

PRODUCT PROFILE

AREXVY Respiratory Syncytial Virus Vaccine, Adjuvanted

Manufacturer

GlaxoSmithKline

Indication

- AREXVY is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years and older.¹

Dosing and Administration

- Administer a single dose (0.5 mL) of AREXVY as an intramuscular injection.¹

Storage and Handling

- AREXVY is supplied as 2 components: a single-dose vial of lyophilized antigen component (powder) and a single-dose vial of adjuvant suspension component (liquid) (packaged without syringes or needles).¹
- Store in the refrigerator at 2 °C to 8 °C (36-46 °F). Store in the original package to protect vials from light. Do not freeze. Discard if the antigen component or the adjuvant suspension component has been frozen.¹
- Once reconstituted, administer immediately. Store in the refrigerator at 2 °C to 8 °C (36-46°F) or at room temperature (up to 25° C [77 °F]) for up to 4 hours prior to use. Discard reconstituted vaccine if not used within 4 hours.¹

Safety/Warnings

- Use of AREXVY is contraindicated in patients with a history of severe allergic reaction (eg, anaphylaxis) to any component of the vaccine.¹
- The most commonly reported adverse reactions (≥ 10%) were injection site pain (60.9%), fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).¹
- In a clinical study (NCT04886596) conducted in Europe, North America, Asia, and the Southern Hemisphere (South Africa, Australia, and New Zealand), the rates of serious adverse events (SAEs) reported within 6 months following vaccination were similar between the AREXVY and placebo groups (4.2% and 4.0%, respectively).¹

Disease State Background

- RSV is a contagious respiratory virus that can lead to severe respiratory illnesses; its effects may range from mild cold-like symptoms, such as nasal congestion and sore throat, to severe bronchiolitis and pneumonia.² Among people 65 years and older in the United States, RSV infection is responsible for 60,000 to 120,000 hospitalizations and approximately 6,000 to 10,000 fatalities annually.^{3,4} The impact of RSV can be especially severe in older adults, with approximately 18% of infected patients admitted to an intensive care unit, 31% receiving home health services following discharge, and 26% facing mortality within 1 year of admission.⁵

Place in Therapy

- The primary strategy in managing acute RSV infection revolves around supportive care.⁶ Therefore, a focus on proactive and preventative measures (eg, vaccination) can help to mitigate the risk of severe illnesses that lead to hospitalizations and other sequelae. On June 21, 2023, the Advisory Committee on Immunization Practices (ACIP) voted on recommendations for RSV vaccination. The ACIP recommended administration of a single dose of RSV vaccine to individuals 60 years or older using a shared clinical decision-making approach.⁷

Managed Care Considerations

- With its propensity to spread rapidly within communities, RSV outbreaks often place strain on health care systems, necessitating proactive management strategies. As a result of the Inflation Reduction Act of 2022 (IRA), vaccinations placed on the ACIP schedule must be covered for patients with Medicare Part D.⁸ GlaxoSmithKline (GSK) has stated that the cost of the vaccine will be between \$200 and \$295 per dose.⁹ Utilization management strategies may include annual quantity limits, similar to how influenza vaccination is managed.

Market Insights

- **Novel Vaccine for RSV Prevention:** AREXVY (respiratory syncytial virus vaccine, adjuvanted) is manufactured by GlaxoSmithKline Biologicals. It is indicated for active immunization to prevent lower respiratory tract disease caused by RSV in individuals 60 years and older. The ACIP recommends that a single dose of the RSV vaccine be given to individuals 60 years and older using a shared clinical decision-making approach. Administration involves a single 0.5-mL intramuscular injection.
- This vaccine is supplied in 2 components that should be stored at 2°C to 8°C. The vaccine has demonstrated localized and systemic reactions typical of vaccines. The most common local reaction is injection site pain, but common systemic reactions include fatigue, myalgia, headache, and arthralgia. Additionally, its use is contraindicated in patients with a history of severe allergic reactions to any vaccine component.
- **Impact on Managed Care Strategies:** RSV vaccines help with the growing importance of preventive measures in managing acute RSV infections. The ACIP's endorsement of a single-dose RSV vaccine for individuals 60 years and older emphasizes a patient-centered approach. Patients with Medicare Part D will receive coverage based on the requirement of the IRA that vaccines on the ACIP schedule be covered. Commercial plans will review placement on formulary. Importantly, incorporating RSV vaccines into managed care plans can proactively address the challenges posed by RSV outbreaks with the broader goal of optimizing patient health outcomes and resource allocation.

REFERENCES

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