

PRODUCT PROFILE

ABRYSVO™ Respiratory Syncytial Virus Vaccine

Manufacturer

Pfizer Laboratories, a division of Pfizer, Inc.

Indication

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

Dosing and Administration

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

Storage and Handling

- ABRYSVO is supplied as a kit with the following components: A single-dose vial of lyophilized antigen component (powder), a pre-filled syringe containing sterile water diluent component, and a vial adapter.¹
- Store refrigerated between 2°C and 8°C (36°F and 46°F). Store in the original package. Do not freeze. Discard if the adjuvant suspension component or antigen component has been frozen.¹
- Once reconstituted, administer immediately or store at room temperature (15°C to 30°C [59°F to 86°F]) and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.¹

Safety/Warnings

- ABRYSVO 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 fatigue (15.5%), headache (12.8%), injection site pain (10.5%), and muscle pain (10.1%).¹
- In the RENOIR clinical trial (NCT05035212), 2.3% of participants in both the ABRYSVO and placebo groups reported serious adverse events (SAEs). Three participants in the ABRYSVO group experienced SAEs that were assessed as possibly related to vaccination: Guillain-Barré Syndrome, Miller Fisher Syndrome, and hypersensitivity.¹

Disease State Background

- Respiratory Syncytial Virus (RSV) is a contagious respiratory virus that can lead to severe respiratory illnesses, ranging from mild cold-like symptoms, such as nasal congestion, sore throat, and hoarseness, to severe bronchiolitis and pneumonia.² In the US, it results between 60,000 and 120,000 hospitalizations and between 6,000 to 10,000 deaths annually among individuals aged 65 and older.^{3,4} This impact is particularly pronounced in older adults, with approximately 18% requiring intensive care, 31% needing post-discharge home health services, and 26% experiencing mortality within a year of admission.⁵

Place in Therapy

- Supportive care is central to managing acute RSV infection.⁶ Therefore, prioritizing proactive preventive measures, like vaccination, can effectively reduce the likelihood of severe illnesses that often result in hospitalizations and subsequent complications. Notably, on June 21, 2023, the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP) met and voted on recommendations for RSV vaccination. ACIP endorsed a single-dose RSV vaccine for individuals aged 60 years or older, following a collaborative clinical decision-making approach.⁷

Managed Care Considerations

- The rapid spread of RSV within communities places considerable pressure on health care systems, demanding preemptive management tactics. The Inflation Reduction Act of 2022 mandates coverage for ACIP-scheduled vaccinations among Medicare Part D beneficiaries.^{8,9} Pfizer indicated that the cost of the vaccine could be between \$180 and \$270 per dose, but that it was not guaranteed due to ongoing price negotiations with managed care entities.¹⁰ Strategic utilization management could involve annual quantity limits, akin to annual influenza vaccination protocols.

Market Insights

- **Novel Vaccine for RSV Prevention:** ABRYSVO is a respiratory syncytial virus vaccine manufactured by Pfizer Inc, designed for active immunization to prevent lower respiratory tract disease caused by the virus in individuals aged 60 years and older. The ACIP endorsed a single-dose RSV vaccine for individuals aged 60 years or older, adhering to a collaborative, clinical decision-making approach. Administration involves a single 0.5 mL intramuscular injection. The vaccine is supplied as a kit containing lyophilized antigen component, sterile water diluent component, and a vial adapter. It must be refrigerated at 2°C to 8°C and reconstituted vaccine should be used within 4 hours, with the option to store reconstituted vaccine at room temperature for immediate use. Common adverse reactions include fatigue, headache, injection site pain, and muscle pain. Serious adverse events were infrequent and had a low occurrence rate. The vaccine is contraindicated in patients with a history of severe allergic reactions to any vaccine component.
- **Impact on Managed Care Strategies:** RSV vaccines bolster the escalating significance of preventive strategies in tackling acute RSV infections. ACIP's backing of a single-dose RSV vaccine for those aged 60 years and older underscores a patient-centric stance. Coverage for Medicare Part D beneficiaries aligns with the IRA's ACIP-schedule coverage mandate. Commercial plans will consider formulary inclusion. Integrating RSV vaccines into managed-care strategies can proactively combat RSV outbreaks, aligning with the overarching objective of enhancing patient health outcomes and resource optimization.

REFERENCES

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