Over-the-Counter COVID-19 Testing:
Insurance Coverage Strategies to Support Equitable Access

May 25, 2022

Duke | MARGOLIS CENTER *for* Health Policy

Authors

Katie Huber, Policy Analyst, Duke-Margolis Center for Health Policy
Thomas Roades, Policy Analyst, Duke-Margolis Center for Health Policy
Aparna Higgins, Senior Policy Fellow, Duke-Margolis Center for Health Policy
Mara Aspinall, Professor of Practice, Arizona State University
Christina Silcox, Research Director, Duke-Margolis Center for Health Policy
Mark McClellan, Director, Duke-Margolis Center for Health Policy

Acknowledgments

We would like to thank the diverse stakeholders who joined our January 2022 Duke-Margolis workshop and participated in informational calls for sharing their expertise. We also thank the Covid-19 Testing Strategies Group at Duke-Margolis; Jennifer Jones at the Blue Cross Blue Shield Association; Blue Cross and Blue Shield of Vermont; and the National Association of Medicaid Directors for their thought leadership and content assistance. We thank Patricia Green and Laura Hughes for their communication and design support.

Funding

This issue brief was funded by The Rockefeller Foundation.

Disclosures

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Mara Aspinall is an independent director on the public company boards of Abcam, Allscripts, Castle Biosciences, DA 32 and OraSure Technologies. She receives fees for serving as an advisor for The Rockefeller Foundation, and The Business Roundtable.

Aparna Higgins is founder of Ananya Health Solutions LLC and consults with private sector purchasers and think tanks on healthcare transformation. She also serves on the Board of PCPA and on the National Cardiovascular Disease Registry's Management Oversight Committee.

Duke | MARGOLIS CENTER *for* Health Policy

Executive Summary

Systematic, predictable, and equitable access to Covid-19 testing is essential for both successfully treating patients at risk of severe disease and slowing spread. At-home over-the-counter (OTC) tests are reliable tools for individuals to quickly and conveniently detect Covid-19, but their cost can be a deterrent to appropriate early testing. Starting January 15, 2022, the Biden Administration required private insurance plans to cover the full cost of eight OTC Covid-19 tests per enrollee per month for the duration of the Covid-19 Public Health Emergency (PHE). Medicare beneficiaries received similar coverage beginning in early April. This coverage of Covid-19 OTC tests could increase access to testing and help to break chains of transmission and reduce the spread of the virus, especially with the emergence of new variants, such as the Omicron BA.2 subvariant, that appear to be more infectious. The individual health benefits of timely, no-cost access to OTC tests could be especially important for individuals experiencing elevated risk of severe illness and mortality from Covid-19, including Medicare and Medicaid beneficiaries, as they could seek treatment sooner when current therapeutics are more effective.

The individual health benefits of timely, no-cost access to OTC tests could be especially important for individuals experiencing elevated risk of severe illness and mortality from Covid-19.

However, especially with the Covid-19 PHE potentially coming to an end later this year, there is no clear or widely accepted understanding of policies for how rapid OTC tests fit into the nation's longer-term strategy for controlling Covid-19. Health plans generally have not covered OTC tests, especially when used for surveillance and screening rather than diagnosis to facilitate treatment. President Biden's recent proposal for federal purchasing of tests raises questions about how new federal initiatives will complement or replace current coverage requirements, both during the Covid-19 PHE and potentially beyond it, when future Covid-19 cases and surges may still occur. With more widespread availability of effective oral and intravenous treatments, reliable and broad availability of timely Test to Treat care pathways for people at elevated risk of severe Covid-19 complications will be a key element in preventing future infections from translating into serious complications and health system impacts. There is potential bipartisan agreement on additional funding for the procurement of tests, treatments, and vaccines for some period beyond the PHE, but no agreement on funding for mechanisms to distribute the tests. Especially if Congress does not authorize broad ongoing funding for federal test purchases, and for widespread availability of Test to Treat capabilities through public health delivery sites, insurance coverage could be an important avenue for reliable access to tests and Test to Treat pathways. If federal and state governments plan to depend on continued insurance coverage of tests outside of the PHE, it will be necessary to develop guidance around coverage requirements, longer-term affordable access strategies, and educational plans on when to use these tests and how to understand and act on the results. Under the insurance coverage approach, important gaps in access to testing would remain for people who are uninsured as well as for any insured individuals who face unaffordable upfront costs for testing or treatment. With the growing availability of rapid diagnostic tests as well as effective but underused treatments for a range of infectious and chronic diseases, these issues of optimal insurance coverage related to rapid diagnostics and treatment pathways will arise in an increasing number of disease contexts in the future.

