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IN BRIEF

RSV Vaccine (*Arexvy*) for Ages 50-59

The recombinant respiratory syncytial virus (RSV) vaccine *Arexvy* (GSK) has now received FDA approval for use in adults 50-59 years old who are at increased risk for lower respiratory tract disease (LRTD) caused by RSV. It was previously approved only for adults ≥60 years old.[1] Two other RSV vaccines have received FDA approval: *Abrysvo*, a recombinant vaccine that is licensed for use in adults ≥60 years old and in pregnant women at 32-36 weeks' gestation to prevent RSV-associated LRTD in their infants,[1] and *mResvia*, an mRNA vaccine recently licensed for use in adults ≥60 years old that will be available for the 2024-25 RSV season.

RSV DISEASE — RSV typically causes a mild upper respiratory tract infection, but older adults, particularly those with underlying health conditions, have an increased risk of hospitalization due to RSV-associated LRTD. RSV epidemics in the Northern Hemisphere typically occur between October and April, peaking in December or January.

CLINICAL STUDIES — *Arexvy* has been shown to reduce the incidence of RSV-associated LRTD in adults ≥60 years old for up to 2 RSV seasons (median follow-up 17.8 months).[1] FDA approval of *Arexvy* for the expanded indication was based on the results of an unpublished immunogenicity trial that included 1152 adults 50-59 years old who were randomized to receive *Arexvy* or placebo; about 50% had chronic medical conditions (pulmonary or cardio-vascular disease, diabetes, kidney or liver disease). Persons with immunocompromising conditions were excluded. The trial also enrolled a comparator group of adults ≥60 years old who received the vaccine. Among persons vaccinated with *Arexvy*, RSV-A and RSV-B neutralizing antibody responses at one month in adults 50-59 years old (with and without chronic medical conditions) were noninferior to those in adults ≥60 years old.[2]

Table 1. Risk Factors for Severe RSV Disease

- Chronic medical conditions (e.g., pulmonary, cardiac, renal)
- Moderate or severe immune compromise
- Frailty
- Advanced age
- Residence in a nursing home or other long-term care facility

ADVERSE EFFECTS — In the clinical trial, adverse effects of *Arexvy* were similar in participants 50-59 years old and ≥60 years old but were reported at slightly higher rates in the younger age group. The most common adverse effects reported in adults 50-59 years old within 4 days of receiving *Arexvy* were injection-site pain (75.8%), erythema (13.2%) and swelling (10.4%), fatigue (39.8%), myalgia (35.6%), headache (31.7%), and arthralgia (23.4%). *Arexvy* was not associated with an increased risk of serious adverse events or potential immune-mediated diseases, compared to placebo, within 6 months post vaccination. Inflammatory neurologic events, including Guillain-Barré syndrome, and an increased risk of atrial fibrillation have been reported following vaccination with *Arexvy* in other trials.

ACIP RECOMMENDATIONS — The CDC Advisory Committee on Immunization Practices (ACIP) has recently updated its recommendations for use of RSV vaccines in older adults. A single dose of RSV vaccine is now recommended for all adults ≥75 years old and for those 60-74 years old at increased risk of severe RSV disease (see Table 1).[3] The ACIP has not yet issued a recommendation for RSV vaccination in adults 50-59 years old; an ACIP Work Group has suggested that RSV vaccination is likely to be beneficial in certain adults 50-59 years old at risk of severe RSV disease, but more data are needed.[4] For optimal protection, the vaccine should be given before the onset of the RSV season. Administration of an RSV vaccine and other adult 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 $280.[5] ■

1. Two vaccines (Arexvy and Abrysvo) for prevention of RSV disease. Med Lett Drugs Ther 2023; 65:155.
2. S Gerber. GSK's RSVPreF3 +AS01E vaccine (Arexvy). Advisory Committee on Immunization Practices meeting, ACIP Respiratory Syncytial Virus (RSV) Older Adults Vaccine; Atlanta, GA; October 25-26, 2023. Available at: https://bit.ly/3RMF5RQ. Accessed July 2, 2024.
3. CDC. CDC updates RSV vaccination recommendation for adults. June 26, 2024. Available at: https://bit.ly/3W45v4c. Accessed July 2, 2024.
4. A Britton et al. Evidence to recommendations framework (EtR): RSV vaccination in adults aged 50-59 years, 60-74 years, and 75 years and older. Advisory Committee on Immunization Practices (ACIP) presentation slides: June 26-28, 2024 meeting. Available at: https://bit.ly/4ciO7hH. Accessed July 2, 2024.
5. 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. June 5, 2024. Reprinted with permission by First Databank, Inc. All rights reserved. ©2024. www.fdbhealth.com/drug-pricing-policy.

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