Clinical Policy: Respiratory syncytial virus vaccine (Abrysvo, Arexvy)

Reference Number: MDN.CP.PHAR.658
Effective Date: 2.1.24
Last Review Date: 9.19.24
Line of Business: Meridian Illinois 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™, Arexvy™) are vaccines.

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

Arexvy is indicated for:

- Active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older
- Individuals 50 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 , attestation, 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 and Arexvy are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria for Pharmacy Benefits ONLY

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

1. For Abrysvo member meets one of the following:
   a. Age ≥19 years
   b. Member is pregnant at 32 through 36 weeks gestational age;
   c. Member has been informed of benefits vs risks (“signed informed consent”);
   d. Prescriber assumes responsibility for communicating that mother has received the vaccine to birthing center/hospital and pediatrician assigned to care for newborn baby;
2. For Arexvy member meets the following:
   a. Age ≥ 50 yeas old;
3. 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 – 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 or Arexvy
- 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 aged < 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 intramuscular 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; August 2023. Available at: https://labeling.pfizer.com/ShowLabeling.aspx?id=19589. Accessed November 7, 2023.

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. September 2023. Available at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination. Accessed November 7, 2023.
4. Arexvy Prescribing Information. Durham, NC: GSK; August 2024. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF. Accessed September 19, 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
90679	Respiratory Syncytial Virus vaccine, preF, subunit, bivalent, for intramuscular use

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created to align with State of Illinois HFS Provider notice regarding Abyrsvo	2.6.24	
Removed 2023-2024 season dates; Arexvy added to policy; references reviewed and updated.	9.19.24	

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.