount an adequate immune response to Covid-19 vaccination or SARS-CoV-2 infection Unvaccinated individuals—aged ≥75 years or aged ≥65 years with additional risk factors—at highest risk of severe Covid-19 illness
2	Unvaccinated individuals not in Tier 1— aged ≥65 years or aged <65 years with clinical risk factors—at risk for severe Covid-19 illness
3	Vaccinated individuals—aged ≥75 years, aged ≥65 years with clinical risk factors, or not having received a Covid-19 vaccine booster dose—at high risk of severe Covid-19 illness
4	Vaccinated individuals—aged ≥65 years, aged <65 years with clinical risk factors, or not having received a Covid-19 vaccine booster dose—at risk for severe disease

Source: [NIH Covid-19 Treatment Guidelines Panel](#)

Recommendation: Improve Guidelines and Foster Evidence Development

- Improve evidence and guidance on deploying antiviral treatments, including monoclonal antibody (mAb) and oral treatments, with practical and [equitable considerations](#) for access.
- Support education and outreach efforts to health care workers and to the public to ensure that individuals at high risk of severe Covid-19 illness, and particularly those who have tested positive using at-home antigen tests, know both that they are eligible for and encouraged to receive treatment as well as where they can receive treatments.
- Identify and, in case of future supply or access constraints, prioritize patient populations or subgroups who experience high risk of severe Covid-19 illness and would benefit most from therapeutics.
- Communicate with state and health system leaders the anticipated allocations of therapeutic products and availability of timely testing to enable planning for reliable pathways.

Maintaining Stable Financing for Predictable Access to Priority Covid-19 Therapeutics

Federal advance procurement has been essential in providing access to Covid-19 therapeutics. Continued use of such advance purchase agreements, beyond the PHE, will likely remain critical for ensuring adequate supply to meet demand and for ensuring that sufficient reserve is available for surges. Advanced procurement will enable continued clarity with state and local public health officials, health care providers, and payers regarding the availability of treatments—including fostering clearer public planning and communication around reliable testing and treatment strategies. Advance procurement also will allow for advance planning for future surge response and encourage pharmaceutical companies to develop up-to-date mAb treatments that remain effective against emerging variants and to pursue innovative research and development of treatments against other novel infectious diseases. Innovative research may include antivirals, with mechanisms of action that differ from those available today, to provide stronger protection against variants that pierce immunity from current vaccines and infections. It should also include research on treatments that could be effective against a much broader range of coronaviruses.

Long-term commitments to federal advance procurement will facilitate a “warm base” of reliable, ongoing manufacturing operations—a key bipartisan priority for US preparedness for future public health emergencies. Finally, pharmaceutical companies cannot market products authorized for emergency use. Given that important treatments for early-stage Covid-19 patients have no short-term path to full approval, government purchases may be needed beyond the PHE to foster continued development and manufacturing of treatments by pharmaceutical companies.

As previously noted, Congress has already demonstrated bipartisan interest in providing continued financial support for sufficient therapeutic supply. The \$5 billion commitment to treatments—as part of negotiations on a larger \$10 billion Covid-19 response appropriation—is necessary to provide sufficient funding for mAb and existing oral therapeutic availability and access for the rest of 2022, unless there is a major surge. The funding would allow for Test to Treat and other administration sites to continue receiving replenishments of mAb and oral antiviral treatments. Specifically, supplemental funding will likely be needed to [secure the second order](#) of 10 million Paxlovid courses. Additionally, the federal government would be able to [exercise an option](#) to purchase an additional 500,000 doses of bebtelovimab. It also would support the development of next-generation treatments. These efforts are a critical foundation for further steps to make available effective Test to Treat pathways.

Recommendation: Maintain Stable Financing for Predictable Access to Priority Covid-19 Therapeutics

- Procure testing and treatments for adequate supply in advance of widespread case surges and facilitate rapid, broad distribution. Federal funding for reliable availability of tests and mAb and antiviral Covid-19 treatments will enable effective health care and public health planning around Test to Treat strategies and help protect against variants that pierce immunity or develop resistance to current therapies.
- Provide federal funding for advanced research and development of novel infectious disease therapeutics.
- Maintain a “warm capacity” for adequate manufacturing if a major surge requires additional therapeutics and to support future U.S. pandemic preparedness.
- Conduct ongoing assessment of adequacy of advance purchase funding. In particular, an investment of at least \$5 billion in advance purchases and further treatment development is necessary to provide sufficient supply to support reliable availability of Test to Treat pathways for the remainder of this year. While conditions may change, continued federal funding for emergency use therapies will likely be required to ensure sufficient access to limit Covid-19 public health impacts after the PHE.

