

September 28, 2018



## 2018 Immunization Updates: Flu, Tdap, HepB, Zoster, MMR, Adult Vaccines

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 recommended immunization schedules for 2018 in the United States can be accessed on the Centers for Disease Control and Prevention (CDC) website:

- [Persons aged 0 through 18 years](#)
- [Persons aged 19 years or older](#)

### Influenza Vaccine

As in prior years, routine annual influenza vaccination is recommended for everyone 6 months of age and older without contraindications. For the 2018 – 2019 season, standard-dose, unadjuvanted, and inactivated influenza vaccines are available in quadrivalent (IIV4) as well as trivalent (IIV3) formulations. Recombinant influenza vaccine (RIV4) and live attenuated influenza vaccine (LAIV4) are available in quadrivalent formulations. High-dose inactivated influenza vaccine (HD-IIV3) as well as adjuvanted and inactivated influenza vaccine (aIIV3) are available in trivalent formulations.

For the past two seasons (2016 – 2017 and 2017 – 2018), the federal Advisory Committee on Immunization Practices (ACIP) recommended that LAIV4 (also known as the “nasal spray” flu vaccine) not be used. However, for the 2018 – 2019 season, LAIV4 is again an option available to those for whom it is appropriate. For more information on the updated LAIV4 recommendations, refer to [Update: ACIP Recommendations for the Use of Quadrivalent Live Attenuated Influenza Vaccine \(LAIV4\) — United States, 2018–19 Influenza Season](#), published in the *Morbidity and Mortality Weekly Report (MMWR)*, which is available on the CDC website.

Vaccine viruses in 2018 – 2019 U.S. trivalent influenza vaccines include:

- An A/Michigan/45/2015 (H1N1) pdm09-like virus (same as last season)
- An A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus (different strain from last season)
- A B/Colorado/06/2017-like virus (Victoria lineage) (different strain from last season)

In addition to these viruses, quadrivalent influenza vaccines contain a B/Phuket/3073/2013-like virus (Yamagata lineage), which was in influenza vaccines last season.

All women who are pregnant or who might become pregnant during the influenza season should receive an age-appropriate IIV or RIV4 vaccine, administered at any time during pregnancy. LAIV4 should not be used during pregnancy.

Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine (IIV, RIV4, or LAIV4). IIV and RIV4 have been previously recommended. Use of LAIV4 for persons with an egg allergy was approved by ACIP in February 2016.

Health care providers should offer vaccination by the end of October each year, if possible. Children who require two doses should receive their first dose as soon as possible after vaccine becomes available to allow the second dose (which must be administered  $\geq 4$  weeks later) to be received by the end of October. Vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available.

For additional information about available formulations of influenza vaccine and recommendations for dosing in children, older adults, and among persons with a history of egg allergy, see [Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2018–19 Influenza Season](#), published in the *MMWR*, which is available on the CDC website.

### **Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine**

In July 2018, CDPH announced that pertussis, better known as whooping cough, claimed the life of a San Bernardino County infant. This is the first confirmed infant death from the disease since 2016, when two deaths occurred.

As a reminder, pregnant women should receive a Tdap shot at the earliest opportunity between 27 and 36 weeks' gestation of every pregnancy, even if previously immunized. This is vital to both decrease the risk of pertussis infection in the mother and provide the baby with antibody protection from the mother until the baby is old enough to be vaccinated (between six to eight weeks of age).

To avoid the spread of pertussis, CDPH also recommends that:

- Parents immunize their babies against pertussis as soon as possible. The first dose is recommended at two months of age, but can be given as early as six weeks of age.
- California 7<sup>th</sup> grade students receive a Tdap booster
- Adults receive at least one Tdap booster

Current information on pertussis, as well as the status of outbreaks within California, can be found on the [Pertussis \(Whooping Cough\)](#) page of the CDPH website. For a summary of ACIP recommendations, see [Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#), published in the *MMWR*, which is available on the CDC website.

