

# 2023 Immunization Update: COVID-19, Influenza, RSV, HepB, Pneumococcal, HPV, Polio, Mpox, and MMR

November 1, 2023

Each year, the California Medi-Cal Drug Use Review (DUR) program issues an annual summary of updates on immunization guidelines, products, and/or research in collaboration with the California Department of Public Health (CDPH) Immunization Branch. For reference, the most recently recommended immunization schedules for the United States can be accessed on the Centers for Disease Control and Prevention (CDC) website:

- Persons 18 years of age or younger
- Persons 19 years of age or older

## **Learning Objectives**

- Discuss strategies for improving vaccination rates and vaccine confidence among high-risk populations for the three respiratory viruses co-circulating this fall and winter: SARS-CoV-2, influenza virus, and respiratory syncytial virus (RSV).
- Describe the updated vaccines currently available for SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19).
- Review the Advisory Committee on Immunization Practices (ACIP) updated recommendations for COVID-19, influenza, RSV, pneumococcal disease, polio, mpox, and measles, mumps, and rubella (MMR) vaccines.

This is the first fall and winter virus season where vaccines are available for the three respiratory viruses responsible for the most hospitalizations: SARS-CoV-2, influenza, and RSV. Health care providers can ensure that all their patients protect themselves by encouraging them to stay up to date on COVID-19, influenza, and RSV vaccinations.

CDPH has developed a new <u>Respiratory Virus</u> page to provide important resources to improve vaccination rates and vaccine confidence among populations at higher risk for serious illness, including communications toolkits for <u>COVID-19 Treatments</u>, <u>Flu & COVID Vaccines</u>, <u>Long</u> <u>COVID</u>, <u>Respiratory Virus Prevention</u>, and <u>Respiratory Syncytial Virus (RSV)</u>. CDPH has developed materials for patients as well, including <u>6 Tips for Staying Healthy this Virus Season</u> and a <u>Fall-Winter 2023-24 Immunizations</u> infographic.

### **COVID-19 Vaccine**

Updated 2023-2024 COVID-19 vaccines include a monovalent (single) component that corresponds to the SARS-CoV-2 omicron subvariant XBB.1.5. On September 11, 2023, the U.S. Food and Drug Administration (FDA) approved and authorized updated (2023-2024 formula) mRNA COVID-19 vaccines by Moderna and by Pfizer-BioNTech for use in individuals 6 months and older. On October 3, 2023, the FDA amended the emergency use authorization (EUA) for an updated (2023-2024 formula) protein subunit vaccine (Novavax COVID-19-Vaccine, Adjuvanted) for use in individuals 12 years of age and older.

On September 12, 2023, both the ACIP and CDC recommended updated 2023-2024 COVID-19 vaccines for everyone 6 months of age or older to protect against potentially serious consequences from COVID-19, including long COVID, hospitalization, and death. There is no preferential recommendation for use of one COVID-19 vaccine over another, when more than one recommended and age-appropriate vaccine is available.

CDC recommendations for COVID-19 vaccine include the following:

- Everyone 5 years of age or older should get one dose of an updated COVID-19 vaccine to protect against serious illness from COVID-19.
- Children 6 months through 4 years of age need multiple doses of COVID-19 vaccines to be up to date, including at least one dose of updated COVID-19 vaccine.
- People who are moderately or severely immunocompromised may get additional doses of updated COVID-19 vaccine.
- A dose of the updated COVID-19 vaccine is most important for people who are at the highest risk from COVID-19 infection, including adults 65 years of age or older, people who are immune compromised, anyone who has not yet been vaccinated against COVID-19, and pregnant people.

For comprehensive COVID-19 vaccine recommendations, providers may refer to <u>Use of</u> <u>COVID-19 Vaccines in the United States – Interim Clinical Considerations | CDC</u>. For patients younger than 18 years of age, the American Academy of Pediatrics (AAP) has several resources available on their <u>Critical Updates on COVID-19</u> page, including the <u>Pediatric COVID-19</u> <u>Vaccine Dosing Quick Reference Guide</u>. Finally, CDPH has developed several updated COVID-19 resources for both <u>providers</u> and <u>patients</u>, including a *COVID-19 Vaccine Timing 2023-24 – Routine Schedule* infographic that is available in both <u>English</u> and <u>Spanish</u>.

Finally, as of September 11, 2023, bivalent mRNA COVID-19 vaccines (based on the ancestral SARS-CoV-2 strain and BA.4/BA.5 variants) are no longer authorized for use in the United States, and as of October 3, 2023, original monovalent COVID-19 vaccine, adjuvanted (based on the ancestral SARS-CoV-2 strain) is no longer authorized for use in the United States. To minimize the risk of vaccine administration errors, providers should remove these vaccines from inventory immediately, regardless of expiration dates, and dispose of them per their usual protocols.

# Influenza Vaccine

As in prior years, routine annual influenza vaccination is recommended for everyone 6 months of age or older without contraindications. <u>Adults 65 years of age or older</u> should preferentially receive either high dose or adjuvanted influenza vaccines. For the current influenza season, widespread influenza vaccination is again critical to reduce the impact of respiratory illnesses in the population and the resulting burden to the healthcare system.

For the 2023 – 2024 season, inactivated influenza vaccines (IIVs), recombinant influenza vaccine (RIV4), and live attenuated influenza vaccine (LAIV4) are available (all quadrivalent). U.S. IIV4s and LAIV4 (egg-based) influenza vaccines contain hemagglutinin (HA) derived from the following influenza viruses:

- A/Victoria/4897/2022 (H1N1) pdm09-like virus (different strain from last season)
- A/Darwin/9/2021 (H3N2)-like virus
- B/Austria/1359417/2021-like virus (B/Victoria lineage)
- B/Phuket/3073/2013-like virus (B/Yamagata lineage)

U.S. cell culture–based inactivated (ccIIV4) and recombinant (RIV4) influenza vaccines contain HA derived from the following influenza viruses:

- A/Wisconsin/67/2022 (H1N1) pdm09-like virus (different strain from last season)
- A/Darwin/6/2021 (H3N2)-like virus
- B/Austria/1359417/2021-like virus (B/Victoria lineage)
- B/Phuket/3073/2013-like virus (B/Yamagata lineage)

For most persons who need only one dose of influenza vaccine for the season, vaccination should ideally be offered during September or October. However, vaccination should continue throughout the season as long as influenza viruses are circulating. Vaccination during July and August is not recommended for most groups. Timing considerations include:

- For most adults (especially those 65 years and older) and pregnant people in the first and second trimesters, vaccination in July and August should be avoided unless there is concern that later vaccination might not be possible.
- Pregnant people in their third trimester can get an influenza vaccine in July or August to ensure their babies are protected from influenza after birth, when they are too young to get vaccinated.
- Children 6 months through 8 years of age who need two doses of influenza vaccine should get their first dose of vaccine as soon as vaccine becomes available, with the second dose given at least four weeks after the first.
- Vaccination in July or August can be considered for children who have health care visits during these months if there might not be another opportunity to vaccinate them. For example, some children might have medical visits in the late summer before school starts and might not return to see a health care provider in September or October.

The best way to prevent influenza and its potentially serious complications is by getting a yearly influenza vaccination. Even when influenza vaccination does not prevent illness entirely, it has been shown in several studies to reduce severity of illness.

Finally, there was another important change for the 2023 – 2024 season related to giving influenza vaccine to people with egg allergies. Previously, ACIP had recommended additional safety measures when administering egg-based influenza vaccine to people who have had severe allergic reactions to egg. In June 2023, ACIP and CDC recommended that people with an egg allergy may receive any influenza vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended for influenza vaccination beyond those recommended for receipt of any vaccine. Prior to the ACIP vote, the Joint Task Force on Practice Parameters of the American Academy of Allergy, Asthma & Immunology (ACAAI), the American College of Allergy, Asthma, & Immunology (ACAAI), and the American Academy of Pediatrics (AAP) had also recommended that no additional precautionary measures were needed when administering influenza vaccine to people with an egg allergy.

For additional information about influenza vaccine recommendations, providers may refer to the <u>Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the</u> <u>Advisory Committee on Immunization Practices – United States, 2023–24 Influenza Season</u>, published in the Morbidity and Mortality Weekly Report (MMWR), which is available on the CDC website. In addition, the American Pharmacists Association (APhA) recently developed the <u>Tips</u> from the Field video series, which includes pharmacist best practices for increasing influenza vaccination rates and safe co-administration of influenza and other vaccines.

### **RSV Vaccine**

RSV is a common respiratory virus that usually causes a mild cold, but can also cause severe disease, especially in infants and older adults. RSV is the most common infection of the lungs and reason for hospitalization in children younger than 1 year of age in the United States. Almost all children get RSV at least once before they are 2 years old.

