BlueCross BlueShield
Federal Employee Program

BEYFORTUS
(nirsevimab-alip)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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

BlueCross BlueShield
Federal Employee Program

BEYFORTUS
(nirsevimab-alip)

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