This report describes the challenges and potential solutions related to health plan coverage of OTC tests as a means of addressing the challenge of timely and appropriate Covid-19 testing access. It reflects findings from a private Duke-Margolis workshop in January 2022, and subsequent updates, regarding how plans, retailers, and other key stakeholders are implementing these policies. Key issues include:

- Addressing the absence of a unique billing code for covered OTC tests;
- Identifying alternatives to pharmacy-based solutions, such as direct to consumer shipping, to provide efficient and timely access to tests;
- Limiting workload for pharmacy staff, who already have increased responsibilities with Covid-19 testing and vaccination;
- Tracking quantity of tests covered or reimbursed across medical and pharmacy benefits;
- Ensuring access to tests when demand surges;
- Educating people on when to use tests and how to track and interpret results; and
- Reviewing policy options for efficient and equitable access to rapid OTC tests as part of implementing Test to Treat strategies for Covid-19.

We offer the following recommendations to address these issues:

- The Centers for Medicare & Medicaid Services (CMS) in collaboration with other federal agencies should provide clear guidance on whether and how OTC test coverage may extend beyond the Covid-19 PHE, so that plans and health systems can plan accordingly. If broad coverage of tests does not continue, some plans and Medicare may continue coverage to support Test to Treat access for high-risk enrollees who may benefit from treatment, and greater public health support will be needed to provide access to tests for people who are uninsured or have other barriers to access.
- CMS and/or the American Medical Association (AMA) should create a new, distinct Healthcare Common Procedure Coding System (HCPCS) or current procedural terminology (CPT) coding for OTC tests (separate from point-of-care and lab-based tests) for plans to use when processing claims for covered OTC tests.
- OTC test manufacturers and the U.S. Food and Drug Administration (FDA) should assign National Drug Codes (NDCs) for all covered OTC rapid tests and provide regulatory guidance on the use of standing orders to address billing issues.
- Plans should monitor utilization of OTC purchases to identify potential fraud and abuse, and CMS and other federal agencies should consider modifying their coverage guidance in response to significant problems. Employers, working with their pharmacy benefit managers, should also consider establishing systems to share data between the pharmacy benefit manager and the health plan to mitigate concerns about monitoring utilization.
- Alternative distribution processes could reduce the burden on retail pharmacies and improve access in areas with fewer pharmacies. One approach is for plans to offer and promote direct-to-consumer OTC test shipping methods. In addition, plans could work with retailers to move in-person no-cost test access to the "front of the store" instead of the pharmacy counter.
- Public health agencies should work with health plans to create guidance and educational campaigns with consistent yet culturally-responsive messaging to maximize the public health impact of OTC testing.
- Given the higher risks of severe Covid-19 illness in Medicare and Medicaid beneficiaries, CMS, states, and plans should work with test manufacturers to create tailored educational campaigns on the importance of testing and early treatment for individuals experiencing high risk of severe Covid-19 illness, and consider how to facilitate access to testing for these individuals after the PHE ends. CMS should also explore options that allow direct shipping or front-of-store purchases for Medicare and Medicaid beneficiaries.

- The U.S. Department of Health and Human Services (HHS) should continue supports or incentives for longer-term purchase agreements that reward reliability and ability to stockpile for surges, rather than short-term volume-based procurements alone, to ensure an efficient and adequate test supply.
- The Administration, with support from Congress, should provide more details about the expected scale of rapid testing supply, and its availability to augment test access for states and health plans in the event of shortages.
- The federal government should take steps to assist health plans and states to plan for and participate in advance purchase agreements to help lower costs and assure overall adequacy of supply.
- Complementary policy steps for efficient and equitable access to treatments are explored in our companion paper, *COVID-19 Test to Treat Pathways: Policy Options for Achieving National Implementation*.

