Official websites use .gov A .gov website belongs to an official government organization in the United States. Secure .gov websites use HTTPS A lock ( ) or https:// means you've safely connected to the .gov website. Share sensitive information only on official, secure websites. There are three RSV vaccines licensed for use in adults ages 60 years and older in the United States: GSK’s AREXVY, Moderna’s mRESVIA, and Pfizer’s ABRYSVO. For additional details on the recommendations of the Advisory Committee on Immunization Practices (ACIP) for RSV vaccination, see Adult RSV ACIP Vaccine Recommendations. CDC recommends a single dose of RSV vaccines for: Epidemiologic evidence indicates that all adults ages 75 or older and adults ages 60-74 with certain risk factors are at increased risk of severe RSV. The following conditions increase the risk of severe RSV: As well as: *Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity. †Retirement communities and independent living communities for seniors are not considered long-term care facilities. Adults 60-74 living in these facilities may still be recommended to receive RSV vaccination if they have certain medical conditions listed above. For patients who have not already received an RSV vaccine and decide to get one, CDC encourages healthcare providers to maximize the benefit of RSV vaccination by giving them their RSV vaccine in late summer or early fall. The RSV vaccine is not currently an annual vaccine, meaning eligible adults do not need to get a dose every RSV season. Currently, CDC recommends only a single dose of RSV vaccine for all adults ages 75 and older and adults ages 60-74 with increased risk of severe RSV disease. Additional surveillance and evaluation activities are ongoing to determine whether adults might benefit from receiving additional RSV vaccine doses in the future.

So far, RSV vaccines appear to provide some protection for at least two RSV seasons. GSK's AREXVY should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine. Information about GSK's AREXVY can be found in the manufacturer's package insert. Pfizer's ABRYSVO should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine. Information about Pfizer's ABRYSVO can be found in the manufacturer's package insert. Moderna's mRESVIA should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine. Information about Moderna's mRESVIA can be found in the manufacturer's package insert. To learn more, see ACIP Contraindications Guidelines for Immunization, General Best Practice Guidelines for Immunization. There are three RSV vaccines licensed by the Food and Drug Administration (FDA) for use in U.S. adults ages 60 and older: GSK's AREXVY consists of a recombinant RSV F protein antigen (based on the RSV-A subtype), stabilized in the prefusion conformation (preF), and AS01E adjuvant. The AS01 adjuvant system is the same used in GSK's recombinant zoster vaccine (RZV, Shingrix), but at a lower dose. The vaccine is supplied as a single-dose vial of 120 µg of lyophilized preF antigen component to be reconstituted with the accompanying vial of AS01E adjuvant suspension component. A single dose after reconstitution is 0.5 mL. Consult the package insert for proper storage and handling details, shelf life, and reconstitution instructions: Package Insert – AREXVY (fda.gov). In June 2024, FDA licensed AREXVY for use in people ages 50–59 who are at increased risk of RSV lower respiratory tract disease. ACIP did not hold a vote to recommend AREXVY for people ages 50–59. At this time, ACIP concluded more information is needed to determine the best policy option for the use of RSV vaccines in people ages 50–59. CDC will continue to monitor the effectiveness and safety of these vaccines in people ages 60 and older and is committed to re-evaluating potential RSV vaccine recommendations for people ages 50–59 when additional information becomes

available. Pfizer’s ABRYSVO consists of a recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes), stabilized in the prefusion conformation (preF). The vaccine is supplied as a single-dose vial of 120 µg of lyophilized preF antigen component (60 µg from RSV-A, 60 µg from RSV-B) to be reconstituted with the accompanying vial of sterile water diluent component. A single dose after reconstitution is approximately 0.5 mL. Consult the package insert for proper storage and handling details, shelf life, and reconstitution instructions: Package Insert – ABRYSVO (fda.gov). Moderna’s mRESVIA consists of a single 0.5 mL-dose vial containing 50 µg of nucleoside modified mRNA encoding the RSV F glycoprotein (monovalent, based on the RSV-A subtype), stabilized in the prefusion conformation (pre-F protein). Consult the package insert for proper storage and handling details, shelf life, and more: Package Insert – MRESVIA (fda.gov). Protein Subunit Vaccines (GSK’s AREXVY and Pfizer’s ABRYSVO) During clinical trials, RSV vaccines for people ages 60 and older reduced the risk of symptomatic lower respiratory tract disease by 80%-90% in the first season after RSV vaccination. While the protection provided by RSV vaccines wanes over time, they still offer significant protection against serious RSV illness for at least 2 years. CDC data from the first season of use showed that RSV vaccine provided protection against hospitalization, critical illness (ICU admission and death), and emergency department visits among people ages 60 and older. During 2023-2024: Ongoing monitoring is needed to assess RSV vaccine effectiveness beyond the first season after vaccine receipt and in different risk groups as RSV vaccine coverage increases. mRNA Vaccine (Moderna’s mRESVIA) A summary of Moderna’s large phase 2/3 randomized, blinded placebo-controlled clinical trial in participants ages 60 and older can be found in the manufacturer’s package insert. GSK’s AREXVY In clinical trials, most adults ages 60 and older who received the GSK RSV vaccine experienced vaccine-related reactions. The most common reactions in the large phase 3 clinical trial were pain at the injection site (61%), fatigue (34%), myalgia (29%), and headache (27%) (1). Grade 3 reactions

