Regence
Group Administrators
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July 22, 2022

To Our Valued Clients and Partners,

It's hard to grasp that we are experiencing our third COVID-19 pandemic summer. Many companies have returned to full in-person operations and adapted to new health and safety measures. Others have adapted to new hybrid or remote working models. Most of us know someone personally who has had COVID-19. We've seen some people experience mild symptoms while other become quite ill.

The CDC's reported 7-day average U.S. daily new COVID-19 case count as of July 20th is at 155K new cases per day, which is up from 98K new cases per day one month ago and 49K cases per day two months ago. The 7-day average daily new case count on any given day in July 2021 did not exceed 68K new cases and in June 2020 did not exceed 83K new cases. The summer surge is in full swing.

Earlier this week, the White House announced that President Joe Biden had tested positive for COVID-19, was fully vaccinated and boosted, was experiencing only mild symptoms, and was being treated with the antiviral drug, Paxlovid. 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. Long-COVID is the emerging concern for many of those that have survived COVID.

Regional Stats

Our region has not evaded the summer surge. COVID positivity case rates are up and county health departments are bringing back masking recommendations. Across our region, according to each state's health department, the fully vaccinated rate for ages 6 months and older is 52% in Idaho, 62.7% in Utah, 68.7% in Oregon, and for ages 5 and older in Washington is 82.3%.

Today, full vaccination rates for those aged 5 and over vary widely between states ranging from a low of 55.1% in Alabama to a high of 88.7% in Rhode Island and a national average of 71.4% 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 55.6%, Idaho is at 44.3%, Washington is at 55.1%, and Utah is at 46.5%. Nationally, this metric ranges from a low of 28.2% in North Carolina to a high of 62.7% in Vermont and a national average of 48.2%.

Multiple New Omicron Variants Rising

Over the last two months, the BA.5 variant has accelerated from 4.6% of new cases to nearly 80% of new cases. The BA.4 variant from 2% of new cases to nearly 13% of new cases. These new variants are surging at similar rates as previous Omicron variants. Time will tell if they taper off over time and are overtaken by a new variant.

The CDC started tracking the previous dominant Omicron subvariant BA.2.12.1 in February. This subvariant was less than 1% of cases through early March. By June 4th, it accounted for 62.2% of new cases. As of July 16th, BA.2.12.1 had dropped to 8.6% of cases.

The CDC and the WHO (World Health Organization) started tracking the Omicron variant pango-lineage BA.2, aka "Stealth Omicron" in January. BA.2 accounted for 0% of U.S. cases for the week ending 1/8/22, 1.0% of cases for the week ending 2/5/22, and 11.6% of cases for the week ending 3/3/22, and 72.2% of case for the week ending 4/2/22, reaching its highest proportion at 73.9% for the week ending 4/9/22. BA.2 is less than 1% of cases for the week ending 7/16/22. 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 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 and as of 6/7/22.

Booster and Vaccine Update

Recent Booster and Vaccine Developments

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 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 29th, the CDC updated its vaccine and booster recommended schedule. Check it out here.

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

The National Institutes of Health (NIH) published information on May 10th about new research it is funding at the University of Washington, the Washington University School of Medicine, and Northwestern University using 'designed synthetic mini-proteins' that bind to the spike COVID-19 spike proteins and are showing promise as an antiviral nasal spray COVID treatment to prevent infections. The next step is human clinical trials.

On May 26th, the Biden Administration provided an update on its Test-to-Treat program which funds 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.

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.

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 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@accesstpa.com.

Best Regards,

Lindsay Harris, MPP *President and CEO*

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