Regence
Group Administrators
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To Our Valued Clients and Partners,

Bivalent boosters are here! The FDA has authorized two COVID-19 bivalent vaccines available in a single dose. Pharmacies and health systems across the U.S. are stocked and ready to administer this latest booster to individuals 12 years of age and older whose last monovalent booster was at least two months prior. (Read more about the bivalent boosters below.)

Just as America's youth settle into their classrooms, college dorms, sports, and activities for the Fall term, U.S. health officials are bracing for a COVID and flu surge this fall as they monitor the worst flu outbreak in five years in the southern hemisphere. The good news is that the flu vaccine has been updated for 2022-23 to cover four flu strains and the CDC advises that it is safe to get at the same time as the new COVID booster vaccine.

The CDC's reported 7-day average U.S. daily new COVID-19 case count as of September 13th is at 60.6K new cases per day, which is down from 103K new cases per day one month ago and is 87K new cases per day under where it was one year ago.

While the federal program at COVID.gov/tests for ordering free at-home test kits through the mail was suspended on September 2nd, Washington State residents may order additional free COVID home test kits from the WA Department of Health's "Say Yes, COVID Test" program. Additionally, throughout the national COVID-19 Public Health Emergency, health plans must continue to cover up to eight COVID home tests each month for each plan member.

Regional Stats

Across our region, according to each state's health department, the fully vaccinated rate for ages 6 months and older is 52.3% in Idaho, 63.1% in Utah, 69% in Washington, and 69.4% in Oregon. Today, full vaccination rates vary widely between states ranging from a low of 51.9% in Wyoming to a high of 85% in Rhode Island and a national average of 67.6% 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 56.4%, Idaho is at 46%, Washington is at 55.9%, and Utah is at 47.3%. Nationally, this metric ranges from a low of 28.7% in North Carolina to a high of 63.5% in Vermont and a national average of 48.6%.

BA.5 Omicron Variant Approaching 90% of New Cases

The BA.5 variant appears to have peaked out last week at 87.9% of all COVID-19 new cases which is the highest proportion of any Omicron variant to date. This week, BA.5 dropped slightly to 87.5% of all new cases. The remaining new cases consist of other Omicron variants. The BA.4.6 variant is rising but at a much slower rate than previous variants growing from 6.4% to 9.2% 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 1st. 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 Are Here!

The bivalent vaccines developed over the summer are now available!

On September 1, CDC recommended that everyone ages 12 years and older in the United States receive an updated COVID-19 booster before a possible surge in COVID-19 illnesses later this fall and winter. Like the original boosters, the updated doses help restore protection that might have gone down since your last dose—but they also give extra protection for yourself and those around you against the most recent variants.

The updated booster is a bivalent vaccine because it targets two Omicron subvariants: BA.4 and BA.5. These newest subvariants are more contagious and able to evade protection that your body might have against earlier subvariants. Data suggest that the updated boosters also increase our immune response, which will help protect us against future variants.

Being up to date with COVID-19 vaccines is the best way to protect against severe illness, hospitalization, and death associated with COVID-19. Everyone who is eligible—including those who are moderately to severely immunocompromised—is recommended to receive one dose of the updated bivalent booster at least two months after their last dose (either the final primary series or the last booster). The Moderna COVID-19 Vaccine, Bivalent is authorized for use as a single booster dose in people ages 18 years and older. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use as a single booster dose in people ages 12 years and older. To find a vaccine provider near you, visit vaccines.gov. *Note: the preceding bivalent vaccine update was borrowed directly from the CDC's weekly review and interpretive summary*.

On July 29th, following the FDA's June 30th 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 23rd, the CDC updated its vaccine and booster recommended schedule. Check it out here.

On July 13th, 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 4th 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 30th 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 with this modified booster vaccine, 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 17th, 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 17th, the FDA amended the EUA of the Pfizer- BioNTech vaccine to include children 6 months to 4 years old.

On May 19th, 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 17th 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 5th, 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 29th, 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 5th, 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 9th 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.

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 22nd, 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 reading our newsletter and thank you for your continued trust in our organization.

Our focus, dedication, and support remain steadfast as we navigate these unique times with you. Thank you for healthy. 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@accesstpa.com. Are you following us on LinkedIn? This is a great way to keep a pulse on what is happening between our monthly newsletters.

Best Regards,

Lindsay Harris, MPP *President and CEO*

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