Clinical Criteria, Step Therapy, and Quantity Limits for TennCare Preferred Drug List (PDL):

**Synagis®**

September 1, 2018

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<th>Synagis</th>
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**Note: Synagis® claims may ONLY be dispensed between the dates of 11/1/2018 and 4/30/2019.**

A maximum of 5 doses will be approved during RSV season; however, in infants and children less than 24 months of age, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO). If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. Per AAP guidelines, a maximum of 5 doses during RSV season (November-April) provides 6 months of RSV prophylaxis.

For patients younger than 12 months of age at the onset of Respiratory Syncytial Virus (RSV) season, Synagis® will be approved for patients meeting any ONE of the following:

- Gestational age less than 29 weeks, 0 days
- Diagnosis of Chronic Lung Disease of prematurity (defined as: Gestational Age less than 32 weeks, 0 days and received greater than 21% oxygen for at least first 28 days after birth)
- Anatomic pulmonary abnormalities, neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions
- Profoundly immunocompromised
- Diagnosis of Cystic Fibrosis with Chronic Lung Disease and/or nutritional compromise

For patients 12 months of age or younger at the onset of the RSV season, Synagis® will be approved for patients meeting the following:

- Diagnosis of hemodynamically significant congenital heart disease
  - With acyanotic heart disease on congestive heart failure medications AND are potential candidates for cardiac surgery, OR moderate to severe pulmonary hypertension
  - For cyanotic heart defects, prior authorization must be on recommendation of a Pediatric Cardiologist.

For patients 12 months to younger than 24 months of age at the onset of RSV season, Synagis® will be approved for patients meeting any ONE of the following:

- Diagnosis of Chronic Lung Disease of prematurity (defined as Gestational Age less than 32 weeks, 0 days and received greater than 21% oxygen for at least first 28 days after birth) AND received medical support (chronic systemic steroids, diuretic therapy, or supplemental O₂) within 6 months before the start of 2nd RSV season
- Diagnosis of Cystic Fibrosis with documentation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the 1st year of life or pulmonary abnormalities observed on chest x-ray or CT that persist when stable) or weight for length is less than 10th percentile

For patients younger than 24 months of age at the onset of the RSV season, Synagis® will be approved for patients meeting any ONE of the following:

- Cardiac transplant during RSV season
- Profoundly immunocompromised
### Synagis Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Synagis® will not be approved in the following scenarios:</th>
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<tbody>
<tr>
<td>- Gestational age greater than or equal to 29 weeks, 0 days (otherwise healthy)</td>
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<tr>
<td>- Asthma prevention</td>
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<td>- To reduce wheezing episodes</td>
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<td>- Down Syndrome (otherwise healthy)</td>
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<tr>
<td>- Diagnosis of Cystic Fibrosis (otherwise healthy)</td>
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<tr>
<td>- Healthcare-associated RSV disease</td>
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<td>- Breakthrough RSV hospitalization</td>
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<tr>
<td>- Hemodynamically insignificant CHD:</td>
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<td>- Secundum atrial septal defect</td>
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<td>- Small ventricular septal defect</td>
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<tr>
<td>- Pulmonic stenosis</td>
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<td>- Uncomplicated aortic stenosis</td>
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<tr>
<td>- Mild coarctation of the aorta</td>
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<td>- Patent ductus arteriosus</td>
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<td>- Congenital Heart Disease lesions corrected by surgery, unless patient continue to require CHF meds</td>
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<td>- Congenital Heart Disease and mild cardiomyopathy not on medical therapy</td>
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<td>- For patients greater than 12 months of age at the onset of RSV season:</td>
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<td>- Based on prematurity alone</td>
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<td>- Diagnosis of Chronic Lung Disease of Prematurity without medical support (chronic systemic steroids, diuretic therapy, or supplemental O2)</td>
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<td>- Diagnosis of Congenital Heart Disease</td>
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<td>- Otherwise healthy children in 2nd year of life</td>
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<td>- The dispensing pharmacy fails to include the RSV Preventative Agents Medication Administration Record (MAR) with the initial prescription and each subsequent refill of said prescription.</td>
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<td>- Approved requests are assigned specifically to the dispensing pharmacy</td>
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### REFERENCES

3. Synagis [package insert]. Gaithersburg, MD; MedImmune; March 2014.