



# Clinical Advisory

Fall 2024 Vaccine Season

PharMerica®

## Background

As we approach the fall 2024 vaccine season, it is crucial to educate long-term care staff on current recommendations for vaccinating residents. While certain respiratory infections (e.g., influenza) are known to peak across the fall to winter months, increasing the importance of timely immunization efforts in early fall, the industry would do well to use this as an opportunity to protect all eligible residents against other infectious diseases for which vaccines exist.

This advisory provides essential information on vaccinations for [COVID-19](#), [Influenza](#), [Pneumococcal](#), and [Respiratory Syncytial Virus](#) (RSV) infections, with specific focus on new and recently revised approvals and recommendations from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and Advisory Committee on Immunization Practices (ACIP).

## COVID-19 VACCINATION

### What's New in 2024?

- **Updated Vaccine Formulations:** On 6/27/24, the CDC adopted the ACIP recommendations for use of reformulated 2024–2025 COVID-19 vaccines in people ages 6 months and older as approved or authorized by the FDA.
- Updated 2024–2025 vaccines from Moderna, Novavax, and Pfizer are expected to be available in fall 2024.
- These updated COVID-19 vaccines are being designed to target the predominantly circulating variants (JN.1 lineage) which are descendants of the Omicron version of the SARS-CoV-2 virus.

### Summary of Current CDC Guidance:

- **Everyone ages 6 months and older should receive an updated 2024-2025 COVID-19 vaccine to protect against the potentially serious outcomes of COVID-19 this fall and winter, whether or not they have ever been previously vaccinated with a COVID-19 vaccine.**
- This recommendation will take effect as soon as the new vaccines are available.
- Until the 2024-25 COVID-19 vaccines are available, healthcare providers may continue to vaccinate individuals with authorized/approved COVID-19 vaccine, according to the [current CDC guidance](#) (key points summarized below):
  - Children 6 months to 4 years of age may need multiple doses of COVID-19 vaccines to be up to date, including at least 1 dose of updated COVID-19 vaccine.
  - Everyone  $\geq$  5 years of age should get 1 dose of updated COVID-19 vaccine to protect against serious COVID-19 illness.
  - People who are moderately or severely immunocompromised may get additional doses of updated COVID-19 vaccine.

- People  $\geq$  65 years of age who received 1 dose of any updated 2023-2024 COVID-19 vaccine (Pfizer, Moderna or Novavax) should receive 1 additional dose of updated COVID-19 vaccine  $\geq$  4 months after the previous updated dose.

[!\[\]\(4729e517bc6a7cd81c8025b9646574fb\_img.jpg\) Access the full CDC Interim Clinical Consideration for COVID-19 Vaccination here!](#)

## INFLUENZA VACCINATION

### What's New in 2024?

- **CDC Continues Universal Recommendation: Everyone  $\geq$  6 months of age, with rare exceptions, should receive an updated seasonal flu vaccine to reduce the risk of influenza and potentially serious complications this fall and winter.**
- Updated 2024-2025 flu vaccines will all be **trivalent** and will protect against an H1N1, H3N2 and a B/Victoria virus.
- The 2024-25 flu season continues to apply the recent (2022-23) recommendation to **preferentially recommend select higher-dose and adjuvanted influenza vaccines in older adults  $\geq$  65 years of age.**
- The 2024-25 flu season continues to apply the recent (2023-24) egg-allergy recommendation to **no longer endorse additional safety measures for flu vaccination of people who are allergic to eggs** (beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg).

### Summary of Current CDC Guidance:

- **Everyone  $\geq$  6 months of age, with rare exceptions, should receive an updated 2024-25 flu vaccine.**
- Most people need only one dose of the flu vaccine each season.
- CDC recommends that flu vaccination be offered as long as influenza viruses are circulating, with September and October being the best times for most people to get vaccinated (See CMS Requirements, Timing below).
- Flu vaccination in July and August is not recommended for most people, and for adults, especially those  $\geq$  65 years of age, vaccination in July and August should be avoided unless it won't be possible to vaccinate in September or October.
- People  $\geq$  65 years of age are preferentially recommended to receive one of three flu vaccine options: higher dose flu shots (Fluzone® High-Dose, Flublok® recombinant) or adjuvanted flu shots (Fluad® adjuvanted). There is no preferential recommendation for one of these options over another.
- There is no preferential recommendation for flu vaccine options in people  $<$  65 years of age.