With the development and increasing availability of OTC tests for Covid-19 and other major respiratory pathogens, there are significant opportunities to leverage the infrastructure and knowledge from the Covid-19 testing experience to reduce the burden of these pathogens in the long term. Federal public health authorities and health plans should continue to share experiences with the goal of supporting effective use of OTC tests to reduce transmission and the burden of hospitalizations and deaths from infectious diseases.

Background

On December 2, 2021, the Biden Administration announced a series of urgent actions to protect Americans against the Delta and Omicron variants of Covid-19. These initiatives included steps aiming to expand access to free, at-home rapid Covid-19 testing. Private health plans, covering roughly 150 million Americans, would be required to fully reimburse enrollees for at-home OTC Covid-19 tests authorized by the FDA. However, there were a number of concerns around the initial announcement. These included concerns about equity and administrative burden involved in typical "buy and bill" reimbursement methods, where enrollees need to fill out paperwork and wait to have their costs repaid. They also included concerns about potential fraud and abuse of this system if test purchases were unlimited and unmanaged, potentially reducing access to tests that were already in scarce supply due to increasing case rates.

On January 10, 2022, in response to such concerns and suggestions for addressing them, the Biden Administration released guidance requiring private insurance plans to cover the full cost of up to eight OTC Covid-19 tests per enrollee per month. A "safe harbor" provision was also announced that allowed plans that set up networks for enrollees to obtain tests with no upfront costs, and to limit reimbursement for tests purchased outside their network to a maximum of $12 per test. CMS and other federal agencies released follow-up guidance on February 4, 2022 that stated that plans will be generally required to offer "at least one direct-to-consumer shipping mechanism" and one in-person purchasing option in order to meet safe harbor requirements.

HHS and CMS also announced initiatives for Medicare coverage of eight OTC tests per beneficiary per month, as well as other initiatives to improve access to OTC tests for Americans with other or no insurance coverage.

In conjunction with the State of the Union address in early March 2022, President Biden announced a National Covid-19 Preparedness Plan for expanded and sustained federal support for timely access to testing. The plan includes additional multi-billion-dollar advanced procurement contracts (on top of the one billion tests procured thus far), plus additional support for test development. The goal is to bring down the cost of OTC tests, create a larger national stockpile, and assure broad availability of tests in the event of future surges. The tests have been distributed through postal service mail-order requests from U.S. households; through community sites in underserved areas; to high-risk congregate settings such as nursing homes, shelters, and correctional facilities; and as part of Test to Treat programs in pharmacy clinics, long-term care facilities, and Federally Qualified Health Centers (FQHCs), among other mechanisms.

However, the interactions of these new test procurement and distribution mechanisms with the health plan coverage requirement remain unclear, raising questions about the most efficient ways for health plans to procure tests and to plan reforms to encourage their appropriate and complementary use. In addition, some of the challenges listed below require longer term solutions and infrastructure that may not make sense if coverage requirements end with the PHE. CMS in collaboration with other federal agencies should provide clear guidance on whether and how OTC test coverage may extend beyond the Covid-19 PHE, so that plans and health systems can plan accordingly.

Short-Term Implementation Considerations for Private Health Plan Coverage

The following key challenges are affecting plans, retailers, and manufacturers in the implementation of OTC test coverage requirements:

Coding and Billing: Pharmacies and plans have experienced challenges submitting and processing claims. Submitting through the medical benefit requires a CPT code, and there is currently no CPT code for OTC Covid-19 tests. Plans have instead been using existing codes for POC antigen tests with a modifier indicating that the test was instead distributed OTC. But because POC tests are unlimited coverage, using this code makes limiting quantity of OTC tests difficult. Some plans may choose to use unrelated, rarely-used CPT codes as a workaround, but that has the potential to create confusion. CMS and/or the AMA should work quickly to create a new, distinct HCPCS or CPT code for OTC tests (a separate code than that used for point-of-care and lab-based tests) to alleviate these issues. This will allow plans to monitor usage and better understand if these tests are being used appropriately.

