Clinical Policy: Respiratory Syncytial Virus Vaccine (Abrysvo)

Reference Number: PA.CP.PHAR.658
Effective Date: 11/2024
Last Review Date: 10/2024

Description

Respiratory syncytial virus vaccine (Abrysvo™) is a vaccine.

FDA Approved Indication(s)

Abrysvo is indicated for:

- 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.
- Active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.
- Active immunization for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Abrysvo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Immunization (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Member is pregnant at 32 through 36 weeks gestational age;
   b. Age ≥ 18 years;
2. Dose does not exceed one injection (0.5 mL) given one time.

Approval duration: 1 month

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACIP: Advisory Committee on Immunization Practices
ACOG: American College of Obstetricians and Gynecologists
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
LRTD: lower respiratory tract disease
RSV: respiratory syncytial virus

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of a severe allergic reaction (e.g., anaphylaxis) to any component of Abrysvo
- Boxed warning(s): none reported

Appendix D: General Information

- On September 22, 2023, the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) recommended maternal Abrysvo vaccination in pregnant persons as a one-time dose at 32 weeks and zero days' through 36 weeks and 6 days' gestation using seasonal administration (i.e., September-January in most of the continental United States) for prevention of RSV-associated LRTD in infants through age 6 months.
- In jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands), providers should follow state, local, or territorial guidance on timing of maternal Abrysvo vaccination.
- At least 14 days are needed from the time of maternal vaccination for development and transplacental transfer of maternal antibodies to protect the infant.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RSV prophylaxis	One-time 0.5 mL IM injection	0.5 mL/one-time dose

VI. Product Availability

Single-dose vial: 0.5 mL after reconstitution

VII. References

1. Abrysvo Prescribing Information. New York, NY: Pfizer; October 2024. Available at: www.abrysvo.com. Accessed August 7, 2024.
2. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus–associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1115–1122. DOI: http://dx.doi.org/10.15585/mmwr.mm7241e1. Accessed November 7, 2023.

3. American College of Obstetricians and Gynecologists (ACOG). Practice advisory on maternal respiratory syncytial virus vaccination. December 2023. Available at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination. Accessed August 7, 2024.
4. Britton A, Roper LE, Kotton CN, et al. Use of respiratory syncytial virus vaccines in adults aged ≥ 60 years: updated recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:696-702. DOI: http://dx.doi.org/10.15585/mmwr.mm7332e1. Accessed November 4, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
90678	Respiratory Syncytial Virus vaccine, preF, subunit, bivalent, for intramuscular use

Reviews, Revisions, and Approvals	Date
Policy created	10/2024