### Summary of Current CMS Requirements:

- For the 2024-25 season, the Centers for Medicare and Medicaid Services (CMS) continues the historical requirement for nursing facilities participating in the Medicare and Medicaid programs **to offer all residents influenza vaccines and to document the results.**
- According to the mandates, each resident is to be vaccinated unless medically contraindicated, the resident or a legal representative refuses vaccination, or the vaccine is not available because of shortage (to be supported with documentation).
- This information is to be reported in Section O (MDS Item O0250) of the CMS Minimum Data Set ([MDS 3.0](#)), which tracks nursing home health parameters.
- Timing: Per F883 – §483.80(d)(1)(ii): *“Each resident is [to be] offered an influenza immunization October 1 through March 31 annually...”*

[🔗 Access the full CDC Seasonal Influenza Vaccination Resources for Health Professionals here!](#)

(CDC will update for the 2024-25 season)

## PNEUMOCOCCAL VACCINATION

### What's New in 2024?

- **New FDA-Approved Pneumococcal Vaccine Receives ACIP Endorsement:** On June 27, 2024, ACIP voted in favor of expanding pneumococcal vaccine recommendations to include Merck's **CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine [PCV21])** as an option for adults aged >19 years who are recommended to receive a dose of PCV.
- Based on CDC data from 2018-2021, the serotypes covered by CAPVAXIVE™ are responsible for more cases of Invasive Pneumococcal Disease (IPD) in adults compared to PCV20 (pneumococcal 20-valent conjugate vaccine).
  - In adults 50 years of age and older, CAPVAXIVE covers the serotypes responsible for approximately 84% of IPD cases, compared to approximately 52% covered by PCV20.
  - In adults 65 years of age and older, CAPVAXIVE covers the serotypes responsible for approximately 85% of IPD cases, compared to approximately 51% covered by PCV20.
- Facilities should update internal policies and procedures to incorporate CAPVAXIVE™ (PCV21) into vaccination protocols, in accordance with recommendations adopted and published by the CDC.

### Summary of Current CDC Guidance:

- CDC recommends pneumococcal vaccination for children younger than 5 years and adults 65 years or older.

- CDC also recommends pneumococcal vaccination for children and adults at increased risk for pneumococcal disease.
- Follow the recommended [immunization schedule](#) to ensure that residents get needed and appropriate pneumococcal vaccinations.

### Summary of Current CMS Requirements:

- For the 2024-25 season, the CMS continues the historical requirement for nursing facilities participating in the Medicare and Medicaid programs **to offer all residents pneumococcal vaccines and to document the results.**
- According to the mandates, each resident is to be vaccinated unless medically contraindicated, the resident or a legal representative refuses vaccination, or the vaccine is not available because of shortage (to be supported with documentation).
- This information is to be reported in Section O (MDS Item O0300) of the CMS Minimum Data Set ([MDS 3.0](#)), which tracks nursing home health parameters.

 [Access the full CDC Pneumococcal Vaccine Recommendations here!](#)  
(CDC will update for the 2024-25 season)

## RSV VACCINATION

### What's New in 2024?

- **New RSV Vaccine Receives FDA Approval, CDC Recommendation:** Moderna's mRNA-platform-based mRESVIA®, the third RSV vaccine FDA-approved in the US, received CDC recommendation for use in **adults aged ≥60 years of age.**
- **FDA Expands Indication for GSK's RSV Vaccine; CDC Withholds Recommendation:** While GSK was successful in their bid for regulatory approval to extend **Arexvy RSV vaccination to adults aged 50-59 years at increased risk for lower respiratory tract disease**, the CDC's ACIP abstained from voting on recommendations for use in this expanded age range (citing a need for more info before making a population-level policy recommendation for this age group).
- **Paradigm Shift in RSV Vaccine Recommendations:** Due to industry complaints regarding the ambiguity and implementation challenges of the previous Shared Clinical Decision Making (SCDM) model for RSV vaccination in older adults, ACIP endorsed 2 new age-based and risk-based RSV recommendations (See, Summary of Current CDC Guidance).

### Summary of Current CDC Guidance:

- All older adults **≥ 75 years of age** should receive a single dose of RSV vaccination.

- All adults aged 60 to 74 years of age who are at increased risk of severe RSV disease (with certain chronic medical conditions or other risk factors) should receive a single dose of RSV vaccination.
  - Factors that confer increased risk:
    - Advanced-stage kidney disease
    - Chronic heart disease
    - Chronic lung illnesses
    - Severe obesity
    - Residents dwelling in nursing homes
- Adult RSV vaccination can be administered year-round, but it is most beneficial if given in late summer to early fall.
- Currently, adults are recommended to receive only one lifetime dose of an RSV vaccine (NOT repeated seasonally).

 [Access the full CDC RSV Immunizations Recommendations here!](#)

### **Stay tuned for more supportive vaccine information in the forthcoming PharMerica 2024 - 2025 Influenza and Adult Immunization Guide!**

## REFERENCES

1. CDC Recommends Updated 2024-2025 COVID-19 and Flu Vaccines for Fall/Winter Virus Season. CDC. June 27, 2024. <https://www.cdc.gov/media/releases/2024/s-t0627-vaccine-recommendations.html>
2. Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2024. FDA. Jun 13, 2024. <https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2024>
3. Seasonal Influenza Vaccination Resources for Health Professionals. CDC. Sep 7, 2023. <https://www.cdc.gov/flu/professionals/vaccination/index.htm>
4. Pneumococcal Vaccine Recommendations. CDC. Jun 26, 2024. <https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/index.html>
5. Respiratory Syncytial Virus (RSV) Immunizations. CDC. Jul 3, 2024. <https://www.cdc.gov/vaccines/vpd/rsv/index.html>