Other coding challenges are less universal but still can create challenges in setting up systems that allow individuals to get tests at the pharmacy counter without upfront costs. Submitting claims through the pharmacy benefit may require pharmacists to enter a prescription at the point of purchase. Some states allow "standing order" prescription codes for these OTC tests. For states that don't allow standing orders to be entered as a prescription, the requirement for entering an individual order is a challenge to getting tests at no upfront cost. Moreover, not all OTC tests have received an NDC. **Regulatory guidance on the use of standing orders would be beneficial, and all OTC tests should be assigned NDCs.**

Distribution Mechanisms: With plans and enrollees relying on established in-network pharmacies to quickly stand up a "no upfront cost" solution, people obtaining covered tests has added to the burden at the pharmacy counter. Since the start of the pandemic, pharmacies have taken on important new responsibilities to assist in stopping the spread – performing point-of-care testing and Covid-19 vaccinations, among others, and now have new responsibilities for providing timely treatment with oral Covid-19 therapeutics for patients who test positive and are at elevated risk of severe Covid-19 illness. In combination with nationwide staffing shortages, the pharmacy labor force continues to be stretched thin.

Alternative distribution processes could reduce the burden on retail pharmacies and improve access in areas with fewer pharmacies. One approach is for plans to offer and promote direct-to-consumer OTC test shipping methods. Ideally, direct-to-consumer shipping would be easy for enrollees to access, and bulk purchase orders administered by efficient distribution partners could keep costs down for plans while alleviating some of the burden on network pharmacies. Most United Healthcare commercial plans, for example, offer direct distribution via online ordering, with significant uptake among enrollees.

An alternative option is for plans to work with retailers to move in-person no-cost test access to the "front of store" instead of the pharmacy counter. This would reduce back-of-pharmacy burden and also make it easier for non-pharmacy, in-person retailers to participate "in-network." Paper vouchers or QR codes could potentially be implemented to support these

purchases, but there are multiple technical challenges that would need to be addressed to prevent abuse and link the purchase to a specific enrollee. Plans where enrollees have health savings accounts (HSAs) cards can already use HSA funds to purchase tests at the front of store, though enrollees may be responsible for providing appropriate documentation through the mail or specific online applications to be reimbursed. Some plans allow direct billing to HSAs and have applications to capture receipts or other necessary documentation. Plans that require reimbursement could set up systems for direct billing or reimbursement into HSA accounts. Again, investments associated with these activities are likely to be worthwhile only if plan OTC test coverage remains an important source of test access.

Enrollee and Provider Education: A continuing challenge throughout the pandemic is educating the public about testing – what test to use, when to use it, and how to act on the results, especially as the pandemic and testing capabilities evolve. A study published in JAMA Internal Medicine found "people who use at-home Covid-19 self-test kits may fail to self-quarantine or may quarantine unnecessarily because they misinterpret the implications of test results," suggesting that updating test instructions with information about how to respond to the results could improve tests' public health impact. **Public health agencies should work with health plans on guidance and educational campaigns with consistent yet culturally-responsive messaging to maximize the public health impact of OTC testing. This campaign should reflect the latest public health guidance on appropriate OTC test use.**

It is important to note that plans are not required to reimburse for tests taken because of employment or educational surveillance requirements. Individuals should test when they are experiencing heightened risk of infection, due to presence of symptoms, a known exposure, or a high statistical likelihood of an unreported exposure due to high numbers of contacts with people outside their household when community rates are high. The latter becomes more important as universal contact tracing is no longer recommended, and is a justification for requiring coverage of up to eight tests per month.

It is equally important to educate health care providers about how widespread rapid testing can influence overall testing strategy. For example, as described above, a confirmatory PCR test may be unnecessary for a patient who tests positive with a rapid test and also has symptoms and/or a known recent exposure. Especially in times when cases are high and PCR turn-around times are longer, it is important providers understand how to make efficient use of testing resources and avoid testing and delaying patient management unnecessarily. This becomes more important as antiviral treatments for people experiencing higher risk of severe illness, which are most effective within the first five days after symptom onset and as soon as possible after a confirmed test, are more widely available. Building in reporting mechanisms for OTC tests, such as Washington, D.C.'s online self-reporting tool, can provide more information to public health officials and policymakers determining strategy and offer an opportunity to provide those who test positive with information on isolating and seeking treatment.