(severe enough to prevent normal daily activities) occurred in 4% of vaccine recipients. Across all clinical trials in adults ages 60 and older, inflammatory neurologic events were reported in three of 17,922 participants within 42 days after receipt of the GSK RSV vaccine (2). All three events occurred in trials without a placebo arm. The reported cases included one case of Guillain-Barré syndrome (GBS) with symptom onset 9 days postvaccination in an open-label phase 3 clinical trial and two cases of acute disseminated encephalomyelitis (ADEM) among participants in a randomized phase 3 coadministration study. The two ADEM cases were reported in participants after concomitant receipt of the GSK RSV vaccine and standard dose seasonal influenza vaccine; symptom onset occurred 7 and 22 days postvaccination, and one case was fatal. In both ADEM cases, the diagnosis was based on symptoms and clinical findings only; diagnostic testing (including brain imaging, cerebrospinal fluid testing, and nerve conduction studies) was not performed, leading to uncertainty in the diagnoses. Both ADEM cases were reported from the same study site. The site investigator later revised the diagnosis from ADEM to hypoglycemia and dementia in the fatal case, and from ADEM to stroke in the non-fatal case. In the large phase 3 clinical trial, a higher number of participants who received the GSK RSV vaccine than those who received placebo reported atrial fibrillation within 30 days after injection (10 vs. 4 participants) (2). However, due to the small number of these events, it is not known at this time whether they occurred due to chance, or whether RSV vaccination increases the risk of atrial fibrillation. Pfizer’s ABRYSVO In clinical trials among adults ages 60 and older, vaccine-related reactions were common among participants who received the Pfizer RSV vaccine. The most common reactions in the large phase 3 clinical trial were fatigue (16%), headache (13%), and pain at the injection site (11%) (4). Grade 3 reactions (severe enough to prevent normal daily activities) occurred in approximately 1% of vaccine recipients. Across all clinical trials in adults ages 60 and older, inflammatory neurologic events were reported in three of 20,255 participants within 42 days after

receipt of the Pfizer RSV vaccine (2). The events included one case of GBS with symptom onset 14 days postvaccination, one case of Miller Fisher syndrome (a GBS variant) with symptom onset 10 days postvaccination; and one case of undifferentiated motor-sensory axonal polyneuropathy with worsening of preexisting symptoms 21 days postvaccination. In the large phase 3 clinical trial, a higher number of participants who received the Pfizer RSV vaccine than those who received placebo reported atrial fibrillation within the 30 days after injection (10 vs. 4 participants) (2). However, due to the small number of these events, it is not known at this time whether they occurred due to chance, or whether RSV vaccination increases the risk of atrial fibrillation. Ongoing Studies and Surveillance Preliminary safety surveillance data from the Vaccine Adverse Event Reporting System (VAERS) (co-managed by CDC and FDA) and the Vaccine Safety Datalink (VSD), as well as from a partnership between FDA and the Centers for Medicare and Medicaid Services (CMS), suggest a potential increased risk of GBS after vaccination in older adults. Due to uncertainties and limitations, these analyses cannot establish if there is an increased risk for GBS after RSV vaccination. CDC and FDA are conducting population-based active surveillance to monitor for GBS following RSV vaccination. Additional analyses using these surveillance data are underway and will provide more information about whether there is an association between RSV vaccines and GBS. If a risk if present, these analyses may also be able to determine its magnitude. Due to the small number of inflammatory neurologic events in the clinical trials and the preliminary nature of the post-licensure safety surveillance results regarding GBS, it is not known at this time whether RSV vaccination is associated with increased risk of GBS or other neurologic adverse events. According to FDA post-marketing requirements and commitments, both manufacturers will conduct safety studies to evaluate the risk of neurologic adverse events and atrial fibrillation following RSV vaccination. During the June 2024 ACIP meeting, CDC and FDA presented new data from ongoing safety monitoring which continue to suggest a potential

