

Policy: MBP 297.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Beyfortus (nirsevimab-alip)

I. Policy:

Beyfortus (nirsevimab-alip)

II. Purpose/Objective:

To provide a policy of coverage regarding Beyfortus (nirsevimab-alip)

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.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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

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:

Beyfortus (nirsevimab-alip), a respiratory syncytial virus F protein-directed fusion inhibitor, is a human immunoglobulin G1 (IgG1) kappa monoclonal antibody with anti-respiratory syncytial virus activity.

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

For the Medicaid line of business, Beyfortus (nirsevimab-alip) is provided by the Vaccines for Children (VFC) Program and is not eligible for reimbursement.

For the commercial, exchange, CHIP, and Medicare lines of business, Beyfortus (nirsevimab-alip) will not require prior authorization for patients less than 8 months of age. Beyfortus (nirsevimab-alip) will be considered medically necessary for patients 8 months of age or greater but less than 24 months of age when ALL of the following criteria are met:

- Infants \leq 12 months of age, and born before $<$ 29 weeks gestation at the onset of RSV season **OR**
- Infants $<$ 12 months of age, who have a diagnosis of a congenital abnormality of the airway or a diagnosis of a neuromuscular condition that compromises handling of respiratory secretions **OR**
- Infants and children $<$ 24 months of age who will be profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome) **OR**
- Infants $<$ 12 months of age, born at $<$ 32 weeks gestation, with chronic lung disease of prematurity, defined as $>$ 21% oxygen for at least 28 days after birth **OR**
- Infants and children $<$ 24 months of age with chronic lung disease (CLD) who have required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic steroid use, bronchodilator use or diuretic use) **OR**
- Infants $<$ 12 months of age with hemodynamically significant acyanotic heart disease who:
 - are receiving medication to control congestive heart failure; or
 - have moderate to severe pulmonary hypertension

OR

- Infants $<$ 12 months of age with cyanotic heart disease who have been evaluated and recommended for treatment by a cardiologist **OR**
- Infants or children who have been receiving prophylaxis and undergo cardiopulmonary bypass during RSV season should receive an additional dose of Beyfortus post-operatively as soon as possible after procedure (even if sooner than a month from previous dose) when medically stable (serum concentrations decrease by a mean of 58% following by-pass) **OR**
- Children less than two years of age who undergo cardiac transplantation during the RSV season **OR**
- Infants in the first year of life with CF and clinical evidence of CLD and/or nutritional compromise **OR**
- Infants in the second year of life with CF and who have severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or whose weight for length is less than the 10th percentile.

AND

- Medical record documentation that member has not received Synagis during the current RSV season

AUTHORIZATION DURATION: Prophylaxis of 1 dose should be initiated on November 1 (prior to RSV season). Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive one dose of prophylaxis.

In the event of an atypical RSV season (i.e. unpredicted, early, or late, high rates of RSV circulation), prophylaxis of 1 dose should be initiated on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources. Members born after the start of the atypical RSV season who meet criteria will receive 1 dose on the date deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

Dosing beyond 1 dose will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

QUANTITY LIMIT: 50 mg/0.5 mL: 1 mL (2 syringes) per 5 months
100 mg/1 mL: 4 mL (4 syringes) per 5 months

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.

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

Devised: 9/19/23

Revised:

Reviewed: