



August 18, 2022

## **To Our Valued Clients and Partners,**

U.S. health officials are monitoring COVID and flu surges in the southern hemisphere and warning of the likelihood of a similar surge in COVID and flu cases ahead as America's youth start heading back to classrooms this month for the Fall term. This year, all school-age youth in the U.S. are vaccine eligible and the Biden Administration is urging all school districts to host at least one back-to-school vaccine and booster clinic and helping with resources to do so. On August 16th, the Administration shared how it is also expanding access to free COVID-19 tests in schools through at least January 2023. Read more about it [here](#).

Also on August 16th, in a comprehensive interview with Suzanne Clark, President and CEO of the US Chamber of Commerce, the White House COVID-19 Response Coordinator, Dr. Ashish Jha, detailed how critical it will be this Fall for all Americans to get both their COVID boosters and flu shots, both of which will be in strong supply starting in late September and safe to receive at the same time. Ashish also explained how the new bivalent COVID vaccine and booster that covers the original and Omicron variant will be available as early as next month.

He also shared that Administration will stop buying COVID-19 vaccines, tests, and treatments and that more information on this will come in the Fall. He anticipates an orderly, smooth, and transparent transition. His "hope is that in 2023, you're going to see the commercialization of almost all of these products. We move them into the regular health care system."

The CDC's reported 7-day average U.S. daily new COVID-19 case count as of August 16th is at 99K new cases per day, which is down from 130K new cases per day one month ago and is 10K new cases per day under where it was one year ago.

The good news is all of this is that the COVID-19 survivability rate has nearly doubled compared to a year ago, largely due to the efficacy of vaccines, boosters, and oral anti-viral treatments in reducing the severity of COVID-19 symptoms. On August 11<sup>th</sup>, the CDC streamlined its COVID-19 guidance to "help people better understand their risk, how to protect themselves and others, what actions to take if exposed to COVID-19, and what actions to take if they are sick or test positive for the virus." We have updated the COVID section of our website to reflect the latest guidance.

## **Regional Stats**

Across our region, according to each state's health department, the fully vaccinated rate for ages 6 months and older is 52.1% in [Idaho](#), 62.9% in [Utah](#), 69% in [Washington](#), and 69.2% in [Oregon](#).

Today, full vaccination rates vary widely between states ranging from a low of 51.7% in Wyoming to a high of 84.5% in Rhode Island and a national average of 67.3% according to the CDC (Centers for Disease Control).

The CDC [reports](#) at the state level on the rates of people 5 years and older who are fully vaccinated AND have received a booster. Oregon is at 55.9%, Idaho is at 45.7%, Washington is at 55.5%, and Utah is at 46.7%. Nationally, this metric ranges from a low of 28.5% in North Carolina to a high of 63% in Vermont and a national average of 48.2%.

## **BA.5 Omicron Variant Approaching 90% of New Cases**

Over the last three months, the BA.5 variant has accelerated from 4.6% of new cases to nearly 90% of new cases which is the highest proportion of any Omicron variant to date. The remaining 10% of new cases consist of other Omicron variants. The BA.4 variant peaked in early July only reaching about 12.5% of new cases and is now declining. The BA.4.6 variant is rising but at a much slower rate than previous variants growing from 3.1% to 5.1% of new cases over the last month.

The CDC and the WHO (World Health Organization) started tracking the Omicron variant [pango-lineage BA.2](#), aka "Stealth Omicron" in January. BA.2 reached its highest proportion at 73.9% for the week ending 4/9/22. BA.2 was less than 1% of cases by mid-July. The good news is that all of the Omicron variants and subvariants do not appear to be more deadly than previous variants like Delta.

The CDC classified the original Omicron variant as a Variant of Concern on November 26, 2021. Omicron was first detected in the US on December 1<sup>st</sup>. One month later, Omicron, including all of its variants at the time, accounted for over 92% of all COVID-19 cases in the U.S. Today, Omicron, including all of its variants, represents 100% of all cases. The Delta variant took over four months to reach similar infection rates. The CDC reports the Delta variant at 0% of the total U.S. COVID-19 cases and has moved it from a Variant of Concern to a Variant Being Monitored. Omicron (and its lineages) remains the CDC's only Variants of Concern.