### **Hepatitis B (HepB) Vaccine**

Within the last year, ACIP and CDC have summarized and consolidated previously published recommendations for the prevention of hepatitis B virus (HBV) infection. The consolidated recommendations include:

- Universal HepB vaccination within 24 hours of birth for medically stable infants, followed by the completion of the vaccine series. Previous permissive language for delaying the birth dose until after hospital discharge has been removed.
- Testing all pregnant women for hepatitis B surface antigen (HBsAg) and testing of HBsAg-positive pregnant women for HBV deoxyribonucleic acid (HBV DNA)
- Any infant who is born to an HBsAg-positive woman should receive the HepB vaccine and hepatitis B immunoglobulin (HBIG) within 12 hours of birth, followed by the completion of the vaccine series and post-vaccination serologic testing
- HepB vaccination for all children and adolescents 18 years of age or younger who have not been vaccinated previously
- HepB vaccination for all adults at risk for HBV infection, including adults in settings with risk factors for HBV infection and adults requesting protection from HBV without acknowledgment of a specific risk factor

For complete recommendations, including CDC guidance for post-exposure prophylaxis following occupational and other exposures and a summary of the American Association for the Study of Liver Diseases guidelines for maternal antiviral therapy to reduce perinatal HBV transmission, see [Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices](#), published in the *MMWR*, which is available on the CDC website.

In addition, on November 9, 2017, a single-antigen HepB vaccine with a novel immunostimulatory sequence adjuvant (HepB-CpG) was approved by the U.S. Food and Drug Administration (FDA) for the prevention of HBV infection in adults 18 years of age or older. The HepB-CpG vaccine is administered as two doses, one month apart.

On February 21, 2018, ACIP recommended HepB-CpG for use in adults 18 years of age or older, stating the protection benefits of two doses administered over one month made HepB-CpG an important option for the prevention of HBV infection. For more information, see [Recommendations of the Advisory Committee on Immunization Practices for Use of a Hepatitis B Vaccine with a Novel Adjuvant](#), published in the *MMWR*, which is available on the CDC website.

### **Zoster (Shingles) Vaccine**

On October 20, 2017, the FDA approved a vaccine for the prevention of herpes zoster, which contained recombinant glycoprotein E in combination with a novel adjuvant. The recombinant zoster vaccine (RZV) consists of two doses, administered intramuscularly, two to six months apart. At the October 2017 ACIP meeting, the following three proposed recommendations were presented to the committee and, after a public comment period, were approved by the voting ACIP members:

- RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults 50 years of age or older.
- RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL).
- RZV is preferred over ZVL for the prevention of herpes zoster and related complications.

These recommendations serve as a supplement to the existing ACIP recommendations for the use of ZVL in immunocompetent adults aged 60 years or older. For more information, including precautions and contraindications, see [Recommendations of the Advisory Committee on Immunization Practices for the Use of Herpes Zoster Vaccines](#), published in the *MMWR*, which is available on the CDC website.

### **MMR Vaccine**

Since 2015, numerous outbreaks of mumps have been reported across the U.S. in college campuses, prisons, and close-knit communities, including a large outbreak in northwest Arkansas in 2016, where almost 3,000 cases were reported. To address this public health problem, ACIP now recommends a third dose of a mumps virus-containing vaccine for people previously vaccinated with two doses who are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak. This third dose may be administered as measles, mumps, and rubella (MMR) vaccine or measles, mumps, rubella, and varicella (MMRV) vaccine.

The purpose of the updated recommendation is to improve protection of people at increased risk for mumps and mumps-related complications during an outbreak. For more information, see [Recommendations of the Advisory Committee on Immunization Practices for Use of a Third Dose of Mumps Virus-Containing Vaccine in Persons at Increased Risk for Mumps During an Outbreak](#), published in the *MMWR*, which is available on the CDC website.

