

## UPDATED PALIVIZUMAB RSV PROPHYLAXIS GUIDELINES

### BACKGROUND

Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. The Mississippi Division of Medicaid (DOM) supports the administration of Synagis® for children meeting the American Academy of Pediatrics (AAP) criteria for RSV immunoprophylaxis.

On July 28, 2014, the AAP published their latest policy statement, “Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection” on-line in *Pediatrics*<sup>1</sup>.

#### Summary of current DOM criteria based on the 2012 AAP guidelines found in the 2012 Red Book

Beneficiaries must meet criteria in one of the following five categories:	
<b>Category 1:</b> <ul style="list-style-type: none"> <li>- Prematurity of ≤ 28 weeks 6 days gestation</li> <li>- Age ≤ 1 year at start of RSV season</li> </ul>	<b>Category 2:</b> <ul style="list-style-type: none"> <li>- Prematurity of 29 weeks 0 days – 31 weeks 6 days gestation</li> <li>- Age ≤ 6 months at start of RSV season</li> </ul>
<b>Category 3:</b> <ul style="list-style-type: none"> <li>- Age 0 – 24 months at start of RSV season</li> <li>- Documentation of one of following risk factor(s):                             <ul style="list-style-type: none"> <li>- Chronic lung disease with Dx of BPD</li> <li>- Postmenstrual age or infant of more than 32 weeks gestation receiving oxygen &gt; 28 days</li> <li>- Hemodynamically significant CHD</li> </ul> </li> </ul>	<b>Category 4:</b> <ul style="list-style-type: none"> <li>- Prematurity of 32 weeks 0 days – 34 weeks 6 days gestation</li> <li>- Age &lt; 3 months at start of RSV season or born during RSV season</li> <li>- Documentation of one of following risk factor(s):                             <ul style="list-style-type: none"> <li>- Sibling who is permanent resident of the home &lt; 5 years old</li> <li>- Day Care</li> </ul> </li> <li>- No diagnosis of CLD required</li> </ul>
<b>Category 5:</b> <ul style="list-style-type: none"> <li>- Age 0 – 12 months at start of RSV season</li> <li>- Documentation of congenital abnormalities of the airway that compromise handling respiratory secretions or neuromuscular disease</li> </ul>	
<b>Coverage limitations:</b> <ul style="list-style-type: none"> <li>- Category 3 – authorization will end at age 24 months. Extensions beyond require documentation of extreme clinical necessity.</li> <li>- Authorization will be granted for administration between October 31 and March 31.</li> <li>- Coverage limited to five doses for all categories except 4. Category 4 coverage ends when beneficiary reaches age 3 months with a maximum of 3 doses.</li> </ul>	

<sup>1</sup> American Academy of Pediatric Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics*. Available at <http://pediatrics.aappublicaions.org/content/early/2014/07/23/peds.2014-1665>.

**2014-15 Division of Medicaid  
Palivizumab Prophylaxis Prior Authorization Criteria\***

<b>Beneficiaries must meet one of the bullet point criteria for age at beginning of the RSV season.</b>	
<p><b>Age ≤ 1 year at start of RSV season and one of the following:</b></p> <ul style="list-style-type: none"> <li>- Prematurity of ≤ 28 weeks 6 days gestation</li> <li>- Documentation of <b>chronic lung disease (CLD)</b> of prematurity defined as gestational age of 29 weeks 0 days – 31 weeks 6 days <b>AND</b> requirement for oxygen &gt;21% for at least the first 28 days after birth.</li> <li>- Documentation of <b>hemodynamically significant CHD AND</b> one of the following:             <ol style="list-style-type: none"> <li>(1) <b>acyanotic heart disease</b> receiving medication for congestive heart failure <b>AND</b> will require cardiac surgery.</li> <li>(2) <b>moderate to severe pulmonary hypertension.</b></li> <li>(3) Documentation of <b>cyanotic heart disease</b> through consultation with pediatric cardiologist.</li> </ol> </li> <li>- Documentation of <b>congenital abnormalities of the airway OR neuromuscular disease</b> that impairs the ability to clear secretions from the upper airway because of ineffective cough.</li> <li>- Documentation of <b>cystic fibrosis AND</b> clinical evidence of CLD <b>OR</b> nutritional compromise.</li> <li>- Documentation of <b>profound immunocompromise</b> during the RSV season.</li> </ul>	<p><b>Age 12 – 24 months at start of RSV season and one of the following:</b></p> <ul style="list-style-type: none"> <li>- Documentation of <b>chronic lung disease (CLD)</b> of prematurity defined as gestational age of 29 weeks 0 days – 31 weeks 6 days <b>AND</b> requirement for oxygen &gt;21% for at least the first 28 days after birth <b>AND</b> required continued medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the RSV season.</li> <li>- Documentation of <b>cystic fibrosis AND</b> one of the following:             <ol style="list-style-type: none"> <li>(1) manifestations of <b>severe lung disease</b> (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest compute tomography that persists when stable).</li> <li>(2) weight for length &lt; 10<sup>th</sup> percentile.</li> </ol> </li> <li>- Documentation of <b>profound immunocompromise</b> during the RSV season.</li> </ul>
<p><b>Coverage limitations:</b></p> <ul style="list-style-type: none"> <li>- Authorization will be granted for administration between October 31 and March 31.</li> <li>- Coverage is up to five doses, but will be less for infants born during the RSV season.</li> <li>- Monthly prophylaxis should be discontinued for any infant or young child experiencing a breakthrough RSV hospitalization.</li> </ul> <p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>- Prophylaxis in infants with Down Syndrome is not recommended without the presence of one of the criteria listed above.</li> </ul>	

\* Criteria based 2014 AAP guidance. DOI: 10.1542/peds.2014-1665.

**Recommendation:** MS-DUR recommends the DUR Board approve the revised guidelines that are consistent with the updated AAP Updated Guidance for palivizumab prophylaxis.