## **Booster and Vaccine Update**

### **Bivalent Vaccines Coming this Fall/Winter**

On July 29<sup>th</sup>, following the FDA's June 30<sup>th</sup> recommendation for vaccine manufacturers to develop bivalent (variant specific) vaccines for the Fall, the U.S. Department of Health and Human Services (HHS) announced the purchase of 66 million doses of Moderna's bivalent COVID-19 vaccine booster candidate in collaboration with the U.S. Department of Defense (DOD), for potential use in the fall and winter. This purchase was in addition to the 105 million bivalent COVID-19 vaccine booster doses the U.S. government purchased from Pfizer for potential use later this year, pending FDA authorization and a recommendation by CDC. Pending those FDA and CDC actions, HHS would receive the first deliveries of the Moderna and Pfizer vaccine booster doses in early fall. HHS will need more than triple this number of bivalent vaccines if it wants to boost every eligible person. It has options to purchase enough vaccines to do this but does not have the funding.

On July 23<sup>rd</sup>, the CDC updated its vaccine and booster recommended schedule. Check it out [here](#).

On July 13<sup>th</sup>, the FDA approved the EUA request for Novavax COVID-19 Vaccine, Adjuvanted, a two-dose series, administered three weeks apart, for individuals 18 years of age and old. If approved it would become the 4<sup>th</sup> vaccine available to adults in the U.S. The Novavax formulation is a more traditional, protein-based vaccine unlike the mRNA Moderna and Pfizer-BioNTech COVID-19 Vaccines currently approved. Many health officials are optimistic that people who have been reluctant to receive existing vaccine options may accept Novavax.

On June 30<sup>th</sup> The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss whether and how the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified. The FDA's press release shared that day shared; "An overwhelming majority of the advisory committee voted in favor of including a SARS-CoV-2 omicron component in COVID-19 vaccines that would be used for boosters in the U.S. beginning in fall 2022.

Following the vote, and striving to use the best available scientific evidence, (the VRBPAC) has advised manufacturers seeking to update their COVID-19 vaccines that they should develop modified vaccines that add an omicron BA.4/5 spike protein component to the current vaccine composition to create a two component (bivalent) booster vaccine, so that the modified vaccines can potentially be used starting in early to mid-fall 2022.

As (the VRBPAC) expects this coming year to be a transitional period when this modified booster vaccine may be introduced, they have not advised manufacturers to change the vaccine for primary vaccination, since a primary series with the FDA-authorized and approved COVID-19 vaccines provides a base of protection against serious outcomes of COVID-19 caused by circulating strains of SARS-CoV-2."

On June 17<sup>th</sup>, the FDA amended the EUA of the Moderna COVID-19 mRNA vaccine to include the administration of the primary series to children and adolescents 6 years through 17 years of age. Also on June 17<sup>th</sup>, the FDA amended the EUA of the Pfizer-BioNTech vaccine to include children 6 months to 4 years old.

On May 19<sup>th</sup>, the CDC expanded the eligibility of COVID-19 vaccine booster doses to everyone 5 years of age and older. The CDC now recommends that children ages 5 through 11 years should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series. This followed the FDA's May 17<sup>th</sup> amendment the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine, authorizing the use of a single booster dose for administration to individuals 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 Vaccine.

On May 5<sup>th</sup>, the FDA limited the authorized use of the Janssen COVID-19 vaccine to individuals 18 and over who cannot or will not receive any other authorized COVID-19 vaccine. The FDA determined that the risk of developing rare blood clots warranted this limitation.

On March 29<sup>th</sup>, the [CDC recommended](#) a third shot series (a second booster) for high-risk individuals and people over the age of 50 no less than four months after their prior dose.

While the federal Public Health Emergency declaration remains in place, plans are required to cover COVID-19 vaccines including boosters that have emergency use approval (EUA) by the FDA and follow CDC recommendations. Additionally, once a vaccine receives full FDA approval, it is considered a covered preventive care benefit under the CARES Act, which applies to all non-grandfathered group health plans under the ACA (Affordable Care Act) rules.

