

Policy: MBP 329.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare		ACA	X
CHIP	X		

I. Policy:

Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection)

II. Purpose/Objective:

To provide a policy of coverage regarding Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection) promotes active immunization against respiratory syncytial virus prefusion F3 (RSVPre3) glycoprotein to protect against RSV-A and/or B-associated lower respiratory tract disease. The vaccine is an adjuvanted formulation, which has been shown to increase RSV-specific CD4+ T-cell frequencies.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

For the Medicaid line of business, Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection) will not require prior authorization for patients greater than or equal to 60 years of age. Arexvy is provided by Vaccines for Children (VFC) Program and is not eligible for reimbursement for patients less than 19 years of age. Arexvy will be considered medically necessary for patients greater than or equal to 50 years of age to less than 60 years of age when ALL of the following criteria are met:

- Medical record documentation that the member is 50 to 59 years of age **AND**
- Medical record documentation of a diagnosis of chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney disease, or chronic liver disease **AND**
- Medical record documentation that the member is at an increased risk of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

AUTHORIZATION LIMITATIONS: Approval is for a one-time injection

QUANTITY LIMIT: 0.5mL per 999 days

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

For the commercial, exchange, and CHIP lines of business, Arexvy (Respiratory Syncytial Virus Vaccine (Adjuvanted) Injection) will not require prior authorization for patients greater than or equal to 60 years of age. Arexvy will be considered medically necessary for patients greater than or equal to 50 years of age to less than 60 years of age when ALL of the following criteria are met:

- Medical record documentation that the member is 50 to 59 years of age **AND**
- Medical record documentation of a diagnosis of chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney disease, or chronic liver disease **AND**
- Medical record documentation that the member is at an increased risk of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

AUTHORIZATION LIMITATIONS: Approval is for a one-time injection

QUANTITY LIMIT: 0.5mL per 999 days

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Arexvy [Prescribing Information]. Durham, North Carolina. GlaxoSmithKline Biologicals. August 2024.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 10/18/24

Revised:

Reviewed: