

United States Senate

WASHINGTON, DC 20510

July 13, 2023

Michael J. Barry, M.D.
Chair
United States Preventive Services Task Force
5600 Fishers Lane
Mail Stop 06E35A
Rockville, MD 20857

Dear Dr. Barry:

We are writing to request the United States Preventive Services Task Force (USPSTF) adopt all COVID-19 testing, including polymerase chain reaction (PCR) and antigen testing, as a recommended screening tool for people exposed to COVID-19 to save lives, prevent complications from long COVID, and limit the spread of COVID-19. If adopted, COVID-19 testing will be a covered benefit without cost sharing under the Patient Protection and Affordable Care Act (ACA),¹ ensuring that Americans will retain access to a life-saving tool.

The Department of Health and Human Services (HHS) declared a Public Health Emergency (PHE) for COVID-19 from January 2020 through May 2023.² During the PHE, most private health insurers were required to cover all COVID-19 testing without cost sharing,³ but this coverage was disrupted for many Americans when the PHE ended.⁴ Although insurers can voluntarily cover COVID-19 testing if they choose, and the Biden-Harris Administration is encouraging them to do so, it is up to individual health insurance plans to make this determination, including whether or not to charge a co-pay.⁵ Already, “several major insurers” –

¹ 42 U.S.C. § 300gg-13.

² U.S. Department of Health and Human Services, “Determination that a Public Health Emergency Exists,” Alex M. Azar II, January 31, 2020, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>; White House, “FACT SHEET: Actions Taken by the Biden-Harris Administration to Ensure Continued COVID-19 Protections and Surge Preparedness After Public Health Emergency Transition,” May 9, 2023, [https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf](https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/09/fact-sheet-actions-taken-by-the-biden-harris-administration-to-ensure-continued-covid-19-protections-and-surge-preparedness-after-public-health-emergency-transition/#:~:text=As%20the%20COVID%2D19%20Public,of%20COVID%2D19%20going%20forward; Office of Management and Budget, Statement of Administrative Policy on H.R. 382 and H.J. Res. 7, January 30, 2023, <a href=).

³ Congressional Research Service, “COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions,” Vanessa C. Forsberg, April 9, 2021, p. i, <https://crsreports.congress.gov/product/pdf/R/R46359>.

⁴ U.S. Department of Health and Human Services, “Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap,” February 9, 2023, <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html#:~:text=Coverage%20for%20COVID%2D19%20testing%20for%20Americans%20will%20change.&text=The%20requirement%20for%20private%20insurance,to%20continue%20to%20include%20it>.

⁵ *Id.*

including Cigna and Aetna – “have made it clear that they won’t be covering [over-the-counter] tests any longer.”⁶

Under the ACA, the USPSTF has the authority to require that most commercial health insurance plans cover certain preventive services without beneficiary cost sharing.⁷ For any service that the USPSTF recommends with an A or B rating, “a group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum, provide coverage for and shall not impose any cost sharing requirements” for such services.⁸ We urge the USPSTF to issue such a recommendation for all COVID-19 tests, guaranteeing that insured patients will continue to receive these products without a co-pay.

COVID-19 Testing Meets USPSTF Criteria for Recommendation

COVID-19 testing clearly meets the USPSTF criteria for a recommended screening tool. To make such a determination, the USPSTF first considers whether a nominated topic is within the scope of the USPSTF, meaning that the topic:

1. Relates to a preventive service that is meant to a) avoid the development of disease (primary prevention) or b) identify and treat an existing disease before it results in significant symptoms (secondary prevention);
2. Is relevant to primary care; and
3. Addresses a disease with a substantial health burden.⁹

COVID-19 testing, for those who are exposed, is a secondary preventive service: testing will identify those who have COVID-19 and enable treatment to occur before the disease progresses to potential hospitalization and death.¹⁰ COVID-19 testing is relevant to primary care because it is a disease that impacts the whole body – not just one organ system,¹¹ and COVID-19 is also a disease with a substantial health burden.¹²

⁶ The Hill, “Free COVID tests are ending: Here’s what that means for you,” Joseph Choi, May 10, 2023, <https://thehill.com/policy/healthcare/3996490-free-covid-tests-are-ending-heres-what-that-means-for-you/>.

⁷ 42 U.S.C. § 300gg-13.

⁸ 42 U.S.C. § 300gg-13.

⁹ U.S. Preventive Services Task Force, “Nominate a Recommendation Statement Topic,” September 2017, <https://uspreventiveservicestaskforce.org/uspstf/index.php/public-comments-and-nominations/nominate-recommendation-statement-topic>.

¹⁰ The BMJ, “Impact of community asymptomatic rapid antigen testing on covid-19 related hospital admissions: synthetic control study,” Xingna Zhang, et al., November 23, 2022, <https://www.bmj.com/content/379/bmj-2022-071374>; The New England Journal of Medicine, “Oral Nirmatrelvir for High-Risk, Nonhospitalized Adults with Covid-19,” Jennifer Hammond, Ph.D., et al., April 14, 2022, <https://www.nejm.org/doi/full/10.1056/NEJMoa2118542>.

¹¹ Centers for Disease Control and Prevention, “Symptoms of COVID-19,” October 26, 2022, <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>; Journal of Family Medicine and Primary Care, “Multi-organ system involvement in coronavirus disease 2019 (COVID-19): A mega review,” Naghmeh Moslehi, et al., September 2022, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9731028/>.

¹² Centers for Disease Control and Prevention, “Estimated COVID-19 Burden,” August 12, 2022, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html>.

In addition, the recommendations that USPSTF makes “are intended to improve clinical practice and promote the health of the American public.”¹³ By reducing transmission¹⁴ and decreasing hospitalization,¹⁵ free COVID-19 testing certainly meets this requirement.

Numerous public health agencies and medical bodies recommend testing as a tool to prevent transmission and reduce the severity of COVID-19. The Centers for Disease Control and Prevention (CDC) guidelines already state that “[p]eople who have symptoms of COVID-19 or who have had known exposure to someone with COVID-19 should be tested for SARS-CoV-2 infection.”¹⁶ These guidelines further explain how screening testing can provide important information to limit transmission and outbreaks in high-risk settings.¹⁷ The National Institute on Aging confirms that individuals should get tested “if you have no symptoms but think or were told that you were in contact with a person with COVID-19.”¹⁸ Medical researchers have found that “[t]esting enables a test-trace-isolate strategy, which is effective in controlling further spread.”¹⁹ COVID-19 testing has been shown to reduce hospital admissions,²⁰ and by ensuring an individual is correctly diagnosed, testing also ensures correct treatment, which can decrease the incidence of long COVID.²¹

In addition, the USPSTF “recommendations are meant to prevent the onset, spread of, or complications of disease,” which COVID-19 testing would clearly accomplish.²² Early testing for individuals can ensure early treatment – which is when the treatment is most effective.²³ Testing early further gives individuals the information they need to isolate and prevent the spread of

¹³ U.S. Preventive Services Task Force, “Nominate a Recommendation Statement Topic,” September 2017, <https://uspreventiveservicestaskforce.org/uspstf/index.php/public-comments-and-nominations/nominate-recommendation-statement-topic>.

¹⁴ Centers for Disease Control and Prevention, “Overview of Testing for SARS-CoV-2, the virus that causes COVID-19,” <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>; Nature Medicine, “Table 1 The ten Choosing Wisely for COVID-19 recommendations,” C. S. Pramesh, et al., July 5, 2021, <https://www.nature.com/articles/s41591-021-01439-x/tables/1>.

¹⁵ The BMJ, “Impact of community asymptomatic rapid antigen testing on covid-19 related hospital admissions: synthetic control study,” Xingna Zhang, et al., November 23, 2022, <https://www.bmj.com/content/379/bmj-2022-071374>.

¹⁶ Centers for Disease Control and Prevention, “Overview of Testing for SARS-CoV-2, the virus that causes COVID-19,” May 11, 2023, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>.

¹⁷ *Id.*

¹⁸ National Institute on Aging, “Why COVID-19 testing is the key to getting back to normal,” September 4, 2020, <https://www.nia.nih.gov/news/why-covid-19-testing-key-getting-back-normal>.

¹⁹ Nature Medicine, “Table 1 The ten Choosing Wisely for COVID-19 recommendations,” C. S. Pramesh, et al., July 5, 2021, <https://www.nature.com/articles/s41591-021-01439-x/tables/1>.

²⁰ The BMJ, “Impact of community asymptomatic rapid antigen testing on covid-19 related hospital admissions: synthetic control study,” Xingna Zhang, et al., November 23, 2022, <https://www.bmj.com/content/379/bmj-2022-071374>.

²¹ medRxiv, “Nirmatrelvir and the Risk of Post-Acute Sequelae of COVID-19,” Yan Xie, Taeyoung Choi, and Ziyad Al-Aly, November 5, 2022, <https://www.medrxiv.org/content/10.1101/2022.11.03.22281783v1>.

²² U.S. Preventive Services Task Force, “Nominate a Recommendation Statement Topic,” September 2017, <https://uspreventiveservicestaskforce.org/uspstf/index.php/public-comments-and-nominations/nominate-recommendation-statement-topic>.

