

RSV Vaccines Provider Fact Sheet & FAQs

Quick Facts

- There are 3 FDA-approved RSV vaccines for older adults: GSK (Arexvy) Pfizer (Abrysvo) and Moderna (mRESVIA).
- All 3 vaccines were generally safe and well-tolerated in phase 3 clinical trials, and demonstrated >80% efficacy against symptomatic, lab-confirmed RSV with documented lower respiratory symptoms
- The Pfizer and GSK products are protein-based (not live) vaccines and the Moderna vaccine is an mRNA vaccine
- A single dose of RSV vaccine is recommended to be given late summer/early fall for:
 - All adults ages 75 and older
 - Adults ages 50-74 who are at increased risk of severe RSV disease

Which patients should be offered the RSV vaccine?

Consistent with CDC ACIP recommendations, we suggest offering the RSV vaccine to adult patients ≥ 50 years old who are at highest risk of severe RSV infection (see below). RSV vaccination is currently recommended as a one-time dose. Those who have already received RSV vaccination are NOT recommended to receive another dose. The RSV vaccine studies (Moderna, Pfizer and GSK) excluded immunosuppressed individuals, so efficacy and safety are limited to observational studies. Just as with other aspects of their patients' medical care, providers should discuss the risks and benefits of vaccination with their patients to reach a shared decision.

Who is highest risk for severe RSV infection and may benefit the most from vaccination?

Adults at highest risk for severe RSV infection are those who are ≥ 75 years of age or 50 years and older with any of the following conditions:

- Moderate or severe immunocompromise
- Chronic hematologic disorders
- Chronic heart, lung, liver, or kidney disease
- Diabetes mellitus
- Neurologic or neuromuscular conditions
- Adults living in nursing homes or long-term care facilities

What is different about the three available vaccines?

Abrysvo (Pfizer) is a bivalent vaccine containing stabilized prefusion F glycoproteins from the two major co-circulating antigenic subgroups (RSV A and RSV B). Arexvy (GSK) is a monovalent vaccine containing a stabilized prefusion F glycoprotein from the RSV A subgroup, combined with an adjuvant (AS01_E) to boost immune responses. The adjuvant used in Arexvy is the same one used in the currently available herpes zoster vaccine (Shingrix). mResvia (Moderna) is an mRNA vaccine which uses the same mRNA platform as the Moderna Covid-19 vaccine.

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Is there an advantage of one vaccine over another?

To date there has been no head-to-head comparison of the available vaccines. It is also unclear which of the vaccines will provide the best protection for immunosuppressed patients. Currently, we cannot recommend one vaccine over another. Eligible patients should be encouraged to get whichever vaccine is available based on formulary or coverage constraints.

What are side effects of the vaccines?

Common side effects of the vaccines in the phase 3 studies, included arm soreness/pain, fatigue, headache, and body aches; fever was uncommon after vaccination. In the vaccine trials for Arexvy (GSK) and Abrysvo (Pfizer), there were 6 severe adverse inflammatory neurologic events (Guillain-Barré syndrome, acute disseminated encephalomyelitis) among 38,247 participants (0.016%). There is also an early signal, suggesting a possible increase in atrial fibrillation (an abnormal heart rhythm). It is unknown whether these rare events were vaccine-related and which patient populations might be most affected. In post-market surveillance of the Pfizer and GSK products, data from VAERS (Vaccine Adverse Event Reporting System) found an incidence of Guillain-Barre syndrome of 1.8 cases per million doses of GSK vaccine and 4.4 cases per million doses of the Pfizer vaccine. In the Phase 3 trial of mResvia (Moderna), there were no cases of Guillain-Barre syndrome. Post-market data is not yet available.

How should I discuss this with my patients?

Patients should be made aware of the ACIP recommendation for a single dose of RSV vaccines for all adults ages 75 and older, and for adults ages 50-74 who are at increased risk of severe RSV disease. In addition to immunocompromise, the primary risk factors for severe RSV are being elderly and having cardiac or pulmonary comorbidities. Patients who are older and have more than one comorbidity will be at higher risk for adverse outcomes from RSV and may be most likely to benefit from vaccination. Patients who interact frequently with young children may be at higher risk for acquiring RSV. So far, risk factors predisposing individuals to potential RSV vaccine adverse events remain unknown. These are all considerations when discussing the risks and benefits of vaccination with patients.

Can the RSV vaccine be given at the same time as other vaccines, such as the influenza or COVID vaccines?

Data indicate that co-administration of the RSV vaccine with other vaccines is acceptable. The immune responses to influenza and RSV are similar when given at the same time as when they are given separately. Co-administering RSV vaccine with the influenza vaccine is safe but is associated with higher levels of systemic reactogenicity. When deciding whether to co-administer other vaccines with RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of returning for additional vaccines, and patient preferences. For patients who are concerned about systemic side effects, spacing out vaccines by at least 2 weeks between visits may be preferable.

