

Clinical Policy: Respiratory Syncytial Virus Vaccine (Abrysvo)

Reference Number: CP.PHAR.658

Effective Date: 01.01.24

Last Review Date: 11.24

Line of Business: HIM, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 $\geq$ 18 years;
2. Dose does not exceed one injection (0.5 mL) given one time.

Approval duration: 1 month

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 – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

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.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.07.23	12.23
4Q 2024 annual review: no significant changes; references reviewed and updated. RT4: added the recently FDA-approved indication for use in people aged 18-59 at high risk for LRTD due to RSV.	11.04.24	11.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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