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5.20.015

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Biologicals	**Original Policy Date:**	September 8, 2023
Subject:	Beyfortus	**Page:**	1 of 3

Last Review Date: March 7, 2025

Beyfortus

Description

Beyfortus (nirsevimab-alip)

Background
Beyfortus (nirsevimab-alip) is a recombinant human IgG1κ monoclonal antibody that provides passive immunity by targeting the prefusion conformation of the RSV F protein. Beyfortus is long-acting due to a triple amino acid substitution (YTE) in the Fc region which increases binding to the neonatal Fc receptor and thereby extends serum half-life. Beyfortus binds to a conserved epitope in antigenic site Ø on the prefusion protein; it neutralizes RSV by inhibiting conformation changes in the F protein necessary for fusion of the viral and cellular membranes and viral entry (1).

RSV season is a term used to describe the time of year when RSV infections most commonly occur. RSV season generally lasts from November through April in most locations in the United States. The CDC website (CDC National Respiratory) may be used as a resource when the RSV season starts in a certain area (2).

Regulatory Status
FDA-approved indication: Beyfortus is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in (1):

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Hypersensitivity reactions including anaphylaxis have been observed with other human IgG1 monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy (1).

Safety and effectiveness in children older than 24 months of age have not been established (1).

Related policies
Synagis

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Beyfortus may be considered **medically necessary** if the conditions indicated below are met.

Beyfortus may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Prevention of infection caused by Respiratory Syncytial Virus (RSV)

AND ONE of the following:

1. Less than 12 months of age at the start of RSV season*
2. Child in second year of life (between 12 months and less than 24 months of age) at the start of RSV season* who remain vulnerable to severe RSV disease

*RSV season generally lasts from November through April in most locations in the United States. Consult the CDC National Respiratory and Enteric Virus Surveillance System (NREVSS) for RSV surveillance at https://www.cdc.gov/surveillance/nrevss/rsv/state.html.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months (PA may start 1 month prior to the RSV season*)
Each new RSV season is the initiation of therapy

Rationale

Summary

Beyfortus is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Hypersensitivity reactions including anaphylaxis may occur with Beyfortus use (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Beyfortus while maintaining optimal therapeutic outcomes.

References

1. Beyfortus [package insert]. Swiftwater, PA: Sanofi Pasteur, Inc.; August 2024.
2. The National Respiratory and Enteric Virus Surveillance System (NREVSS) Website. https://www.cdc.gov/surveillance/nrevss/rsv/state.html

Policy History

Date	Action
September 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review
September 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.