Is this vaccine covered by insurance? How much will it cost for patients?

The vaccine is covered by Medicare Part D and by private insurers among patients who meet the ACIP criteria for vaccination.

Are the RSV vaccines safe in immunosuppressed patient populations/cancer patients?

Arexvy and Abrysvo are protein based, not live attenuated vaccines. Other protein-based vaccines are considered safe for use in immunosuppressed patients (including post-transplant and cancer patients),

for example, vaccines such as Hepatitis B and Tdap are safe in these patient populations. mResvia uses an mRNA platform, like the Moderna Covid-19 vaccine, which is considered safe for use in immunosuppressed patients. Although immunocompromised patients, including those with active malignancy, organ transplant, or on immunosuppressing medications, were excluded from the RSV vaccine licensing trials, observational data have not identified safety signals of concern in this population.

My patient is requesting this vaccine posttransplant. When can it safely be given?

Hematopoietic stem cell transplant (HCT)/CAR-T cell therapy: Currently, there are no national recommendations for routine RSV vaccination for HCT recipients, as data on efficacy and optimal timing for vaccination are unknown in these patients. We suggest offering to patients who are eligible (≥ 50 years of age) and are at least 3 months post-HCT/CAR-T cell therapy using a shared clinical decision-making approach. In patients who are eligible and wish to be vaccinated, fall is the ideal time to vaccinate (before RSV season begins)

Solid organ transplant (SOT): For patients who have received solid organ transplants, they should wait at least one month after transplant or ATG to receive the vaccine. Waiting longer after transplant will likely improve immunogenicity, but early vaccination should be prioritized during respiratory virus season.

What are adjuvanted vaccines and are they safe for my patients?

Adjuvants are combined with the main vaccine agents to improve responses to vaccine. Two other adjuvanted vaccines have been approved by the FDA and are currently in use: the herpes zoster vaccine (Shingrix) and an adjuvanted influenza vaccine (FluAD). The Arexvy vaccine is adjuvanted, while the Abrysvo vaccine has no adjuvant. The adjuvant used in Arexvy is also used in the herpes zoster vaccine (Shingrix), although the adjuvant dose in the RSV vaccine is lower, so is felt to be safe. Adjuvanted vaccines may cause minor side effects such as sore arm.

My patient has received an anti-CD-20 antibody (e.g. rituximab), can they be vaccinated?

There is no data to support a recommendation at this time. In patients who are eligible and wish to be vaccinated, ideally the vaccine should be given 6 months after the last dose of rituximab. During RSV season, vaccination can be considered, however, response rates are likely to be significantly lower than in immunocompetent hosts.

My patient is neutropenic, can they get the vaccine?

In patients who are neutropenic with ANC < 500 s, we suggest waiting until count recovery to administer vaccine. It is unknown how effective the vaccine will be in those undergoing therapy for leukemia or other major hematologic malignancies.

My patient is receiving IVIG, can they get the vaccine?

Similar to other vaccine recommendations, we would recommend delaying vaccine in those who are eligible and wish to be vaccinated until 6 months post their last IVIG infusion.

Can patients younger than 50 receive the vaccine?

ACIP recommends RSV vaccination with Abrysvo in pregnant individuals between 32 and 36 weeks' gestation. Beyond 36 weeks and 6 days vaccination is not recommended because there is not enough time for antibodies to develop and confer protection to the infant. This is a one-time vaccination recommendation. That is, if a patient received a maternal RSV vaccine during any previous pregnancy,

CDC does not recommend another dose of RSV vaccine for subsequent pregnancies. Among other individuals under 50 years of age who are at increased risk of severe RSV due to their immune status, there is currently no recommendation for RSV vaccination. Future studies evaluating efficacy in younger patient populations are currently underway, so vaccination recommendations may change in the future.

Where is the vaccine available?

This vaccine will be available at some clinics across UW Medicine. Contact your clinic manager to determine if your clinic will be providing the vaccine. The vaccine will not be provided during inpatient admissions. The vaccine is also available at many local pharmacies. Please contact your local pharmacy for more information.

What other RSV prevention options are available?

It is important to remind patients to avoid sick contacts, particularly children with respiratory symptoms during the fall and winter, when RSV is most commonly transmitted. Washing hands/using hand sanitizer and wearing masks in public places can also help limit RSV exposures. For infants and certain young children, monoclonal antibodies are also available to prevent severe RSV.

Educational materials:

<https://www.cdc.gov/vaccines/vpd/rsv/index.html>

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