²³ Centers for Disease Control and Prevention, “Interim Clinical Consideration for COVID-19 Treatment in Outpatients,” May 26, 2023, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/outpatient-treatment-overview.html>.

COVID-19 throughout the population.²⁴ And testing and treatment also prevents the complications of disease, including the likelihood of developing long COVID.²⁵

It is clear that testing for COVID-19 as a preventive measure meets all the criteria to make it an official USPSTF recommendation.

USPSTF Should Prioritize the COVID-19 Testing Recommendation

According to its website, USPSTF prioritizes topics according to:

1. Public health importance (that is, burden of suffering and expected effectiveness of the preventive service to reduce that burden); and
2. Potential for a recommendation to affect clinical practice (that is, it resolves a controversy or closes a gap between evidence and practice).²⁶

Testing for COVID-19 as a USPSTF screening recommendation should be prioritized because it meets the above criteria. The “burden of suffering”²⁷ from COVID-19 has been enormous. Approximately 1.13 million people have died of COVID-19 in the United States.²⁸ COVID-19 testing reduces this burden of suffering by ensuring the correct diagnosis is made, so treatment can be given that reduces hospitalization and death and prevents long COVID.²⁹

The inclusion of COVID-19 testing as a preventive service by the USPSTF will also affect clinical practice because individuals will be more likely to get tested if the service is available without cost sharing. Once people are tested, they can be treated by their primary care provider. If the USPSTF recommends COVID-19 testing, then testing and treatment for COVID-19 will continue to be a best practice for clinical practices. The USPSTF recommendations for COVID-19 testing would highlight the importance of this public health measure.

The USPSTF should follow its own guidelines as outlined above and recommend COVID-19 testing as a preventive service. Given the need for these tests and the ample evidence supporting their value, we encourage you to evaluate and adopt COVID-19 testing as a recommended

²⁴ Nature Medicine, “Table 1 The ten Choosing Wisely for COVID-19 recommendations,” C. S. Pramesh, et al., July 5, 2021, <https://www.nature.com/articles/s41591-021-01439-x/tables/1>.

²⁵ medRxiv, “Nirmatrelvir and the Risk of Post-Acute Sequelae of COVID-19,” Yan Xie, Taeyoung Choi, and Ziyad Al-Aly, November 5, 2022, <https://www.medrxiv.org/content/10.1101/2022.11.03.22281783v1>.

²⁶ U.S. Preventive Services Task Force, “Nominate a Recommendation Statement Topic,” September 2017, <https://uspreventiveservicestaskforce.org/uspstf/index.php/public-comments-and-nominations/nominate-recommendation-statement-topic>.

²⁷ *Id.*

²⁸ Centers for Disease Control and Prevention, “COVID Data Tracker Weekly Review,” as of July 13, 2023, <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

²⁹ The BMJ, “Impact of community asymptomatic rapid antigen testing on covid-19 related hospital admissions: synthetic control study,” Xingna Zhang, et al., November 23, 2022, <https://www.bmj.com/content/379/bmj-2022-071374>; The New England Journal of Medicine, “Oral Nirmatrelvir for High-Risk, Nonhospitalized Adults with Covid-19,” Jennifer Hammond, Ph.D., et al., April 14, 2022, <https://www.nejm.org/doi/full/10.1056/NEJMoa2118542>; medRxiv, “Nirmatrelvir and the Risk of Post-Acute Sequelae of COVID-19,” Yan Xie, Taeyoung Choi, and Ziyad Al-Aly, November 5, 2022, <https://www.medrxiv.org/content/10.1101/2022.11.03.22281783v1>.

screening tool without delay. Doing so will save lives, prevent COVID-19 complications, and limit the spread of COVID-19.

We also request answers to the following questions by July 31, 2023:

1. Will USPSTF add COVID-19 screening testing to the list of preventive recommendations?
2. Will USPTF expedite the recommendation process in light of the expiration of the PHE on May 11, 2023?
3. If adopted, how will USPSTF ensure this new designation will be announced to the general population so individuals with private insurance know that they can access all COVID-19 testing without cost sharing?

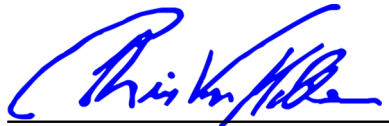
Sincerely,



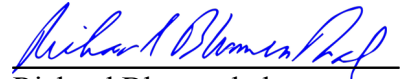
Elizabeth Warren
United States Senator



Tammy Duckworth
United States Senator



Chris Van Hollen
United States Senator



Richard Blumenthal
United States Senator

Cc: Dr. Robert Otto Valdez, Director, Agency for Healthcare Research and Quality (AHRQ)