RSV immunization is now available and recommended for:

- Older adults, ages 60 years and older
- All infants younger than 8 months
- Infants/toddlers 8 through 19 months at high risk for severe RSV
- People who are pregnant at 32 to 36 weeks of pregnancy

#### **RSV Prevention in Older Adults**

In May 2023, the FDA approved two vaccines for use in the United States for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age or older. RSVPreF3 (Arexvy, GSK) is a 1-dose (0.5 mL) adjuvanted (AS01<sub>E</sub>) recombinant stabilized prefusion F protein (preF) vaccine and RSVpreF (Abrysvo, Pfizer) is a 1-dose (0.5 mL) recombinant stabilized preF vaccine. Both RSV vaccines demonstrated moderate to high

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The decision to vaccinate a patient for RSV should be based on a discussion with the patient, which might be guided by the patient's risk for disease and their characteristics, values, and preferences; the provider's clinical discretion; and the characteristics of the vaccine. CDC has developed a job aid titled <u>RSV Vaccination for Adults 60 Years and Older</u> in order to help providers implement shared decision making for RSV vaccination.

Older adults at highest risk for severe RSV who may benefit most from an RSV vaccine include:

- Adults with chronic heart or lung disease, such as asthma.
- Adults with weakened immune systems (for example, HIV or having cancer treatments).
- Adults with certain other underlying medical conditions (for example, diabetes, cancer, kidney disease, sickle cell disease).
- Adults living in nursing homes or long term care facilities.

Patients can receive their RSV vaccine at the same visit as their influenza and COVID-19 vaccines. For the 2023 – 24 season, health care providers should offer RSV vaccination to adults 60 years of age or older as early as vaccine supply becomes available and should continue to offer vaccination to eligible adults who remain unvaccinated.

For additional information about the recommendations for RSV vaccine in older adults, providers may refer to the <u>Healthcare Providers: RSV Vaccination for Adults 60 Years of Age</u> and Over | CDC page, which is available on the CDC website.

### **RSV Prevention in Infants and Toddlers**

In July 2023, the FDA approved nirsevimab, a long-acting monoclonal antibody, for prevention of serious RSV illness in infants. The antibodies in nirsevimab are like those that develop after a typical vaccine. On August 3, 2023, both ACIP and CDC recommended:

- One dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg) for infants younger than 8 months born during or entering their first RSV season; and
- One dose of nirsevimab (200 mg) for infants and toddlers 8 through 19 months of age who are at increased risk of severe RSV disease and entering their second RSV season.

In the context of limited supply of nirsevimab, on October 23, 2023, the CDC issued a <u>Health</u> <u>Alert Network (HAN) Health Advisory</u> that provides interim recommendations to protect infants from RSV during the 2023 – 2024 respiratory virus season. CDC now recommends prioritizing available nirsevimab 100 mg doses for infants at the highest risk for severe RSV disease: young infants (younger than 6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease, including:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of their second RSV season.
- Children with severe immunocompromise.
- Children with cystic fibrosis who have either manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable); or weight-for-length <10th percentile.
- American Indian or Alaska Native children 8 through 19 months of age who are not eligible for palivizumab and who live in remote regions.

Nirsevimab can be administered without regard to timing of routine childhood vaccines. This includes simultaneous administration (for example, same clinic day) with vaccine products. No interval between nirsevimab and live vaccines (such as MMR and Varicella) is necessary.

For additional information about nirsevimab, providers may refer to the <u>Use of Nirsevimab for</u> <u>the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children:</u> <u>Recommendations of the Advisory Committee on Immunization Practices — United States,</u> <u>2023</u> article, published in the *MMWR*, which is available on the CDC website. For additional RSV resources, clinical guidance, and frequently asked questions (FAQs), providers can visit the new <u>RSV Immunization Resources</u> page on the <u>EZIZ.org</u> website.

#### **RSV Prevention during Pregnancy**

On August 21, 2023, the FDA approved the RSVpreF (Abrysvo, Pfizer) vaccine for use in pregnant individuals to prevent LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. This RSV vaccine is approved for use at 32 through 36 weeks gestation and is administered as a single intramuscular injection. On September 22, 2023, both ACIP and CDC recommended one dose of RSVpreF (Abrysvo, Pfizer) be administered to all pregnant people during RSV season (September – January in most of the continental United States) to help protect babies against severe respiratory syncytial virus (RSV) illness after birth. The RSV vaccine should provide protection against severe RSV illness to the recipient's baby up to 6 months of age. However, the infant's protection will wane over time.