Continued educational initiatives and "nudges" or other actions by plans, based on clear guidance from public health officials, can help promote effective use of these tests among enrollees and providers. Ideally, clear messages about appropriate use of OTC tests would be linked to clear communications about how particular types of individuals could access tests. Multiple channels of access are generally helpful, but can leave individuals uncertain about which ones apply to their circumstances.

Expanding Coverage to Medicare and Medicaid

Medicare: Until spring 2022, most Medicare beneficiaries received no coverage for OTC tests. Following an announcement in early February 2022, CMS launched an initiative in early April to allow all Medicare beneficiaries with Part B coverage, including through Traditional Medicare and Medicare Advantage, to access up to eight OTC Covid-19 tests per month at no cost during the PHE. CMS developed a pathway to allow Medicare to directly pay participating pharmacies and health care providers, allowing beneficiaries to access tests without out-of-pocket costs at the point of purchase. Participating pharmacies and health care providers bill Medicare directly for OTC tests, and Medicare pays a fixed national payment rate of $12 per test. Prior to and in addition to this initiative, reimbursement for Medicare Advantage beneficiaries varied by plan. Medicare Advantage beneficiaries in plans with OTC benefits may also be able to use the OTC benefit to cover some of the costs of OTC tests. For example, United Healthcare's Medicare Advantage members can use their OTC benefit to cover the cost of OTC tests. OTC benefit amounts, how they are implemented, and therefore the number of tests that can be covered, vary widely by plan.

The implementation issues described in the previous section likely apply to Medicare-covered tests. In addition, **it will be important to communicate how the Medicare population can access and should use these tests, given their higher risk of severe Covid-19 illness due to age and other factors. By the end of 2021, people ages 65 and older accounted for 12% of U.S. Covid-19 cases, but 76% of deaths. Educational initiatives should also focus on the importance of early treatment, and how to access it, for individuals experiencing high risk of severe Covid-19 illness to minimize the risk of hospitalization and death. Direct shipping options and information available by phone may be a useful to provide for Medicare beneficiaries, who may have less access to or familiarity with online purchasing.** Medicare beneficiaries can call 1-800-MEDICARE for more information about this initiative, and some participating pharmacies offer phone ordering of OTC tests.

Medicaid: In August 2021, CMS issued guidance requiring state Medicaid and Children's Health Insurance Program (CHIP) programs to cover OTC Covid-19 tests for beneficiaries with no cost sharing through the PHE under the American Rescue Plan Act. However, CMS allows states to condition coverage of OTC tests by imposing utilization management techniques, such as requiring individual prescriptions or imposing quantity limits or medical necessity criteria, to encourage appropriate use. While quantity limits in general can help prevent overuse or misuse of covered tests, excessively low limits and prescription requirements can delay diagnosis and therefore the start of antiviral therapeutics for individuals experiencing high risk of severe Covid-19 illness, and the differences in coverage can lead to consumer confusion.

With operational challenges in establishing coverage and timely access to OTC tests for Medicaid beneficiaries, and flexible guidance from CMS, variation has resulted across states. Some Medicaid programs are relying on pharmacy payment systems and prescription drug benefits for reimbursement, while others are categorizing OTC tests as durable medical equipment to cover them. Quantity limits also widely vary by state. For example, Medicaid plans in New York, California, North Carolina, and Illinois match guidance for Medicare and private insurance and require their Medicaid plans to cover up to eight OTC tests per member per month. The number of OTC tests covered per member per month varies in other states – for example, Colorado Medicaid covers 15 tests, Washington Medicaid covers 12 tests, Alabama and Texas Medicaid cover four tests, and Arizona Medicaid covers two tests. Some Medicaid programs, managed care organizations, and pharmacies are also exploring options for facilitating access to OTC tests through mail order. State requirements for individual prescriptions for Medicaid coverage of OTC tests have generally been dropped, removing a previous barrier to access. Some states, including North Carolina, Massachusetts, and Maine, issued standing orders to allow retail pharmacists to dispense covered OTC tests to Medicaid beneficiaries without individual prescriptions. Households with low incomes are experiencing higher risk of severe Covid-19 illness due to structural inequities, including a higher proportion of people working as essential workers, in high-contact jobs without access to paid sick leave, living in poor housing conditions, and