Achieving Effective, Widely Available Test to Treat Care Pathways

There is no “one size fits all” Test to Treat model, with different parts of US health care delivery and public health contributing in key ways to pathways for diverse patients. Additional integrated Test to Treat centers have been established during the PHE, providing timely and effective access for some patients while special funding during the PHE is available. But more generally, testing can occur in multiple settings (including at home), clinicians in a wide range of settings can oversee appropriate prescribing with any needed medication adjustments, and pharmacies (for oral therapies) and infusion facilities (for intravenous therapies) can provide timely access to treatment and help monitor any short-term complications and drug interactions. Moreover, the Test to Treat paradigm should become more prevalent in US health care, with rapid tests and effective therapies now available for all major respiratory illnesses and a growing number of chronic diseases.

The challenge is that the essential elements of effective testing and treatment for Covid-19 are not widely and consistently coordinated into clear and accessible pathways for diverse patient populations--Medicare, Medicaid, commercial insurance, and uninsured--who

often face financial and logistical barriers to timely care.

Pathways that state and health system leaders implement must recognize all of these populations and reflect the diversity of patient journeys due to unique risk factors, patient needs, barriers to access, or health care settings in which patients receive services. While federal PHE aid is likely to recede, there are still important policy steps that the federal government could take to facilitate implementation of these reliable pathways.

Patients must receive therapeutics within five or seven days of symptom onset, with earlier treatment preferred. Co-located or fully coordinated pathways reduce friction between steps as patients move from symptoms or exposure to timely testing, assessment, and therapeutic access.

The public health and health care approaches may complement one another.

For example, more robust pathways supported by a patient’s health plan and usual health care providers can reduce the need for and cost of public health measures to augment access---so that public health measures could focus on the uninsured and those without established primary care access. Adjustments to account for the expiration of the PHE will be needed.

The overall goal is to provide reliable, timely pathways for all types of patients at elevated risk of severe Covid-19 illness to receive treatment when appropriate. Reducing

barriers that may prevent patients from moving through steps in these pathways efficiently will reduce disparities in access further. Education initiatives and new Test to Treat community partnerships generally rely on public health resources for sustainability. Health care providers

and payers also can take steps to ensure effective pathways for their at-risk patients. Supporting policies can have an important impact on each step in the pathway.

Recommendation: Ensure Widely-Available Test to Treat Care Pathways

- Develop public health educational campaigns and information resources that can rapidly connect patients to testing and Test to Treat locations.
- Implement health plan- and health care provider-driven outreach programs and reliable Test to Treat pathways for at-risk patients, and plans to expand these programs in response to surging case rates to avoid hospitalizations.
- Prioritize sustainable funding for Test to Treat services that improve access in underserved areas and for uninsured patients.
- Generate further evidence on best practices to implement and flexibly scale testing and treatment capacity to ensure continued availability and access for treatments during surges, and to support and coordinate their adoption at the regional and state levels.

Addressing Payment Policy Barriers to Testing and Therapeutic Access

Sustained support for Test to Treat approaches also must include sustainable payment mechanisms that enable both uptake among populations at highest risk of severe Covid-19 illness as well as the ability to deliver testing and therapeutics efficiently. This support will require additional action by federal and state policy makers and health plans.

As we have noted, reliable access to tests and treatments is a foundation for effective planning, with further action needed to ensure reliable supplies. There is potential bipartisan support for funding significant advance purchases of rapid tests for use in high-risk settings, and the development and procurement of therapeutics. Coverage requirements without copays for insured patients for rapid and molecular tests has augmented access from public purchases. But that is also expected to end following the expiration of the PHE. Moreover, pending bipartisan legislation includes little additional public health funding or other support for the effective

deployment and use of tests and treatments, and does not address provider reimbursement for testing and treatment of uninsured patients. Federal funding to pay for testing services for uninsured individuals [expired](#) in March 2022, and many states have closed or cut back on free testing centers.

Many physician groups and health systems, Medicare accountable care organizations (ACOs), FQHCs, VA providers, and other health providers have implemented mechanisms to identify and engage their patients at high risk of severe Covid-19 illness, and then to support and track their completion of timely testing and treatment. Some health plans also are expanding access to oral antivirals procured by the government through online physician prescribing and home delivery, at least for some higher risk patients. These programs demonstrate that payment reforms can help expand and sustain reliable Test to Treat capabilities. Coupled with public health funding for Test to Treat sites that are accessible to individuals without insurance or an established

primary care relationship, health care payments and coverage requirements could help ensure appropriate and expanded access to testing and treatment.

Addressing Access and Reimbursement Challenges in Pharmacy Settings

Pharmacies have played a key role in expanding testing and therapeutic access during the Covid-19 pandemic, with pharmacists playing a critical role not just in delivering Covid-19 therapeutics but also in [prescribing](#) certain tests, treatments, and vaccines. However, current [regulatory authorization](#) for Covid-19 oral antivirals limits the ability to prescribe therapies for mild-to-moderate Covid-19 patients to physicians, advanced practice registered nurses, and physician assistants licensed and authorized under state law due to concerns around drug-drug interactions and safety concerns among specific populations, such as pregnant people. At the same time, many primary care providers have limited early familiarity and comfort with prescribing guidelines for Paxlovid and other therapies. Consequently, effective coordination between pharmacists and prescribers could help improve access to Covid-19 therapies.

