COMMUNICATION

# COM-2024-074

NOVEMBER 2024

## PLEASE Drug Information REVIEW PharmPix Clinical Department

### **Drug Information**

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

#### QUESTIONS

Call us at 787-522-5252-ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/ providers/.



PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest upto-date drug information requested.

## Abrysvo™ FDA Approved for Adults 18 to 59 Years

The FDA has approved the use of Abrysvo<sup>™</sup> (respiratory syncytial virus vaccine) in adults aged 18-59 who are at increased risk for lower respiratory tract disease (LRTD) caused by RSV.

### Abrysvo<sup>™</sup> Overview

Abrysvo<sup>™</sup> is a bivalent vaccine developed by Pfizer for the prevention of LRTD caused by respiratory syncytial virus (RSV). Initially approved for adults aged 60 years and older, the vaccine has now been extended to adults aged 18 to 59 who are at increased risk due to underlying chronic conditions such as obesity, diabetes, chronic obstructive pulmonary disease (COPD), heart chronic kidney disease, failure. and asthma. Additionally, Abrysvo<sup>™</sup> is approved for pregnant individuals between 32 to 36 weeks of gestation to protect newborns from RSV-related illnesses from birth through their first six months of life. Abrysvo™ is now the only RSV vaccine available for high-risk adults under 60, older adults, and pregnant women. This provides a significant advantage in controlling RSV outbreaks and minimizing the disease burden across different age groups and vulnerable populations.

### Efficacy, Safety, and Impact

The FDA approved Abrysvo based on data from the pivotal Phase 3 MONeT clinical trial which assessed the vaccine's safety, tolerability, and immunogenicity in adults at higher risk of RSV-related LRTD due to chronic medical conditions. In this trial, participants demonstrated an immune response that significantly reduced their risk of severe illness and hospitalization caused by RSV infection. In adults aged 18 to 59 years, the most frequently reported side effects were pain at the injection site, muscle pain, joint pain, and nausea.

On June 26, 2024, the CDC's Advisory Committee on Immunization Practices (ACIP) issued updated guidance recommending that all adults aged 75 and older, along with adults aged 60 to 74 at higher risk for severe RSV, should receive a single dose of an RSV vaccine. The available vaccine options are Arexvy<sup>™</sup>, Abrysvo<sup>™</sup>, and mResvia<sup>™</sup>.



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#### **REFERENCES:**

- U.S. FDA Approves Pfizer's RSV Vaccine ABRYSVO® for Adults Aged 18 to 59 at Increased Risk for Disease. Pfizer. (2024). https://www.pfizer.com/news/press-release/press-release-detail/us-fda-1. approves-pfizers-rsv-vaccine-abrysvor-adults-aged-18 U.S. Food and Drug Administration. (2024). ABRYSVO (respiratory syncytial virus vaccine) [Package insert]. https://www.fda.gov/media/168889/download Steinzor, P. (2024, August 7). Updated ACIP guidelines: RSV vaccine for adults aged 60 years and older. AJMC. https://www.ajmc.com/view/updated-acip-guidelines-rsv-vaccine-for-adults-aged-60-2
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