Given nirsevimab supply concerns during the 2023 – 2024 season, the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the American Academy of Pediatrics (AAP) issued a <u>statement</u> on October 25, 2023, encouraging prenatal care providers to recommend RSV vaccination for all pregnant patients 32 through 36 weeks of gestation to prevent severe RSV illness in infants, noting that prenatal RSV vaccination is a safe and effective option that will reduce the number of infants requiring nirsevimab during the RSV season. On October 30, 2023, CDPH issued a <u>memo</u> urging prenatal care providers to provide for all pregnant patients or a strong referral to an in-network pharmacy where patients can get immunized. RSV vaccine can be co-administered on the same day as other vaccines, including Tdap, COVID-19, and influenza.

2023 Immunization Update: COVID-19, Influenza, RSV, HepB, Pneumococcal, HPV, Polio, Mpox, and MMR For additional information about the use of the RSV vaccine during pregnancy, providers may refer to the <u>Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the</u> <u>Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants:</u> <u>Recommendations of the Advisory Committee on Immunization Practices — United States,</u> <u>2023</u> article, published in the *MMWR*, which is available on the CDC website.

# Hepatitis B (HepB) Vaccine

In March 2023, the CDC updated their recommendations for screening and testing for hepatitis B virus (HBV) infection. This was the first comprehensive update since 2008 and included a new recommendation for HBV screening using three laboratory tests at least once during a lifetime for all adults 18 years of age or older. In addition, risk-based testing recommendations have been expanded to include the following:

- Persons incarcerated or formerly incarcerated in a jail, prison, or other detention setting.
- Persons with a history of sexually transmitted infections or multiple sex partners.
- Persons with a history of hepatitis C virus (HCV) infection.

HBV testing is now also recommended for anyone who requests testing, regardless of disclosure of risk.

Since January 1, 2022, <u>Assembly Bill (AB) 789 (Low, Chapter 470, Statutes of 2021)</u> has required primary care providers in California to offer screening tests for HBV and HCV to adult patients to the extent these services are covered under the patient's health insurance unless certain conditions apply that include, among others, the patient lacks the capacity to consent to the screening test. More detailed information about the law is available in a <u>March 22, 2022 letter from CDPH</u>.

The new recommendation for at least one HBV screening for all adults complements the 2022 ACIP recommendation to vaccinate all adults 19 through 59 years of age against HBV infection: the one-time screening test determines prior infection history then, if the person tests negative, vaccination protects from future infection and need for any additional testing. Persons recommended to receive HBV vaccination include: all infants, all persons younger than 19 years of age, all adults 19 through 59 years of age, and adults 60 years of age or older with risk factors for HBV. Adults 60 years of age or older without known risk factors for HBV may also receive HBV vaccines.

For additional information about the HBV screening and testing recommendations, providers may refer to the <u>Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations –</u> <u>United States, 2023</u> article, published in the *MMWR*, which is available on the CDC website.

### **Pneumococcal Vaccine**

In April 2023, the FDA approved an expanded use for 20-valent pneumococcal conjugate vaccine (PCV20) to include persons 6 weeks through 17 years of age. On June 22, 2023, the ACIP and the CDC approved the following recommendations regarding the use of PCV20 as another option to 15-valent pneumococcal conjugate vaccine (PCV15):

- All children 2 through 23 months of age with no previous pneumococcal conjugate vaccine (PCV) vaccination should receive either PCV15 or PCV20, according to recommended PCV dosing and schedules.
- For children with an incomplete PCV vaccination status, use of either PCV15 or PCV20 for catch-up vaccination is recommended for:
  - Healthy children 24 through 59 months of age
  - Children 24 through 71 months of age with specified health conditions
- For children 2 through 18 years of age with any risk condition who have received all recommended doses of PCV before 6 years of age,
  - If the recommended PCV doses were completed with ≥1 dose(s) of PCV20: No additional doses of any pneumococcal vaccine are indicated.
  - If the recommended PCV doses were completed with PCV13 or PCV15 (no PCV20): A dose of PCV20 or ≥1 dose of PPSV23 using previously recommended dosing and schedules is recommended. When PPSV23 is used instead of PCV20 for children 2 through 18 years of age with an immunocompromising condition, either PCV20 or a second PPSV23 dose is recommended ≥5 years after the first PPSV23 dose.
- For children 6 through 18 years of age with any risk condition who have not received any dose of PCV13, PCV15, or PCV20, a single dose of PCV15 or PCV20 is recommended. When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks after the last PCV dose, if not previously given.