However, Covid-19 oral antiviral therapies are currently purchased by the government and are available free of cost to the pharmacist, resulting in low dispensing fees that are often inadequate for covering costs related to onboarding new patients; reviewing a patient's eligibility, complex drug interactions, and medical history; and other considerations for safely prescribing oral antivirals. According to the American Pharmacists Association, soon after oral therapies were authorized pharmacists spent an average of 45 minutes to dispense Covid-19 antiviral prescriptions, while dispensing fees [ranged](#) from \$1 to \$10.50. Inadequate reimbursement led to many community pharmacies opting out of early distribution of oral antiviral treatments, reducing the availability of antiviral drugs in some areas.

The Centers for Medicare & Medicaid Services (CMS) has recommended previously that pharmacy benefit managers pay dispensing fees that are “sufficient to ensure eligible patients can readily access these drugs at available pharmacies.” CMS should review whether Test to Treat access is meeting its pharmacy access standards. **If evidence continues to suggest that nearby access to timely antivirals remains**

limited due to pharmacists not participating with current rates, CMS and health plans could implement a range of reforms to improve pharmacist reimbursement. For example, clarifying penalties or consequences for failing to meet minimum access standards (i.e., availability of antiviral prescribing and dispensing at a level that meets pharmacy network standards) could help promote adequate pricing and other payment reforms for wider availability in a pharmacy setting. CMS also could update billing codes for compensation through a Medication Therapy Management program to include Covid-19 antivirals. Medicare Part D plans are not required to pay pharmacists for patient assessment services related to oral antivirals. CMS can outline clearly what services—patient counseling, referral, and assessment—should be covered.

CMS and other payers also could establish performance measures and quality bonuses related to the timely use of therapeutics in higher-risk patients, as CMS has done for other priority opportunities for quality improvement. These steps could include an expansion of allowed diagnoses for Medicare care coordination payments to include billing for Test to Treat coordination services; attestation to the availability of a Test to Treat referral system for a primary care physician's patients; a measure of the rate of timely treatment in Covid-19 patients at high risk of severe illness treated by the physician or health care organization; and/or a Medicare Shared Savings Program or Medicare Advantage STARS measure related to timely use of treatment in high-risk patients.

Insurer Coverage and Payment for Testing and Therapeutic Access Beyond the Public Health Emergency

As previously described, the tests and therapeutics in widespread use for early-stage Covid-19 patients are currently purchased by the federal government and distributed free of cost, with health care payers responsible for reimbursement of fees for diagnostic and administrative services. But it is not clear that such an approach will continue for the remainder of the PHE, or beyond it. The shift could have two consequences, both of which would likely reduce access and impede planning and preparedness for further outbreaks. First, if federal advance purchase arrangements diminish, supplies will decline. With the exception of Veklury, early therapeutics are authorized for emergency use

and not fully FDA-approved, which will limit purchasing and use by private entities. While some states are making purchase commitments, these purchases may compete with each other in the event of a surge and limited supply, and state preparedness planning for Test to Treat capabilities depends on reliable estimates of the supply and costs of tests and treatments. Second, copays are likely to increase for tests and therapeutics in the absence of continuing federal coverage requirements after the PHE, which will significantly reduce utilization.

The very low reported uptake of Veklury use in early-stage Covid-19 demonstrates that such cost-sharing for Covid-19 therapeutics may have significant impacts on equity and access, with consequences for avoiding future Covid-19 hospitalizations and managing surges. There is no federal advance purchase arrangement for this FDA-approved drug. Instead, Veklury is reimbursed at an Average Sales Price (ASP) of \$2200 plus administration fee for the full three-day patient course of treatment—for Medicare beneficiaries, typically with the statutory 20 percent Part B copay plus administration fee. The associated uptake of Veklury is very low, as a result of the substantial out-of-pocket price along with the associated three-day infusion process.

During the PHE, CMS is paying for Covid-19 mAb treatments as a “treatment vaccine,” a reimbursement construction to enable CMS to provide coverage with a meaningful provider administration fee (despite the zero cost of the mAb to the provider) and without a copayment. CMS has stated that it will begin paying providers of mAb treatments for Covid-19 under the same Part B mechanism as is done for other mAb [products](#), effective January 1 the year after the PHE ends. The consequences for reduced utilization and limited use in the event of a Covid-19 surge would likely be substantial.

For oral antivirals, CMS has [recommended but not required](#) that Part D plans provide coverage, even though the definition of a Part D covered drug includes approved therapies and not those with emergency authorization, complicating CMS authority to require coverage. Yet the individual and public health benefits of effective use of oral Covid-19 therapies will remain after the PHE ends.