### **Adult Immunizations in the Medi-Cal Fee-for-Service Population**

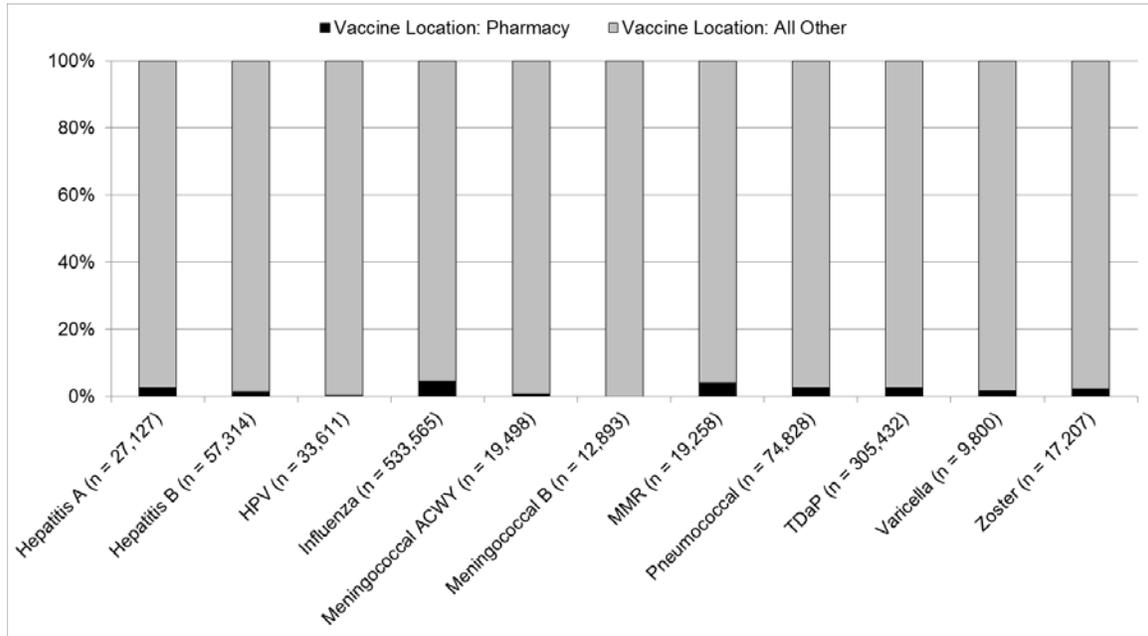
Effective February 1, 2016, the Medi-Cal fee-for-service Contract Drugs List now includes all ACIP-recommended adult immunizations as a pharmacy benefit. A review was conducted in 2017 to determine the frequency of vaccine administration in the pharmacy setting among Medi-Cal fee-for-service beneficiaries between 18 and 64 years of age. The measurement period included all medical and pharmacy claims with dates of service between February 1, 2016, and June 30, 2017. Only two adult vaccinations—influenza and herpes zoster—had more vaccinations in the pharmacy setting than in other locations during that time period.

Medi-Cal Managed Care Plans (MCPs) are also required to have the ACIP-recommended adult immunizations on the Medi-Cal fee-for-service Contract Drugs List as part of their pharmacy formulary benefit and should ensure formulary comparability for these immunizations. See [All Plan Letter 16-009 \(Revised\)](#) and [All Plan Letter 18-004](#) for additional details about immunization requirements for managed care beneficiaries.

Due to similar requirements across the entire adult Medi-Cal population, the previous analysis was repeated and expanded to include all Medi-Cal beneficiaries (fee-for-service and those in an MCP). The measurement period included all medical and pharmacy claims with dates of service between January 1, 2017, and December 31, 2017. The age range from the previous analysis was changed to between 19 and 64 years of age due to the California Vaccines for Children program covering children and adolescents through 18 years of age.

For reference, Medi-Cal beneficiaries with at least one dose of a vaccine that requires multiple doses during the time frame were included in the analysis, not just those beneficiaries who completed the series. Any Medi-Cal beneficiary receiving the hepatitis A and B combination vaccine was counted among both the hepatitis A and hepatitis B totals. Vaccines that averaged <10 immunizations in the pharmacy during this time frame (for example, rabies) were excluded from Figure 1 due to data confidentiality issues.

**Figure 1. Vaccine Location of Medi-Cal Beneficiaries Between 19 and 64 Years of Age (with Dates of Service Between January 1, 2017, and December 31, 2017).**



As shown in Figure 1, adult immunization rates across all Medi-Cal beneficiaries in the pharmacy setting remain low, ranging from 4.5% for influenza to 0.1% for HPV. Figure 1 shows much lower rates of pharmacy administration of all vaccines across the entire Medi-Cal population, in comparison with the earlier analysis of the Medi-Cal fee-for-service beneficiaries.

While a number of factors may account for the difference in pharmacy administration of adult immunizations, MCPs often have pay-for-performance metrics tied to immunizations, which may provide greater incentives to medical providers for administering vaccines in the medical setting. Other factors may include continuity-of-care issues, lower reimbursement in the pharmacy setting, pharmacy-specific rules regarding pharmacy administration of immunizations, lack of training in the pharmacy setting, and time constraints for administration. Future work in this area could try to identify potential barriers and facilitators to adult immunizations, including stratifying by specific vaccines, geographic regions, and/or MCPs, in order to target specific areas for improvement.