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Dear Colleagues:

Key Messages

- Respiratory syncytial virus (RSV) is a significant cause of hospitalizations and death in older adults. This high-risk population can now be immunized to reduce their risk of severe RSV.
- A single dose of *Abyrsvo* or *Arexvy* appears to be effective in preventing RSV-associated lower respiratory tract disease for one and possibly two RSV seasons in adults ≥60 years old.
- <u>CDC</u> recommends that adults <u>></u> 60 years of age may receive a single dose of RSV vaccine using shared clinical decision-making, including consideration of risk factors for severe disease.
- Health care providers should report all vaccines administered to ICARE.

Respiratory syncytial virus (RSV) causes a heavy burden of hospitalizations and deaths each year in infants and those over 60 years of age. According to Centers for Disease Control and Prevention (CDC) estimates, RSV causes about 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years of age and older each year. Those over 60 years of age who are hospitalized with RSV often have more severe disease than those admitted with COVID-19 or influenza, including a greater need for oxygen and intensive care unit (ICU) nursing.

In Illinois, there already is a surge in RSV activity that is leading to a rise in hospital admissions. Fortunately, effective vaccines are now available to protect adults 60 years of age and older from severe RSV infection. This memo addresses vaccination of adults \geq 60 years old to prevent lower respiratory tract disease (LRTD); a separate memo will address RSV prevention strategies for infants and pregnant women.

Efficacy and safety of RSV vaccines for those over the age of 60 years

Two new RSV vaccines have been approved by the Food and Drug Administration (FDA) and recommended by the Advisory Committee on Immunization Practices (ACIP) for use in adults \geq 60 years: *Abrysvo* (Pfizer); and *Arexvy* (GSK).

In clinical trials, both vaccines reduced the incidence of RSV associated LRTD during two RSV seasons, with *a single IM dose being more than 80% effective in preventing RSV LRTD* during the first RSV season after vaccination. The vaccines are considered <u>safe and well tolerated</u> with the most common side effects (injection site reactions, fatigue, headache, and myalgia) comparable to those seen with other vaccines. Grade 3 reactions (severe enough to prevent normal daily activities) occurred in 4% of vaccine recipients. During clinical trials, there were six reported cases of inflammatory neurologic events (e.g., Guillan-Barre syndrome) out of more than 38,000 vaccinated individuals. Ongoing safety monitoring is currently being conducted via the Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datallink (VSD).

As noted above, RSV vaccines appear to provide protection over **two RSV seasons.** Additional surveillance and evaluation activities are planned to assess how long the vaccines protect against RSV and whether additional doses will be needed.

Recommendations for use

The ACIP recommends RSV vaccination with a single dose of *Abrysvo* or *Arexvy* should be targeted to **adults** ≥60 years old at highest risk for severe RSV disease, which includes those with:

- pulmonary or cardiovascular diseases,
- moderate or severe immune compromise,
- diabetes,
- neurologic or neuromuscular conditions,
- renal or hepatic impairment, or
- hematologic disorders.

Advanced age, frailty, and residence in a long-term care facility are also associated with an increased risk of severe RSV disease.

Timing of vaccination

Both *Abrysvo* and *Arexvy* are available for the 2023-24 season; vaccination should be discussed with eligible adults now (and on an ongoing basis with those who remain unvaccinated, because some off-season RSV circulation is possible).

Shared clinical decision-making

ACIP recommends shared clinical decision making (SCDM), with the decision regarding vaccination informed by a patients' health status, their risk of severe RSV disease, the health care provider's clinical judgment, patient preferences, the safety profile of the RSV vaccine products, and other factors. The SCDM recommendation for RSV vaccination is intended to allow providers and patients flexibility based on what is best for each individual patient.

<u>Co-administration of RSV vaccines and other adult vaccines</u> during the same visit is acceptable, but data on co-administration is limited. Administering RSV vaccines with other vaccines might increase local or systemic reactogenicity. If vaccines are not administered the same day, *there is no required interval between RSV and other vaccines*.

Reporting adverse events

Providers should report adverse events after RSV vaccination to 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 <u>https://vaers.hhs.gov/index.html</u> or by telephone at 1-800-822-7967. Later this fall, it is expected that CDC will release a new version of <u>v-safe</u>, which will allow patients to complete health surveys to share their post-RSV vaccination experiences.

Insurance coverage

Insurance claims should include documentation of the above risk conditions to support the medical necessity of RSV vaccination as well as SCDM.

Both Abrysvo and Arexvy are expected to become available for uninsured and underinsured adults through the Section 317 program later this year. Local health departments, federally qualified health centers (FQHCs), and rural health centers (RHCs) that are enrolled VFC providers may also participate in the Section 317 adult vaccine program.

Uninsured individuals should contact their <u>local health department</u> or <u>FQHC</u> in their area for information on access to RSV vaccines.

Illinois Comprehensive Automated Immunization Registry Exchange (ICARE)

All vaccinations, including RSV vaccination, should be reported to ICARE. New providers should <u>follow this</u> <u>link</u> to enroll their organization and clinical sites into ICARE, designate a Portal Registration Authority (PRA), and request access to the web portal and ICARE for all users.

Resources

- RSV for health care providers (CDC). Older adults | FAQs adults | General.
- RSV Vaccination for Adults 60 years of Age and Older Job Aid (CDC): <u>Shared Clinical Decision Making.</u>

We are grateful for your efforts to help reduce the impact of RSV in Illinois.

Sincerely,

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References:

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