Health care providers and payers need to take further steps now to ensure the availability of reliable and equitable Test to Treat care pathways for high-risk patients, supported by aligned payments and other steps to increase effective health care provider participation in appropriate access to Covid-19 therapeutics.

Even after the PHE, there is a public health risk from cases that progress to hospitalization or worse, especially in the event of a future surge resulting from a new variant or declining immunity. These steps should include requirements for evidence-based Test to Treat coverage in Medicare and commercial insurance plans with low or no copayments for patients at high risk of severe Covid-19 illness.

Without further steps to clarify substantial ongoing coverage of the elements of Covid-19 Test to Treat pathways, and payment incentives to encourage and support appropriate testing and treatment in patients at high risk of severe Covid-19 illness, Test to Treat strategies are unlikely to be widely or consistently available following the PHE.

These steps should address access to testing, provide appropriate and timely use of oral and intravenous therapeutics, and enable tracking of how widely Test to Treat programs continue to be implemented. In addition, some continued public health funding is needed for patients who are not insured, underinsured, or have a health plan that does not cover the evaluation and prescribing costs.

Recommendation: Clarify Insurer Coverage and Payment for Test to Treat Beyond the PHE

- Clarify coverage and payment for Test to Treat in Medicare to promote affordability, availability, and equitable access of treatments and testing for patients at elevated risk of severe Covid-19 illness. These include requiring Medicare to cover Test to Treat care pathway services after the PHE.
- Require Medicare and private health insurance plans to cover and limit cost-sharing for evidence-based Test to Treat care pathway services—to promote affordability, availability, and equitable access of authorized testing and treatment for patients at elevated risk of severe Covid-19 illness.
- Establish payment incentives for coordination of testing, assessment, and treatment services that encourage the development and sustainability of Test to Treat pathways.
- Provide incentive payments for timely use of Covid-19 therapeutics in patients at high risk of severe Covid-19 illness.
- Provide funding for testing and treatments for patients without insurance.

Conclusion

Test to Treat strategies are a key element of enabling Covid-19 containment in the United States, both to save lives and prevent further disruptions from new variants or surges. But fulfilling this promise requires additional steps by the federal government to improve evidence-based guidance on testing and treatment, continuing federal procurement support to assure adequate supplies, further steps by health care and public health organizations to implement reliable care pathways for diverse patient populations, and additional payment reforms to sustain these new capabilities. These further actions by Congress and by federal, state, payer, and health system leaders are needed not just now but to prepare for long-term Covid-19 containment after the PHE. Viral variants and immunity will continue to evolve, but adequate ongoing support for testing and treatment will help ensure that potential Covid-19 surges will not lead to inequitable outcomes and major disruptions. Implementing Test to Treat strategies effectively provides a foundation for a health care and public health system that better incorporates new biomedical capabilities to contain outbreaks, and is capable of delivering care that is far more resilient to future infectious disease threats.

