

HealthAlliance**MEDICARE**

PURPOSE OF THE POLICY

To establish guidelines for coverage of Synagis® (palivizumab).

STATEMENT OF THE POLICY

The following criteria must be met for coverage of Synagis® (palivizumab), and applies to new starts only for Medicare Part D members.

PROCEDURES

1. One of the following criteria must be met for coverage:

- 1.1 All approved FDA indications not otherwise excluded from Part D.
- 1.2 Pediatrician or Pediatric Pulmonologist.
- 1.3 Children less than two years old with chronic lung disease who have required medical therapy (supplemental oxygen, bronchodilator, diuretic or corticosteroid therapy) for chronic lung disease within 6 months before the anticipated start of the RSV season.
- 1.4 Infants less than one (1) year old born at less than 28 weeks of gestation.
- 1.5 Infants less than six (6) months old born at 29-32 weeks of gestation.
- 1.6 Infants less than six (6) months old born at 32-35 weeks of gestation who have **two (2) or more** documented additional risk factors for RSV infection.
 - Additional risk factors include:
 - Low birth weight (<2500 Gm)
 - School-age siblings
 - Day care attendance
 - Multiple birth
 - Family history of asthma
 - Limited availability of hospital care for severe respiratory illness
 - Other underlying conditions such as neuromuscular disease and congenital abnormalities of the airways.
 - Infants less than two (2) years old with hemodynamically significant congenital heart disease (children with severe immunodeficiencies (e.g. severe combined immunodeficiency of severe acquired immunodeficiency syndrome)

2. References

- 2.1 American Academy of Pediatrics. Committee on Infectious Diseases and Committee on Fetus and Newborn. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics, 2003;XXX:XXX-XXX