For complete PCV recommendations for children and adolescents, providers may refer to the <u>ACIP Updates: Recommendations for Use of 20-Valent Pneumococcal Conjugate Vaccine in</u> <u>Children — United States, 2023</u> article, which is available on the CDC website. CDPH has also developed a <u>Pneumococcal Vaccine Timing – For Children</u> infographic for reference. For complete PCV recommendations for adults, providers may refer to the <u>Pneumococcal Vaccine</u> for Adults Aged  $\geq$  19 Years: Recommendations of the Advisory Committee on Immunization <u>Practices, United States, 2023</u> article, which is also available on the CDC website.

# Human Papillomavirus (HPV) Vaccine

Since 2007, the ACIP has recommended routine HPV vaccination for boys and girls at 11 to 12 years of age, beginning as early as 9 years old. Both the <u>AAP</u> and the <u>American Cancer Society</u> have endorsed the strategy of offering HPV vaccine to children at 9 years of age. Research has shown several key benefits to starting the HPV vaccination series sooner, including allowing for more time to complete the two-dose series. Additional benefits include an earlier strong immune response, increased likelihood of vaccinating prior to first HPV exposure, decreased

2023 Immunization Update: COVID-19, Influenza, RSV, HepB, Pneumococcal, HPV, Polio, Mpox, and MMR questions about sexual activity by parents and guardians, decreased requests for only vaccines that are required for school, decreased number of shots per visit, increased completion of the HPV vaccination series, and therefore more cancers prevented overall. Initiating HPV vaccination at age 9 has also been shown to be highly acceptable by health systems, providers, and parents. Since HPV vaccination has shown no sign of waning protection over time, there is no known downside to this approach. For more evidence supporting this recommendation, providers may refer to the <u>Start HPV Vaccination at Age 9</u> campaign, which is located on the <u>National HPV Vaccination Roundtable</u> website.

# **Polio Vaccine**

In June 2023, the ACIP recommended that all adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with inactivated polio vaccine (IPV). In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. In addition, the ACIP recommended that adults who have received a primary series of trivalent oral polio vaccine (tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Situations that put adults at increased risk of exposure to poliovirus include the following:

- Travelers who are going to countries where polio is epidemic or endemic (see <u>Polio: For</u> <u>Travelers</u>, which is available on the CDC website).
- Laboratory and health care workers who handle specimens that might contain polioviruses.
- Health care workers or other caregivers who have close contact with a person who could be infected with poliovirus.

Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults. For more information, providers may refer to <u>Polio Vaccination Recommendations</u> <u>for Adults</u>, which is available on the CDC website.

### **Mpox Vaccine**

Mpox is a rare disease caused by infection with the mpox virus, which is related to the variola (smallpox) virus. In February 2023, the ACIP recommended the two-dose JYNNEOS vaccine series for people 18 years of age or older who are at increased risk of mpox infection. For the most protection from mpox, the CDC recommends getting both doses of JYNNEOS vaccine, with the second dose given four weeks after the first dose. A recent study from California found that receiving at least one dose of vaccine reduced the odds of mpox-associated hospitalization.

For more information about this study, providers may refer to the <u>Reduced Odds of Mpox-</u> <u>Associated Hospitalization Among Persons Who Received JYNNEOS Vaccine – California,</u> <u>May 2022 – May 2023</u> article, published in the <u>MMWR</u>, which is available on the CDC website. Additional mpox resources for California providers are also available on the Division of Communicable Disease Control (DCDC) <u>mpox</u> page on the CDPH website.

# Measles, Mumps, and Rubella (MMR) Vaccine

In June 2022, the FDA licensed a second MMR vaccine. Both MMR vaccines are interchangeable for all indications for which MMR vaccination is recommended. Availability from multiple manufacturers safeguards U.S. vaccine supply.

For additional information about the new MMR vaccine, providers may refer to the <u>Measles</u>, <u>Mumps, Rubella Vaccine (PRIORIX): Recommendations of the Advisory Committee on</u> <u>Immunization Practices – United States, 2022</u> article, published in the MMWR, which is available on the CDC website.