THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: Beyfortus (nirsevimab-alip) **Effective Date:** 11/23

DESCRIPTION

Respiratory syncytial virus (RSV) causes acute respiratory illness in individuals of all ages. Almost all children have been infected by age two. Outbreaks are seasonal and typically occur from October to May in the northern hemisphere. According to a study evaluating infant inpatient hospitalizations from 2009 to 2019, the leading cause of admission in the US was acute bronchiolitis from respiratory syncytial virus (RSV). This results in approximately 79,850 hospitalizations across the US each year. Children with certain underlying medical problems are at higher risk for severe disease.

Nirsevimab is a monoclonal antibody that targets the prefusion conformation of the RSV F glycoprotein. One dose of nirsevimab is expected to provide protection for at least five months.

DEFINITIONS

Respiratory syncytial virus (RSV): A single-stranded, negative-sense ribonucleic acid (RNA) virus and a member of the Pneumoviridae family that causes acute respiratory tract illness in all age groups.

Respiratory syncytial virus (RSV) season: For the purposes of this policy, RSV season is defined as October through May.

Monoclonal antibody: An antibody produced by a single clone of cells or cell line and consisting of identical antibody molecules.

POLICY GUIDELINES

OSU Health Plan considers a single dose of Beyfortus (nirsevimab-alip) medically necessary for the prevention of respiratory syncytial virus (RSV) respiratory tract disease when either of the following criteria are met:

- For all infants younger than 8 months old who are born during or entering their first RSV season and have not previously received a nirsevimab-alip or palivizumab dose; or
- For children 8 - 19 months of age who are high-risk for severe RSV disease during their second RSV season and have not received nirsevimab-alip or palivizumab in the same season. Children are considered high-risk if they have one or more of the following risk factors:
    - Chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; or
    - Severe immunocompromise; or
    - Cystic fibrosis with either:
        - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable); or
        - Weight-for-length <10th percentile
    - American Indian or Alaska Native heritage

PROCEDURE S

Beyfortus (nirsevimab-alip) is only available through the medical benefit.

OSU Health Plan does not require prior authorization for one dose of Beyfortus (nirsevimab-alip) in infants under 8 months of age. Prior authorization is required for the second dose of Beyfortus (nirsevimab-alip) or when administered in an infant or child 8 months of age and older.

Recommended dosing for Beyfortus (nirsevimab-alip):

- Neonates and infants under 8 months of age who are born during or entering their first RSV season:
  - 50 mg if less than 5 kg in body weight [90380 x 1 unit = 1 dose]
  - 100 mg if greater than or equal to 5 kg in body weight [90381 x 1 unit = 1 dose]
- Children who remain vulnerable through their second RSV season:
  - 200 mg (2 x 100 mg injections) [90381 x 2 units = 1 dose]

Consistent with the Advisory Committee on Immunization Practices (ACIP) recommendation, OSU Health Plan covers Beyfortus (nirsevimab-alip) at 100% of the allowed amount when the above criteria are met. Network restrictions may apply based on benefit plan.

EXCLUSIONS

OSU Health Plan considers Beyfortus (nirsevimab-alip) experimental and investigative when the above criteria are not met. This includes the following (not all-inclusive):

- More than one dose of Beyfortus (nirsevimab-alip) per RSV season
- More than two lifetime doses of Beyfortus (nirsevimab-alip) [two RSV seasons]
- Use of Beyfortus (nirsevimab-alip) in children over the age of 19 months
- Use of Beyfortus (nirsevimab-alip) in children aged 8-19 months who are not high-risk for severe disease according to ACIP recommendations.

CODES

CPT codes covered when criteria are met:	
90380	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use
90381	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use

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