other conditions associated with increased risk of severe Covid-19 illness. There are also higher proportions of low-income and Medicaid eligible populations in medically underserved communities, where community testing sites may be less available as cases decrease. **Therefore, CMS and states should work to ease remaining access issues, particularly if long-term Medicaid coverage of OTC tests is expected and as states begin to wind down other public testing options. In addition, an educational campaign on access to treatments and the importance of getting tested and treated early is needed, and should build on prior outreach to populations experiencing high risk of severe Covid-19 illness.**

Multiple Initiatives to Expand Access to OTC Tests

Health plan OTC test coverage is part of a set of initiatives to expand access to OTC tests:

Direct ordering: HHS set up a direct mail opportunity for Americans to order free OTC tests through a U.S. Postal Service website, which enables each U.S. household to order two sets of up to four tests each, with potential further availability in the future. The Department of Defense also announced a program that provides access to eight free tests per month for military beneficiaries. These programs have benefitted from the federal government's ability to negotiate discounts, prioritize orders, and use existing distribution channels to reduce costs.

Provision through states: Some states, such as Ohio and Virginia, have set up access programs for free tests, often focusing on populations and communities experiencing higher risk of contracting Covid-19 or severe illness. In addition, in partnership with HHS and six pilot states, The Rockefeller Foundation has established Project Access Covid Tests (ACT) for individuals experiencing high risk of contracting Covid-19 to order OTC tests that are free to them. States can make aggregated purchases using their federally allocated or other Covid-19 testing funds, with an "all-in" price per delivered test that includes iHealth's rapid antigen OTC tests, a technology platform managed by CareEvolution, and logistics and distribution through Amazon.

Provision through federal distribution: The federal government is also distributing tests to health centers supported by the Health Resources & Services Administration (HRSA) through the HRSA Covid-19 Testing Supply Program as well as community initiatives intended to address gaps in access to OTC tests through other means. The Biden Administration also announced plans to provide access to free oral therapeutics and tests for its nationwide Test to Treat Initiative in pharmacy clinics, long-term care pharmacies, and FQHCs. These programs are potentially critical to expand test access to uninsured individuals and insured individuals that aren't able to take advantage of the private insurance mandate, including individuals who are currently unable to get free OTC tests and can't afford the upfront costs.

However, without Congress authorizing additional funding, the future and viability of these programs is unclear. Without federally purchased OTC tests, people who are uninsured would need to pay out of pocket. Additionally, because federally purchased tests are also available to individuals with private insurance, there may be implications for insured individuals as well. Private insurers would also need to establish new contracts and negotiate prices on their own, and the time and costs needed to do so could limit access.

Building on current bipartisan legislation, Congress and the Administration should consider ongoing funding and availability of free tests through a national distribution system (e.g., utilizing mail-order systems and community sites such as libraries, post offices, FQHCs, etc.). This may be a more cost-effective, accessible, and straightforward method for obtaining tests, particularly for screening purposes, compared to insurance coverage. There may be significant economies of scale between the ability to achieve lower prices at scale, conduct national information campaigns, redirect supplies to areas where cases are rising, and connect people who test positive to treatment options when appropriate.

Longer-Term Considerations for Coverage of OTC Tests Beyond the Covid-19 PHE

Programs to ensure appropriate access to OTC testing will remain important after the PHE ends, particularly to ensure individuals experiencing high risk of severe Covid-19 illness can test as soon as symptoms appear or once they have been exposed, when treatments are most effective. Stakeholders have identified further actions from federal and state public health authorities, in coordination with health plans and health care providers, that will be critical to longer-term success in containing Covid-19, as well as other respiratory pathogens and future pandemic threats.

Clarify Availability, Reliability, and Affordability of Test Supply Beyond the PHE: As has been the case throughout the pandemic, demand for tests is likely to continue to fluctuate substantially as case rates change in response to seasonal surges, fading population immunity, and potential new variants. **Supports or incentives for longer-term purchase agreements that reward reliability and ability to stockpile for surges, rather than depending on short-term volume-based procurements alone, are needed to ensure an efficient and adequate test supply.** Longer-term, high-volume agreements will enable lower per-test prices and greater confidence in planning to manage potential future surges in cases.

