New Hampshire Medicaid Fee-for-Service Program

Synagis® Criteria

Approval Date: July 12, 2022

Pharmacology

A humanized monoclonal antibody (IgG1K) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of respiratory syncytial virus (RSV). Palivizumab exhibits neutralizing and fusion-inhibitory activity against RSV. These activities inhibit RSV replication in laboratory experiments.

Indication

For the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

Medications

Brand Name	Generic Name	Dosage Strengths
Synagis®	palivizumab	50 mg and 100 mg (lyophilized powder or liquid solution)

Criteria for Approval

1. Infants born ≤ 29 weeks, 0 days' gestation and are currently ≤ **one** year of age; **OR**
2. Infants who are currently ≤ **one** year of age with chronic lung disease (CLD) of prematurity, defined as born < 32 weeks, 0 days' gestation and required > 21% oxygen for at least 28 days after birth; **OR**
3. Children ≤ **two** year of age with CLD of prematurity (defined as born < 32 weeks, 0 days' gestation and required > 21% oxygen for at least 28 days after birth) who continue to require medical intervention (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the 2nd RSV season; **OR**
4. Infants who are currently ≤ **one** year of age with hemodynamically significant congenital heart disease(CHD) (acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures, and infants with moderate to severe pulmonary hypertension); **OR**
5. Infants who are currently ≤ **one** year of age with cyanotic heart defect and consultation with and if recommended by a pediatric cardiologist; OR

6. Children ≤ **two** year of age who undergo cardiac transplantation during the RSV season; **OR**
7. Infants who are currently ≤ **one** year of age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways; **OR**
8. Children ≤ **two** year of age who will be profoundly immunocompromised during the RSV season.
9. Children with cystic fibrosis and active lung disease ≤ 2 years of age may be considered at the review/recommendation of a pulmonologist.

Criteria for Denial

1. Failure to meet criteria for authorization; **OR**
2. Children > 2 years of age born at any premature gestational age; **OR**
3. Healthy infants born after 29 weeks, 0 days' gestation; **OR**
4. Infants with CLD who do not continue to require medical support in the second year of life; **OR**
5. Children with cystic fibrosis with no other qualifying criteria; **OR**
6. Children with Down syndrome with no other qualifying criteria; **OR**
7. Infants and children with hemodynamically insignificant heart disease including:
    a. Secundum atrial septal defect
    b. Small ventricular septal defect
    c. Pulmonic stenosis
    d. Uncomplicated aortic stenosis
    e. Mild coarctation of the aorta
    f. Patent ductus arteriosus; **OR**
8. Infants with lesions adequately corrected by surgery unless they continue to require medication for CHF; **OR**
9. Infants with mild cardiomyopathy who are not receiving medical therapy.

Length of Authorization: Between October and April only (five doses only, not to exceed the RSV season of October–April). Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
Pharmacy & Therapeutic Committee	New	11/02/2006
Commissioner	New	11/16/2006
Pharmacy & Therapeutic Committee	Update	04/16/2009
Commissioner	Approval	05/12/2009
DUR Board	Revision	03/22/2010
Commissioner	Approval	04/30/2010
DUR Board	Revision	05/31/2016
Commissioner	Approval	06/18/2016
DUR Board	Revision	09/27/2018
Commissioner Designee	Approval	11/27/2018
DUR Board	Revision	10/28/2019
Commissioner Designee	Approval	12/03/2019
DUR Board	Revision	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022