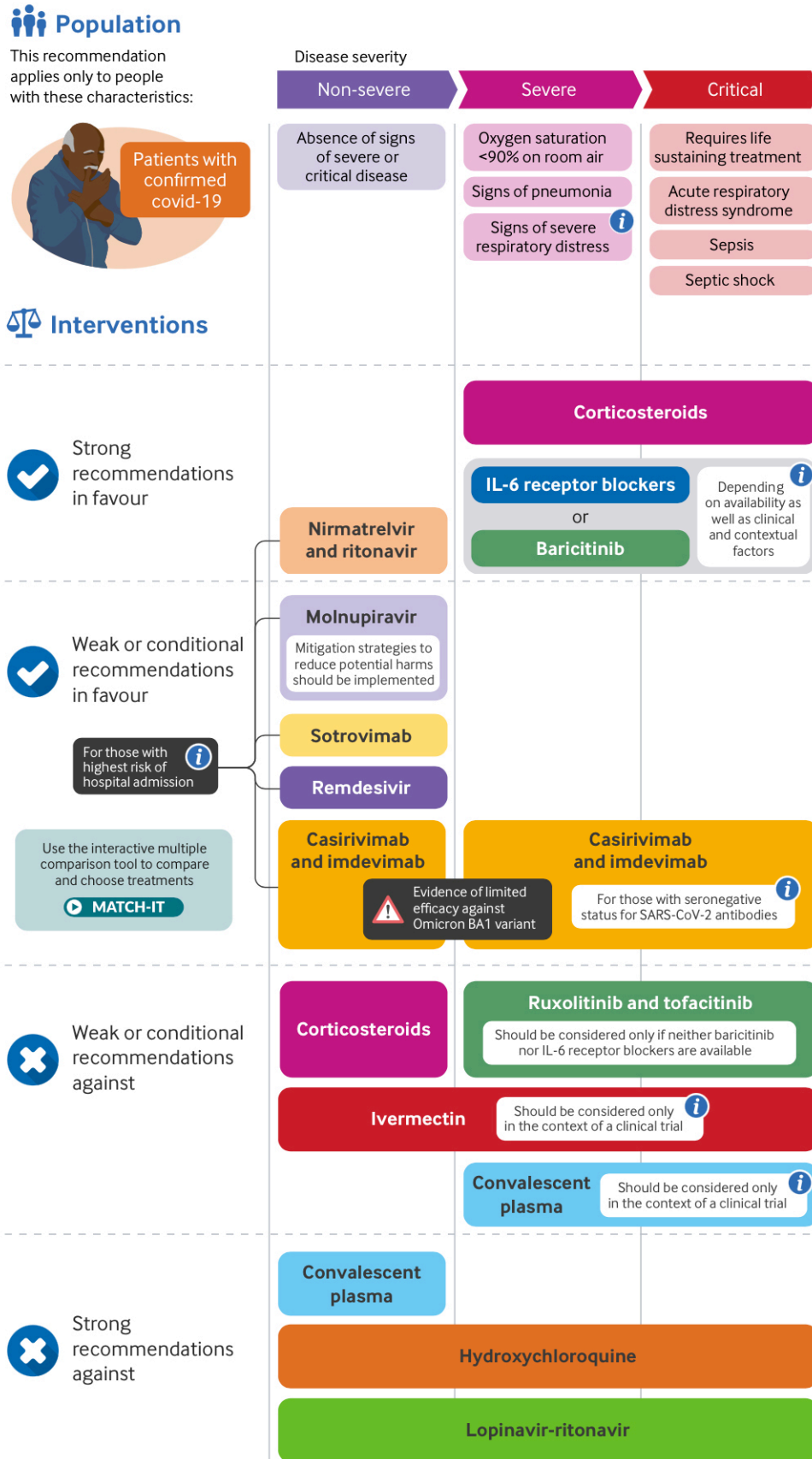
Appendix

Figure 1. Overview of Treatment Recommendations for Non-Hospitalized Adults

PATIENT DISPOSITION	PANEL'S RECOMMENDATIONS
<p>Does Not Require Hospitalization or Supplemental Oxygen</p>	<p>All patients should be offered symptomatic management (AIII).</p> <p>For patients who are at high risk of progressing to severe COVID-19,^a use 1 of the following treatment options:</p> <p>Preferred Therapies <i>Listed in order of preference:</i></p> <ul style="list-style-type: none"> • Ritonavir-boosted nirmatrelvir (Paxlovid)^{b,c} (AIIa) • Remdesivir^{c,d} (BIIa) <p>Alternative Therapies <i>For use <u>ONLY</u> when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:</i></p> <ul style="list-style-type: none"> • Bebtelovimab^e (CIII) • Molnupiravir^{c,f} (CIIa) <p>The Panel recommends against the use of dexamethasone^g or other systemic corticosteroids in the absence of another indication (AIII).</p>
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Weak Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>	

Adapted from: [NIH Covid-19 Treatment Guidelines Panel](#)

Figure 2. A Living WHO Guideline on Drugs for Covid-19



Source: [The British Medical Journal](#)

Figure 3. Covid-19 Outpatient Treatment Guidelines Roadmap

Last Updated: May 3, 2022

This resource is intended to serve as a guide on available outpatient COVID-19 treatment options, with links to FDA Emergency Use Authorization information and guideline recommendations from national guideline-developing organizations, where available. **It is not intended to endorse or otherwise promote a specific clinical recommendation or course of action.** Additionally, it does not include other forms of guidance that may be available for specific subsets of populations. Finally, the guidelines referenced here may not consider local allocation and availability of scarce resources. Additional information on where to access these therapeutics can be found at the [National Infusion Center Association](#)¹⁶ and [HHS](#).¹²