## **COVID Treatment Options**

On August 5<sup>th</sup>, The CDC updated its [COVID-19 Treatments and Medications page](#) with a wealth of information on available and recommended treatments. The CDC emphasizes the importance of starting treatment as early as possible upon the onset of symptoms.

Several studies are showing promise in the development of an antiviral nasal spray COVID treatment to prevent infections. The next step is human clinical trials. Read more about the studies here: [University of Washington Collaborative](#), [UC Berkley Study](#).

The HHS' Administration for Strategic Preparedness & Response now runs the Biden Administration's [Test-to-Treat program website](#). Test-to-Treat funds the direct allocation of anti-viral treatments; Merck (molnupiravir) and Pfizer (Paxlovid), to pharmacy-based clinics, health centers, and long-term care facilities. The FDA granted emergency use authorization for both of these treatments in late December 2021.

Through the Test-to-Treat program, distribution of these oral antiviral pills began earlier this year. Now, there are more than 2,500 Test-to-Treat locations at local pharmacies and community health centers across the U.S. and over 40,000 locations where people oral antivirals are now available. The federal Office of the Assistant Secretary for Preparedness & Response (ASPR) has [a website locator](#) to help people find COVID-19 medications and testing.

On May 9<sup>th</sup> the FDA gave full approval to baricitinib (Olumiant) for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). This follows the drug's initial Emergency Use Authorization (EUA) in November of 2020 and subsequent revised EUA in July 2021. This treatment remains in EUA status for patients aged 2-17.

Be sure to remind people that the US government authorized the second round of free COVID-19 at-home tests kits. Ordering is easy at [COVID Home Tests | USPS](#).

Additionally, Washington State residents may order additional free COVID Home Test kits from the Department of Health's "[Say Yes, COVID Test](#)" program.

Vaccines remain the most effective treatment to reduce the risk of severe COVID-19 infections. [Long-COVID](#) is the emerging concern for many of those that have survived COVID.

## **What do we know about these oral antiviral treatments?**

HHS has a robust [public information page](#) explaining everything you might want to know about oral antivirals to help the body fight off serious COVID-19.

The FDA first issued an [emergency use authorization](#) on December 23rd, 2021, for Merck's Lagevrio (molnupiravir) antiviral pill for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. Molnupiravir is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset.

Molnupiravir is not authorized for use in patients younger than 18 years of age because molnupiravir may affect bone and cartilage growth. It is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to COVID-19 because benefit of treatment has not been observed in people when treatment started after hospitalization due to COVID-19.

On December 22<sup>nd</sup>, 2021, the FDA issued an [emergency use authorization](#) (EUA) for Pfizer's Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is available by prescription only and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. We are currently working with our contracted PBM partners to confirm how this drug will be covered on your Pharmacy benefit plans.

### **Regular COVID Reporting Continues**

All clients currently receive regular reporting on their plan's COVID-related claims and payments. Please contact your Account Manager to receive your latest report or you can access this report in BenefitFocus.

Our focus, dedication, and support remain steadfast as we navigate these unique times with you. Know that our Care Management nurses are reaching out to those members diagnosed with COVID-19 to help them access the care and resources they need to recover safely.

### **Updated COVID-19 Member Information and Resources on Our Website**

We update our COVID-19 information and resource pages for members regularly. Many members call us with questions that are of a more clinical nature that we do not address on our website. We recommend that members consult their primary care physician for clinical questions. For non-clinical questions, please share this [page](#) with members where they will find links to additional resources on self-care, vaccines, and other useful information.

## **We're Here for You**

Thank you for your continued trust in our organization.

Please reach out to your Account Manager if you have any questions or if there is anything we can do to help. We would also love to hear your feedback on future content and story ideas for this newsletter. Drop us your ideas and feedback at [TPAMarketing@accesspa.com](mailto:TPAMarketing@accesspa.com).

Best Regards,

**Lindsay Harris, MPP** *President and CEO*

**Regence Group Administrators**