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DEPARTMENT OF HEALTH AND HUMAN SERVICES





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TECHNICAL BULLETIN

DATE: September 8, 2023

TOPIC: FDA Approves Use of Respiratory Syncytial Virus Vaccines (RSV) for Adults 60 and Older

CONTACT: Jessica Lamb, RN, Nevada State Immunization Program

TO: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

BACKGROUND

In May 2023, the <u>U.S. Food and Drug Administration (FDA)</u> approved two different vaccines (from GSK and Pfizer) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) for use in adults aged 60 years and older. Both RSV vaccines have demonstrated moderate to high efficacy in preventing RSV-associated LRTD and have the potential to prevent substantial morbidity and mortality among older adults. This technical bulletin summarizes the most recent RSV vaccine recommendations from the Centers for Disease Control and Prevention (CDC), including eligibility and schedule.

Both new vaccines — which are the first ones licensed in the United States to protect against RSV — are expected to be available in the fall of 2023. These vaccines provide an opportunity to help protect older adults against severe RSV illness at a time when multiple respiratory infections such as COVID-19 and seasonal influenza are likely to circulate. The decision to vaccinate a patient for RSV should be based on a discussion between the health care provider and the patient, which might be guided by the patient's risk for disease as well as their characteristics, values and preferences, and the provider's clinical discretion, and the characteristics of the vaccine. Data on co-administration of the RSV vaccine with other adult recommended vaccines is limited. Additionally, data are lacking on the safety of coadministration with other vaccines that might be recommended for adults, such as COVID-19 vaccines; pneumococcal vaccines; adult tetanus, diphtheria, and pertussis vaccines; and the recombinant zoster vaccine. The only currently available data is on the coadministration of RSV and influenza vaccines, however, the evidence is mixed regarding increased reactogenicity. When deciding whether to coadminister other vaccines with an RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccines, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences. ¹

Those eligible to receive a one-time, single dose of GSK's RSV Vaccine, AREXVY, include:	Those eligible to receive a one-time, single dose of <u>Pfizer's RSV Vaccine, ABRYSVO</u> , include:
Individuals 60 years of age and older	Individuals 60 years of age and older
<u>Dose amount:</u> 0.5 mL single dose, to be administered intramuscularly	<u>Dose amount:</u> 0.5 mL single dose, to be administered intramuscularly

Storage and handling: Store in the original package to protect vials from light. Store adjuvant suspension component vials and lyophilized antigen component vials between 2°C and 8°C (36°F and 46°F) before reconstitution. After reconstitution, administer immediately or store between 2°C and 8°C (36°F and 46°F) or at room temperature up to 25°C (77°F) for up to four hours prior to use and protect from light. Discard reconstituted vaccine if not used within four hours. Do not freeze. Discard if reconstituted vaccine, adjuvant suspension, or lyophilized antigen components have been frozen.

Storage and handling: Before reconstitution, store between 2°C and 8°C (36°F and 46°F) in the original carton. After reconstitution, administer immediately or store at room temperature (15°C to 30°C [59°F to 86°F]) and use within four hours. Do not store under refrigerated conditions once reconstituted. Discard reconstituted vaccine if not used within four hours. Do not freeze before, during or after reconstitution.

Note: AREXVY is supplied in two vials that must be reconstituted prior to administration. Please refer to the full <u>prescribing information</u> for AREXVY for full details.

Note: ABRYSVO must be reconstituted prior to administration. ABRYSVO must be reconstituted with provided syringe of sterile water diluent component. Please refer to the full <u>prescribing information</u> for ABRYSVO for full details.

For more information and/or additional resources, CDC has published an <u>RSV Vaccine Information</u> <u>Statement</u>, which includes specific RSV vaccine guidance and administration information. To access vaccine information statements in Spanish and other languages, visit https://www.immunize.org/vis/. In addition, the CDC has also updated their <u>RSV Infection webpage</u> and <u>RSV for Healthcare Providers webpage</u>.

Adverse reactions should be reported to the <u>Vaccine Adverse Event Reporting System (VAERS)</u>. Health care providers will usually file this report, or individuals may complete the form. Visit the <u>VAERS website</u> or call 1-800-822-7967. VAERS is only for reporting reactions. VAERS staff members do not give medical advice.

Questions

For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page regularly. Email nviz@health.nv.gov for other questions regarding RSV.

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¹ CDC: Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023