In addition to existing advance purchases of OTC tests, the Biden Administration's National Covid-19 Preparedness Plan proposes larger multi-billion-dollar advance test purchases to create a national stockpile of tests to help avoid shortages in the event of future surges from reduced immunity or new variants. **Federal bulk contracting approaches provide opportunities to coordinate test purchases across state public health agencies, the federal government, and insurers; without such coordination, shortages during surges or due to supply disruptions lead to state and private purchasers bidding against each other for a limited supply and complicates effective test distribution.**

Complementing its own advance purchase planning, **the federal government should take steps to assist health plans and states in planning for and participating in advance purchase arrangements to help lower costs and assure overall adequacy of supply.** If the federal government stockpile alone is insufficient to manage test demand, more stable and reliable purchasing agreements supported by reliable supply chains will also contribute to manufacturers maintaining efficient production capacity. The Biden Administration and members of Congress have also proposed additional steps to strengthen supply chains; bipartisan legislation like the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) would help strengthen medical device supply chains, prevent shortages, and support a dynamic federal stockpile.

Clarify Role of Health Plans in Diagnostic Testing and Treatment to Contain Covid-19: With more extensive, longer-term federal steps coming to assure low-cost OTC test availability, greater clarity about the role of health plans in supporting appropriate use of these tests is needed. As noted above, health plans can take important steps to help ensure that Americans who have Covid-19 symptoms or exposures have appropriate and timely access to testing and treatment, and plans are already doing so.

In addition to providing more clarity on test supply and distribution, federal and state public health authorities should coordinate with health plans to determine how health plans can help to educate their enrollees about Test to Treat pathways and ensure those who test positive and are experiencing high risk of severe Covid-19 are quickly connected to oral or intravenous treatments that can mitigate the consequences of infection. The availability of multiple channels for access to testing for screening, diagnosis, and treatment is important, but more clarity about the best ways for these channels to fit together can help avoid duplication, excess costs, and gaps in access.

Until health plans have more certainty, they are unlikely to make significant new steps and investments as described above to optimize their OTC coverage programs. As a result, plans' coverage programs may have limited impact and lead to unevenness in access to appropriate and timely OTC testing.

Build on Covid-19 Experience to Develop Effective Public Health Strategy for Managing Infectious Disease Threats: Lessons learned from this initiative will have important implications for how plans, pharmacies, and medical

device manufacturers can address infectious disease threats beyond Covid-19 in the future. Rapid OTC tests and effective treatments are or could be widely available for flu, RSV, and other high-burden respiratory illnesses, contributing to much greater health system resilience. Timely access to OTC tests could augment vaccines and treatments for these conditions to limit their impact on stressing health systems and the economy.

However, there is not yet policy consensus on how and how much to support rapid testing technology to limit future threats from Covid-19, let alone other infectious diseases. With the availability of rapid OTC tests, a first step is continuing to update guidance on screening and diagnostic testing and, when test results are positive, on whether isolation is needed and when oral or intravenous therapies should be used. Then, aligning free or subsidized coverage of OTC testing to encourage timely and appropriate use as part of routine public health and clinical care models could be a more cost-effective approach to preventing Covid-19 spread and costly complications. On the other hand, if broad free availability or coverage of OTC tests encourages large numbers of individuals experiencing low risk of contracting Covid-19 or severe illness to engage in testing without much benefit in terms of Covid-19 containment, the cost implications for health plans, the federal government, and ultimately for consumers could be much more substantial, with less clear public health benefits.

Stakeholders are already considering which current strategies may be sustainable and productive in the longer term. Leadership and guidance from federal public health authorities will continue to be essential to build a stronger public health infrastructure for the future on the foundations being laid now. More robust evidence on the appropriate use and coverage of OTC tests as part of community-based approaches to detect, manage, and treat infections, and their impact on downstream healthcare costs and utilization, can help sustain these models in the private sector, prepare for the next epidemic or pandemic, and potentially lead to cost-effective ways to treat infectious diseases.