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IN BRIEF

RSV Vaccine (Arexvy) for Ages 18-49

The FDA has expanded the licensed use of the recombinant respiratory syncytial virus (RSV) vaccine Arexvy (GSK) to include adults 18-49 years old. Arexvy and the two other available RSV vaccines, *Abrysvo* and *mResvia*, are now all licensed for prevention of RSV lower respiratory tract disease in persons ≥ 60 years old and in those 18-59 years old who are at increased risk of lower respiratory tract disease caused by RSV.¹ *Abrysvo* is also licensed for use in pregnant women at 32-36 weeks' gestation to prevent RSV-associated lower respiratory tract disease in their infants from birth to 6 months.

RSV DISEASE – RSV typically causes a mild upper respiratory tract infection in adults, but older adults and adults of any age with certain underlying health conditions have an increased risk of RSV-associated lower respiratory tract disease. RSV epidemics in the Northern Hemisphere typically occur between October and April, peaking in December or January.

CLINICAL STUDIES – A single dose of *Arexvy* has been shown to reduce the incidence of RSV-associated lower respiratory tract disease in adults ≥ 60 years old for up to 3 RSV seasons (median follow-up 30.6 months). FDA licensure for use in younger patients was based on the results of an immunogenicity trial that included 1029 adults 18-49 years old with chronic medical conditions (kidney or liver disease, diabetes, or cardiopulmonary, neuromuscular, or neurologic conditions), but not immunosuppression. The trial also enrolled a comparator group of adults ≥ 60 years old who received the vaccine. One month after vaccination with *Arexvy*, RSV-A and RSV-B neutralizing antibody responses in adults 18-49 years old were noninferior to those in adults ≥ 60 years old.² In a previous immunogenicity trial, immune responses to the vaccine in adults 50-59 years old with or without chronic medical conditions were noninferior to those in adults ≥ 60 years old.³

ADVERSE EFFECTS – Adverse effects reported with *Arexvy* in the immunogenicity trial were similar in participants 18-49 years old and ≥ 60 years old but were reported at higher rates in the younger age group. The most common adverse effects reported in adults 18-49 years old within 4 days of receiving the vaccine were injection-site pain (76%), myalgia

Table 1: Risk Factors for Severe RSV Disease¹

- ▶ Chronic medical conditions (e.g., pulmonary, cardiac, renal, hepatic, neurologic, neuromuscular, hematologic)
- ▶ Diabetes²
- ▶ Severe obesity (BMI ≥ 40 kg/m²)
- ▶ Moderate or severe immune compromise
- ▶ Frailty
- ▶ Residence in a nursing home or other long-term care facility
- ▶ Residence in a rural or remote community

1. CDC. RSV vaccine guidance for adults. February 24, 2026. Available at: <https://bit.ly/3QwvPTS>. Accessed April 23, 2026.
2. Complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or a sodium-glucose cotransporter-2 (SGLT2) inhibitor.

(60%), fatigue (60%), headache (44%), and arthralgia (28%). Guillain-Barré syndrome and atrial fibrillation have been reported rarely following vaccination with *Arexvy*; a causal relationship has not been established.⁴

RECOMMENDATIONS – The CDC Advisory Committee on Immunization Practices (ACIP) recommends one-time RSV vaccination for all adults ≥ 75 years old and for those 50-74 years old at increased risk for severe RSV disease (see Table 1).⁵ The ACIP has not yet issued a recommendation for RSV vaccination of adults < 50 years old. The Infectious Diseases Society of America (IDSA) and the American Medical Association recommend RSV vaccination for all immunocompromised adults ≥ 18 years old.^{6,7}

For optimal protection, the vaccine should be given before the onset of the RSV season. Administration of a RSV vaccine and other vaccines during the same visit is acceptable, but local or systemic reactogenicity could increase.

DOSAGE, ADMINISTRATION, AND COST – *Arexvy* is given as a single 0.5-mL IM injection. The wholesale acquisition cost (WAC) for one dose is \$321.⁸ ■

1. In brief: RSV vaccine (*Arexvy*) for ages 50-59. *Med Lett Drugs Ther* 2024; 66:113.
2. E Mitha et al. Immunogenicity and safety of the AS01E-adjuvanted respiratory syncytial virus (RSV) prefusion F protein vaccine in adults aged 18-49 years at increased risk of RSV disease compared with adults aged ≥ 60 years. *Clin Infect Dis* 2026 Feb 27 (epub).

3. M Ferguson et al. Noninferior immunogenicity and consistent safety of respiratory syncytial virus prefusion F protein vaccine in adults 50-59 years compared to ≥60 years of age. *Clin Infect Dis* 2024; 79:1074.
4. In brief: New warning for the RSV vaccines Arexvy and Abrysvo. *Med Lett Drugs Ther* 2025; 67:31.
5. CDC. RSV vaccine guidance for adults. February 24, 2026. Available at: <https://bit.ly/3QwvPTS>. Accessed April 23, 2026.
6. AMA. Vaccine recommendations. March 2, 2026. Available at: <https://bit.ly/3Q2XCLB>. Accessed April 23, 2026.
7. A Nellore et al. IDSA 2025 guidelines on the use of vaccines for the prevention of seasonal COVID-19, influenza, and RSV infections in immunocompromised patients. November 18, 2025. Available at: <https://bit.ly/4t3g1qp>. Accessed April 23, 2026.
8. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. April 5, 2026. Reprinted with permission by First Databank, Inc. All rights reserved. ©2026. www.fdbhealth.com/drug-pricing-policy.

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