Risk factors for severe COVID-19¹¹

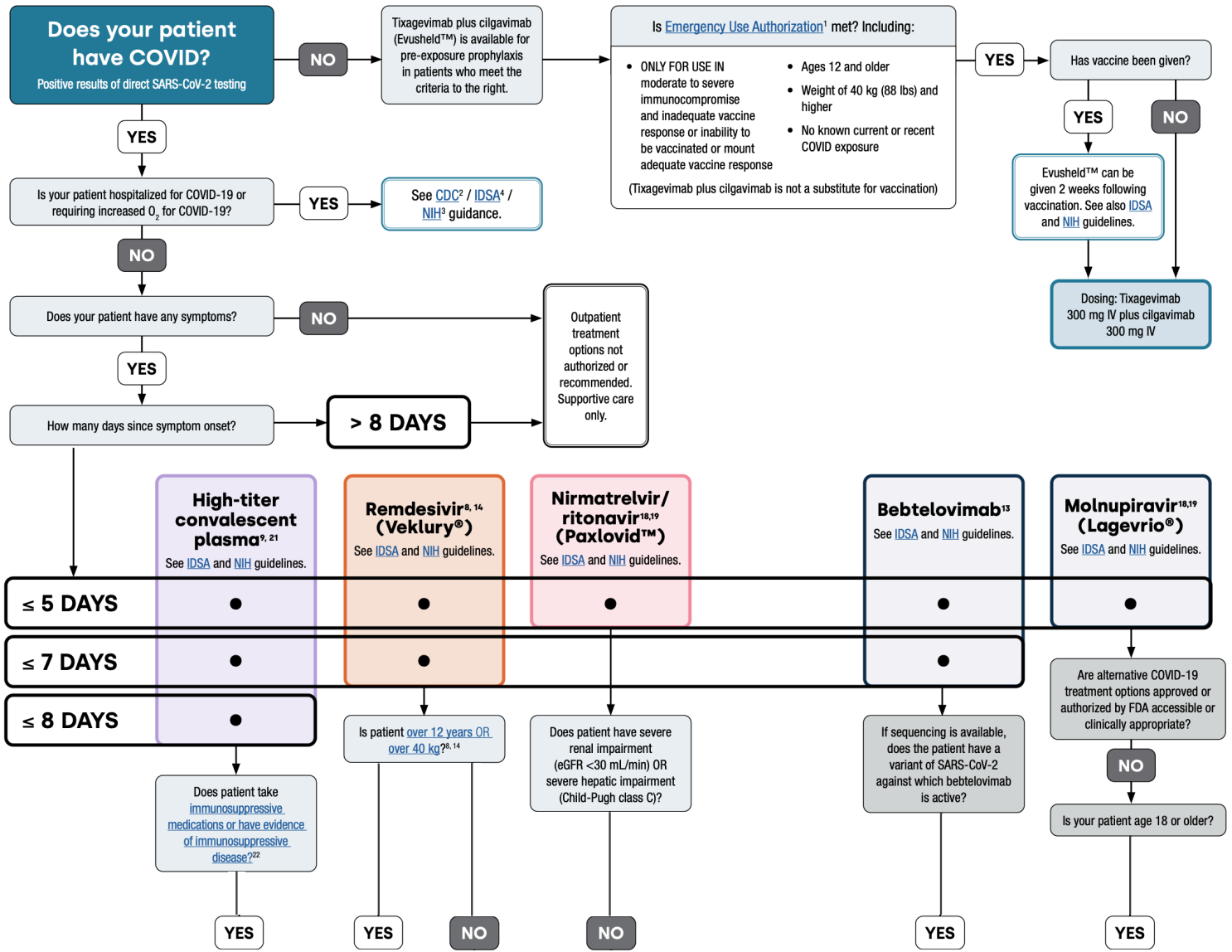
Included here are some [medical conditions](#) that may place patients at a higher risk for progression to severe COVID-19:

- Age 65 years and older
- BMI of more than 25 kg/m²
- Pregnancy
- Chronic kidney disease
- Diabetes mellitus
- Immunosuppressing medications
- Cardiovascular disease or hypertension
- Chronic lung disease
- Sickle cell disease
- Neurodevelopmental disorders or conditions that confer medical complexity
- Medical technological dependence, e.g., tracheostomy

When giving products under Emergency Use Authorization, providers must:

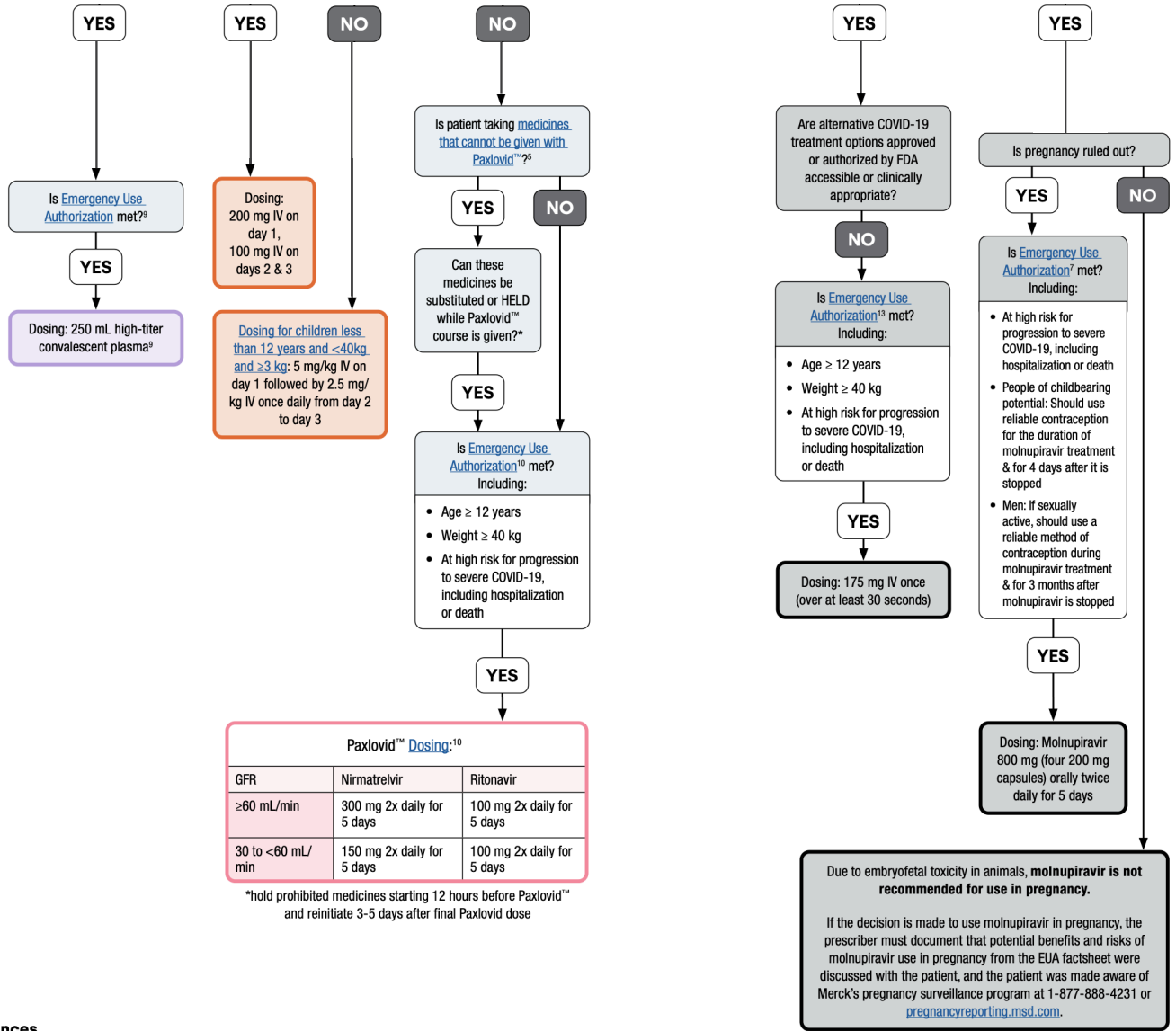
1. Give patient fact sheet for patients.
2. Inform patient of alternatives to treatment.
3. Inform patient that this is an unapproved drug.

Options depicted in gray should be considered AFTER other options, if other options are unavailable, or only in certain clinical situations.



Continued on next page

Figure 3. Covid-19 Outpatient Treatment Guidelines Roadmap



Paxlovid™ Dosing: ¹⁰		
GFR	Nirmatrelvir	Ritonavir
≥60 mL/min	300 mg 2x daily for 5 days	100 mg 2x daily for 5 days
30 to <60 mL/min	150 mg 2x daily for 5 days	100 mg 2x daily for 5 days

*hold prohibited medicines starting 12 hours before Paxlovid™ and reinstate 3-5 days after final Paxlovid dose

