

**SYNAGIS® (PALVIZUMAB)**  
**Prior Authorization Criteria**

MS Medicaid will approve the administration of Synagis® for children meeting the American Academy of Pediatrics (AAP) Redbook recommendations for RSV immunoprophylaxis. The criteria detailed below are based on the 2012 AAP recommendations.

Beneficiaries must meet criteria in one of five categories:

<u>Category 1</u> Prematurity of $\leq$ 28 weeks 6 days gestation Age: $\leq$ 1 year	<u>Category 2</u> Prematurity of 29 weeks 0 days - 31 weeks 6 days gestation Age: $\leq$ 6 months at the start of Respiratory Syncytial Virus season.
<u>Category 3</u> Age: 0 – 24 months old Risk factor(s) as noted below are present, documented and indicated on PA form.	<u>Category 4</u> 32 weeks 0 days - 34 weeks 6 days gestation Age: < 3 months old at start of RSV season, or born during RSV season Risk factor as noted below is present, <b>documented</b> and indicated on PA form. No diagnosis of CLD is required.
<u>Category 5</u> <b><i>Documentation must be included</i></b> Age: 0-12 months old Congenital abnormalities of the airway that compromises handling respiratory secretions or neuromuscular disease	

**Coverage limitations:**

- Category 3 only: Authorization will end at age 24 months (last day of the child’s birthday month). Extension beyond age 24 months will be considered on an individual basis when supported by clinical documentation of extreme necessity.
- Authorization will be granted for administration between October 31 and March 31.
- Coverage will be limited to five doses for all categories except category 4. For category 4, coverage will end when the beneficiary reaches 3 months of age, with a maximum of 3 doses allowed. Doses administered during hospitalization will be included as part of these three / five covered doses.

**RSV Risk Factors**

**For category 3:**

One of the following are considered sufficient:

- Chronic lung disease with a diagnosis of BPD requiring medical treatment within the past six months prior to the start of the RSV season (e.g. diuretics, systemic steroids, oxygen on a continuous basis, bronchodilators or ventilation-dependent); **Chronic Lung Disease (CLD)**: also known as bronchopulmonary dysplasia (BPD): an infant less than 32 weeks’ gestation evaluated at 36 weeks’

- postmenstrual age or an infant of more than 32 weeks' gestation evaluated at more than 28 days but less than 56 days of age who has been receiving supplemental oxygen for more than 28 days. CLD of prematurity is defined as CLD with gestational age less than 35 weeks. High risk is defined as those who receive treatment within the previous 6 months prior to RSV season, specifically treatment with corticosteroids, diuretics, bronchodilators or oxygen. Note: CLD *does not* include croup, URI, bronchitis, bronchiolitis, asthma, or wheezing.
- Hemodynamically significant Congenital Heart Disease – beneficiaries with moderate to severe pulmonary hypertension, cyanotic heart disease, and those requiring medication to control congestive heart failure [simple, small Atrial Septal Defects (ASD), Ventricular Septal Defects (VSD), pulmonary stenosis, uncomplicated aortic stenosis, mild coarctation of aorta, mild cardiomyopathy and Patent Ductus Arteriosus (PDA), and those whose lesions have been adequately corrected by surgery (unless they continue to require medication for congestive heart failure) are not eligible]

**For category 4**

**One** of the following is considered sufficient:

- Sibling who is a permanent resident of the home < 5 years old; and/or
- Day Care (defined as a home or facility where care is provided for any number of infants or young toddlers)

**\*\*\*PLEASE HAVE ALL DOCUMENTATION IN PATIENT'S RECORD THAT IS SUBMITTED ON PA REQUEST FORM AVAILABLE UPON REQUEST FROM MEDICAID\*\*\***