Dear Customer,

ABRYSVO is the ONLY RSV vaccine approved and recommended for use in pregnant women for the protection of infants.[1]

On August 21, 2023, the FDA approved ABRYSVO™ (Respiratory Syncytial Virus Vaccine) for the active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.[1,2]

On September 22, 2023, the ACIP approved the recommendation, and it has been adopted by the CDC Director and is now official.[3] It will be published in *MMWR* and reflected in CDC's print and digital resources in the coming months.

Respiratory Syncytial Virus (RSV) Vaccines—Pediatric/Maternal

- Maternal Respiratory Syncytial Virus (RSV) vaccine is recommended for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants.[3]

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. A numerical imbalance in preterm births was observed compared to placebo in 2 clinical studies. Data are insufficient to establish or exclude a causal relationship between preterm birth and ABRYSVO. To avoid potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer to pregnant individuals at 32 through 36 weeks gestational age.

ABRYSVO is the ONLY RSV vaccine approved for 2 indications.[1] On May 31, 2023, the FDA approved ABRYSVO as a vaccine indicated for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.[1,4] The ACIP recommendations for older adults have been published in the July 21, 2023, issue of *MMWR*.[5] Below is a link to the publication:
https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7229a4-H.pdf

Avoid potential medication errors—ONLY ABRYSVO should be administered to pregnant women

Two RSV vaccines are currently approved and recommended for use in adults 60 and older.[5] To avoid potential medication errors, it is critical to educate staff and implement systems to ensure that **only ABRYSVO** is used to immunize pregnant women at 32 to 36 weeks gestation against RSV.

IMPORTANT SAFETY INFORMATION (continued on p2)

- 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

Please see additional Important Safety Information on page 2. Please see accompanying full prescribing information for ABRYSVO.

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 with older adults, 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%)
- In clinical trials with pregnant individuals, the most commonly reported (≥10%) adverse reactions were pain at the injection site (40.6%), headache (31.0%), muscle pain (26.5%), and nausea (20.0%)
- In clinical trials with infants born to pregnant individuals, low birth weight (5.1% ABRYSVO versus 4.4% placebo) and neonatal jaundice (7.2% ABRYSVO versus 6.7% placebo) were observed

Individuals who received ABRYSVO during pregnancy are encouraged to call 1-800-616-3791 to enroll in a Pregnancy Exposure Registry.

INDICATIONS

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
- active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age

Please see accompanying full prescribing information for ABRYSVO.

I look forward to supporting your immunization efforts to help protect your RSV-vaccine eligible patients during this respiratory season. If you no longer wish to receive email communications and/or marketing information regarding ABRYSVO™ (Respiratory Syncytial Virus Vaccine), please let me know.

Sincerely,

Pfizer Account Representative

ACIP = Advisory Committee on Immunization Practices; CDC = Centers for Disease Control and Prevention; FDA = U.S. Food and Drug Administration; *MMWR = Morbidity and Mortality Weekly Report*.

1. ABRYSVO™ Prescribing Information, Pfizer Inc. August 2023. **2.** U.S. Food and Drug Administration (FDA). BL125768/0 [BLA approval letter]. August 21, 2023. Accessed September 22, 2023. https://www.fda.gov/media/171492/download?attachment **3.** Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP). Last reviewed September 22, 2023. Accessed September 24, 2023. https://www.cdc.gov/vaccines/acip/recommendations.html **4.** U.S. Food and Drug Administration (FDA). BL125769/0 [BLA approval letter]. May 31, 2023. Accessed September 22, 2023. https://www.fda.gov/media/171492/download?attachment **5.** Melgar M, Britton A, Roper LE, et al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. *MMWR Morb Mortal Wkly Rep*. 2023;72(29): 793-801.

Marketed by Pfizer Inc.
Printed in USA/September 2023