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3. NIH guidelines: [COVID-19 Treatment Guidelines \(nih.gov\)](https://www.nih.gov/health-topics/covid-19-treatment-guidelines)
4. IDSA guidelines: [IDSA Guidelines on the Treatment and Management of Patients with COVID-19 \(idsociety.org\)](https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/)
5. NIH Guidelines Panel's Statement on Drug Interactions with Paxlovid: [Statement on Paxlovid Drug-Drug Interactions | COVID-19 Treatment Guidelines \(nih.gov\)](https://www.nih.gov/health-topics/covid-19-treatment-guidelines)
6. Sotrovimab EUA fact sheet: [SOTROVIMAB-EUA.PDF \(gskpro.com\)](https://www.fda.gov/oc/ohrt/sotrovimab)
7. Molnupiravir EUA fact sheet: [FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR MOLNUPIRAVIR \(fda.gov\)](https://www.fda.gov/oc/ohrt/molnupiravir)
8. Remdesivir (Veklury™) Package Insert (Prescribing Information) with the extended approval for outpatient use: [veklury_pi.pdf \(gilead.com\)](https://www.fda.gov/oc/ohrt/remdesivir)
9. Convalescent Plasma EUA fact sheet and List of Tests and Cutoffs of High Titers (table on page 9): <https://www.fda.gov/media/141477/download>
10. Paxlovid EUA Fact Sheet for Healthcare Providers: <https://www.fda.gov/media/155050/download>
11. CDC List of Medical Conditions with risk of progression to severe COVID-19: Patient-directed format: [People with Certain Medical Conditions | CDC Healthcare provider format: Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers \(cdc.gov\)](https://www.cdc.gov/media/releases/2020/s1105-covid-19-treatment.html)
12. HHS Therapeutics Locator: [COVID-19 Therapeutics Locator \(arcgis.com\)](https://www.arcgis.com)
13. Bebtelovimab EUA fact sheet: [Fact Sheet for Healthcare Providers: Emergency Use Authorization for Bebtelovimab](https://www.fda.gov/oc/ohrt/bebtelovimab)
14. Remdesivir EUA fact sheet for use in CHILDREN weighing 3.5 kg to <40 kg OR those less than 12 years old weighing at least 3.5 kg, who are NOT HOSPITALIZED: [EUA 046 Veklury \(remdesivir\) FS for HCPs \(01212022\) \(fda.gov\)](https://www.fda.gov/oc/ohrt/remdesivir)
15. Combat COVID Website on Treatment Options: [COVID-19 Resources For Healthcare Providers | combatCOVID.hhs.gov](https://www.combatCOVID.hhs.gov)
16. National Infusion Center Association Website: [National Infusion Center Association. Relates to the Access and Availability link.](https://www.nationalinfusioncenter.org)
17. FDA CDER Scientific Review Documents for COVID-19 Related EUAs: [CDER Scientific Review Documents Supporting Emergency Use Authorizations for Drug and Biological Therapeutic Products | COVID-19 | FDA](https://www.fda.gov/oc/ohrt/cder-scientific-review-documents)
18. University of Liverpool COVID-19 Drug Interactions Page: https://www.covid19-druginteractions.org/prescribing_resources
19. NIH guidance on therapies for high-risk non-hospitalized patients: [https://www.nih.gov/health-topics/covid-19-treatment-guidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/](https://www.nih.gov/health-topics/covid-19-treatment-guidelines)
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Original publication available online at <https://www.idsociety.org/globalassets/covid-19-real-time-learning-network/outpatientroadmap-v10.pdf>

Figure 4. Summary Table of Authorized or Approved Treatments for Mild-Moderate Covid-19

PRODUCT	MONOCLONAL ANTIBODIES (mAbs)		IV ANTIVIRALS	ORAL ANTIVIRALS	
	Preventative (PrEP)	Treatment	Treatment	Treatment	
	Evusheld (tixagevimab/cilgavimab)	bebtelovimab	Veklury (remdesivir)	Paxlovid (nirmatrelvir/ritonavir)	Lagevrio (molnupiravir)
Manufacturer	AstraZeneca Pharmaceuticals LP	Eli Lilly and Company	Gilead Sciences, Inc.	Pfizer, Inc.	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Product Websites	Evusheld website	bebtelovimab website	Veklury website	Paxlovid website	Lagevrio website
Package Insert	N/A	N/A	Veklury package insert	N/A	N/A
Fact Sheets for Healthcare Providers	Evusheld Healthcare Provider Fact Sheet	bebtelovimab Healthcare Provider Fact Sheet	Veklury Prescribing Information	Paxlovid Healthcare Provider Fact Sheet	Lagevrio Healthcare Provider Fact Sheet
Fact Sheets for Patients, Parents, and Caregivers (English)	Evusheld Patient Fact Sheet (English)	bebtelovimab Patient Fact Sheet (English)	Veklury Patient Information (English)	Paxlovid Patient Fact Sheet (English)	Lagevrio Patient Fact Sheet (English)
Fact Sheets for Patients, Parents, and Caregivers (Spanish)	Evusheld Patient Fact Sheet (Spanish)	bebtelovimab Patient Fact Sheet (Spanish)	N/A	Paxlovid Patient Fact Sheet (Spanish)	Lagevrio Patient Fact Sheet (Spanish)
Mechanism of Action	mAb against conserved epitope of spike protein; blocks viral entry	mAb against spike protein; blocks viral attachment to host cells	Nucleotide analog ribonucleic acid (RNA) polymerase inhibitor that halts viral replication	Viral protease inhibitor that halts viral replication	Nucleoside analog that inhibits viral replication by viral mutagenesis
Treatment Efficacy per Clinical Trials ²	77% reduction in developing symptomatic COVID-19	Symptomatic improvement and Day 5 reduction in viral load vs. placebo ³	87% reduction in hospitalizations/deaths ⁴	88% reduction in hospitalizations/deaths	30% reduction in hospitalizations/deaths
Activity Against SARS-CoV- 2 Variants ⁵	See Section 12.4 of Evusheld Healthcare Provider Fact Sheet	See Section 12.4 of bebtelovimab Healthcare Provider Fact Sheet	See Section 12.4 of Veklury package insert	See Section 12.4 of Paxlovid Healthcare Provider Fact Sheet	See Section 12.4 of Lagevrio Healthcare Provider Fact Sheet
Authorized Use(s)	Pre-exposure prophylaxis (PrEP)	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19

Source: [HHS Therapeutics Team](#)