increased risk of GBS after RSV vaccination with the two protein subunit vaccines (AREXVY by GSK and ABRYSVO by Pfizer). However, at this time, more data are needed to determine if there is an increased risk of Guillain-Barré Syndrome after RSV vaccination. CDC will continue to monitor adverse events following RSV vaccination through its vaccine safety surveillance systems. This information will be updated with results from post-marketing safety studies and from vaccine safety surveillance, as they become available. For more information on vaccine safety, see Vaccine Information and Safety Studies | Vaccine Safety | CDC. Adverse events after RSV vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), even if it is not clear that the vaccine caused the adverse event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or by telephone at 1-800-822-7967. Moderna's mRESVIA In clinical trials among adults ages 60 and older, vaccine-related reactions were common among participants who received mRESVIA. The most common reactions in the large phase 3 clinical trial were pain at the injection site (56%), fatigue (31%), headache (27%), and myalgia (26%), arthralgia (22%), axillary (underarm) swelling or tenderness (15%), and chills (12%). See the manufacturer's package insert for more safety information about mRESVIA. As with all vaccines, CDC and FDA will conduct routine post-licensure safety surveillance for adverse events following vaccination with mRESVIA. References Proper vaccine storage and handling practices play an important role in protecting individuals and communities from vaccine-preventable diseases. For general recommendations and guidance, see Vaccine Storage and Handling. Provided below is guidance specific to RSV vaccines. GSK's AREXVY: GSK's vaccine is supplied in two vials that must be reconstituted prior to administration. One vial is a lyophilized antigen component and the second is a liquid diluent adjuvant suspension. You MUST use the diluent provided by the manufacturer. Refer to the manufacturer's package insert for specific instructions on reconstituting the vaccine: Package Insert – AREXVY (fda.gov). Before reconstitution:

After reconstitution: Pfizer’s ABRYSVO: Pfizer’s vaccine is supplied in a kit with three components: a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component, and a vial adapter. Refer to the manufacturer’s package insert for specific instructions on reconstituting the vaccine: Package Insert – ABRYSVO (fda.gov). Before reconstitution: After reconstitution: Moderna’s mRESVIA: During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Refer to the manufacturer’s package insert for specific instructions on storage and thawing: Package Insert – mRESVIA (fda.gov). Frozen Storage Store frozen between -40°C to -15°C (-40°F to 5°F). Storage after Thawing Storage at 2°C to 8°C (36°F to 46°F): Storage at 8°C to 25°C (46°F to 77°F): This page provides a summary of guidance for administering FDA-licensed RSV vaccines for use in U.S. adults ages 60 and older RSV vaccines, including route, number of doses, and co-administration with other vaccines. Do not use any RSV vaccine beyond the expiration date printed on the label. Administer RSV vaccine intramuscularly. The preferred site of administration is the deltoid region of the upper arm. Do not administer RSV vaccine intravenously, intradermally, or subcutaneously. Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines are currently limited. Coadministration of RSV and seasonal influenza vaccines met noninferiority criteria for immunogenicity with the exception of the FluA/Darwin H3N2 strain when the GSK RSV vaccine was coadministered with adjuvanted quadrivalent inactivated influenza vaccine. RSV and influenza antibody titers were somewhat lower with coadministration; however, the clinical significance of this is unknown. Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Data are only available for coadministration of RSV and influenza vaccines, and evidence is mixed regarding increased reactogenicity. Data are lacking on the safety of

coadministration with other vaccines that might be recommended for persons in this age group, such as COVID-19 vaccines; pneumococcal vaccines; adult tetanus, diphtheria, and pertussis vaccines; and the recombinant zoster vaccine (the recombinant zoster vaccine and GSK’s RSV vaccine contains the same adjuvant). 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 vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences. Post-licensure efficacy and safety monitoring of coadministered RSV vaccines with other vaccines will further direct guidance. References and Resources

Source URL: https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html