

**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 2009 AAP recommendations.

Beneficiaries must meet criteria in one of four categories:

<u>Category 1</u> Prematurity of ≤ 28 weeks gestation Age: ≤ 1 year	<u>Category 2</u> Prematurity of 29 weeks - 31 weeks 6 days gestation Age: ≤ 6 months at the start of Respiratory Syncytial Virus season.
<u>Category 3</u> Prematurity of ≤ 35 weeks gestation 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 - 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, documented and indicated on PA form. No diagnosis of CLD is required.

**Coverage limitations:**

- Authorization will end at age 24 months (last day of child’s birthday month), except for those beneficiaries in category 4. Extension beyond age 24 months for all other categories will be considered on an individual basis when supported by clinical documentation of extreme necessity.
- Authorization will be granted for administration between October 26 and March 31.
- Second season authorizations will be limited to severe CLD and HSCHD who continue to require medical therapy.
- 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 five covered doses.

**RSV Risk Factors**

**For category 3 (First season requests only):**

One of the following are considered sufficient:

- Chronic lung disease requiring medical treatment within the past six months (e.g. diuretics, systemic steroids, oxygen on a continuous basis, bronchodilators or ventilation-dependent); or
- 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) are not eligible]
- Congenital abnormalities of the airway or a neuromuscular condition (cystic fibrosis is not eligible).

**OR**

**For category 3 (Second season requests only):**

One of the following must be present (with documentation of continued medical therapy):

- Severe chronic lung disease (CLD); or
- Hemodynamically significant congenital heart disease (HSCHD)

**OR**

**For category 4 (First season requests only):**

One of the following is considered sufficient:

- School age Siblings < 5 years old; and/or
- Day Care