Now ACIP Recommended for Adults 60 Years and Older*

Consider ABRYSVO™ to Help Protect Eligible Older Adult Patients From RSV

ABRYSVO™
Respiratory Syncytial Virus Vaccine

*Adults 60 years and older may receive a single dose of ABRYSVO using shared clinical decision making. This recommendation has been officially adopted by the CDC Director on June 27, 2023. Publication in the *MMWR* is forthcoming.[1]

Effective protection against RSV-associated lower respiratory tract disease[2]

RENOIR is an ongoing Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of ABRYSVO in the prevention of RSV-associated lower respiratory tract disease in individuals 60 years of age and older. Participants are planned to be followed for up to two RSV seasons, approximately 25 months. Participants were randomized (1:1) to receive ABRYSVO (n=17,197) or placebo (n=17,186). Healthy adults and adults with stable chronic diseases were included and 15% of participants had stable chronic cardiopulmonary conditions such as chronic obstructive pulmonary disease (COPD), asthma, or congestive heart failure (CHF). The median duration of follow-up for efficacy was 7 months.[2]

85.7% reduction in RSV-LRTD with ≥3 symptoms
96.66% CI (32.0%, 98.7%)
2 cases in ABRYSVO group vs 14 cases in placebo group.

66.7% reduction in RSV-LRTD with ≥2 symptoms
96.66% CI (28.8%, 85.8%)
11 cases in ABRYSVO group vs 33 cases in placebo group.

- The most commonly reported local and systemic reactions in clinical studies in individuals 60 years of age and older were fatigue (15.5%), headache (12.8%), injection site pain (10.5%), and muscle pain (10.1%)[2]
- Solicited local and systemic reactions had a median duration of 1-2 days[2]
- SAEs were reported by 2.3% of participants in both the ABRYSVO and placebo groups[2]

Studied in healthy people and those with important risk factors for RSV

~1 in 3 patients were aged ≥70 years[2]

52% had a prespecified underlying medical condition[3†]

†Including heart disease, lung disease, ≥1 cardiopulmonary condition (asthma, COPD, or congestive heart failure), diabetes, current tobacco use, renal disease, and liver disease.

Primary efficacy endpoint[2]

Relative risk reduction (vs placebo) of first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) in the first RSV season,‡ defined as ≥2 or ≥3 lower respiratory tract symptoms (new or worsened).

Cough	✓
Sputum production	✓
Wheezing	✓
Shortness of breath	✓
Tachypnea	✓

‡As determined by positive RT-PCR test within 7 days of symptom onset and lasting more than 1 day during the same illness.[2]

INDICATION

ABRYSVO is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

IMPORTANT SAFETY INFORMATION

- Do not administer ABRYSVO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO
- Appropriate medical treatment must be available in case of an anaphylactic reaction
- Syncope (fainting) may occur in association with administration of injectable vaccines, including ABRYSVO. Procedures should be in place to avoid injury from fainting

(continued on next page)

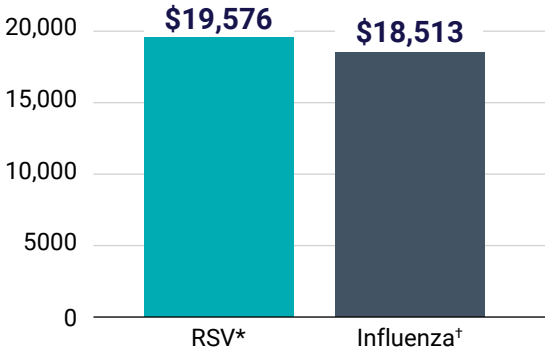
ACIP = Advisory Committee on Immunization Practices; CDC = Centers for Disease Control and Prevention; LRTD = lower respiratory tract disease; *MMWR* = *Morbidity and Mortality Weekly Report*; RSV = respiratory syncytial virus; RT-PCR = reverse transcription polymerase chain reaction; SAE = serious adverse event.

Please see full Prescribing Information for ABRYSVO.

RSV Can Have Higher Hospitalization Costs Than Influenza

ABRYSVO™
Respiratory Syncytial Virus Vaccine

Mean cost per inpatient episode, adjusted to 2022 dollars[4,5]



Among vaccine-preventable diseases, RSV has one of the highest costs per adult inpatient episode[4,6,7]

5.6 days
Average length of stay among adults aged 60+ with RSV infection[8‡]

Essential coding information

NDC numbers[2]	**00069-0344-01**	(carton, 1 dose)
	00069-0344-05	(carton, 5 doses)
Billing codes[9]	**90678 CPT®** code for vaccine	
	90471 HCPCS code for administration (Immunization administration [includes percutaneous, intradermal, subcutaneous, or intramuscular injections]; one vaccine [single or combination vaccine/toxoid])	
	Z23 ICD-10 code for diagnosis	

*RSV cost data are from a period when no vaccine was available.
†National Inpatient Sample daily average hospitalization cost per DRG in 2013 for patients aged ≥60.
‡Based on historical data from the National Inpatient Sample (1997-2012, N=16,316) of hospitalized adults aged 60 and older with ICD-9 codes 079.6 (RSV, 466.11 (bronchiolitis due to RSV), and 480.1 (pneumonia due to RSV).[8]

CPT = Current Procedural Technology; HCPCS = Healthcare Common Procedure Coding System; ICD-10 = International Classification of Diseases, 10th Revision; NDC = National Drug Code; RSV = respiratory syncytial virus

IMPORTANT SAFETY INFORMATION (continued)

- Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to ABRYSVO
- Vaccination with ABRYSVO may not protect all vaccine recipients
- In clinical trials, the most commonly reported (≥10%) adverse reactions were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%)

Please see additional Important Safety Information on previous page. Please see full Prescribing Information for ABRYSVO.

1. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP). Last reviewed June 28, 2023. Accessed June 29, 2023. https://www.cdc.gov/vaccines/acip/index.html **2.** ABRYSVO Prescribing Information. Pfizer Inc., 2023. **3.** Walsh EE, Marc GP, Zareba AM, et al. Efficacy and safety of a bivalent RSV prefusion F vaccine in older adults. *N Engl J Med.* 2023 Apr 5. doi: 10.1056/NEJMoa2213836. Online ahead of print. **4.** Ackerson B, et al. *Clin Infect Dis*. 2019;69(2):197-203. **5.** US Bureau of Labor Statistics. CPI inflation calculator. Accessed March 29, 2023. https://www.bls.gov/data/inflation_calculator.htm **6.** US Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project database. https://hcupnet.ahrq.gov **7.** Meyers JL, et al. *Vaccine*. 2019;37(9):1235-1244. **8.** Pastula ST, et al. *Open Forum Infect Dis*. 2017; 4(1):ofw270. **9.** Data on file, Pfizer Inc., 2023.

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