

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

Synagis®

October 1, 2014

Synagis	
Prior Authorization Criteria	PA Form
<p>Note: Synagis® claims may ONLY be dispensed between the dates of November 1, 2014, and April 30, 2015.</p> <p>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.</p>	
<p>For patients younger than 12 months of age at the onset of Respiratory Syncytial Virus (RSV) season, Synagis® may be approved for patients meeting any ONE of the following:</p> <ul style="list-style-type: none"> ▪ 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 	
<p>For patients 12 months of age or younger at the onset of the RSV season, Synagis® may be approved for patients meeting the following:</p> <ul style="list-style-type: none"> ▪ Diagnosis of hemodynamically significant congenital heart disease <ul style="list-style-type: none"> – With <i>acyanotic</i> heart disease on congestive heart failure medications AND will require cardiac surgery, OR moderate to severe pulmonary hypertension – For <i>cyanotic</i> heart defects, prior authorization must be requested by a pediatric cardiologist. 	Synagis PA Form
<p>For patients 12 months to younger than 24 months of age at the onset of RSV season, Synagis® may be approved for patients meeting any ONE of the following:</p> <ul style="list-style-type: none"> ▪ 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 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 	
<p>For patients younger than 24 months of age at the onset of the RSV season, Synagis® may be approved for patients meeting any ONE of the following:</p> <ul style="list-style-type: none"> ▪ Cardiac transplant during RSV season ▪ Profoundly immunocompromised 	

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<p>Synagis® will not be approved in the following scenarios:</p> <ul style="list-style-type: none"> ▪ Gestational age greater than or equal to 29 weeks, 0 days (otherwise healthy) ▪ Asthma prevention ▪ To reduce wheezing episodes ▪ Down Syndrome (otherwise healthy) ▪ Diagnosis of Cystic Fibrosis (otherwise healthy) ▪ Healthcare-associated RSV disease ▪ Breakthrough RSV hospitalization ▪ Hemodynamically <i>insignificant</i> CHD: <ul style="list-style-type: none"> – Secundum atrial septal defect – Small ventricular septal defect – Pulmonic stenosis – Uncomplicated aortic stenosis – Mild coarctation of the aorta – Patent ductus arteriosus ▪ Congenital Heart Disease lesions corrected by surgery, unless patient continue to require CHF meds ▪ Congenital Heart Disease and mild cardiomyopathy not on medical therapy <p>For patients greater than 12 months of age at the onset of RSV season:</p> <ul style="list-style-type: none"> ▪ Based on prematurity alone ▪ Diagnosis of Chronic Lung Disease of Prematurity without medical support (chronic systemic steroids, diuretic therapy, or supplemental O₂) ▪ Diagnosis of Congenital Heart Disease ▪ Otherwise healthy children in 2nd year of life 	

REFERENCES

- 1 American Academy of Pediatrics. Position Statement. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics* 2014; 134;415. DOI: 10.1542/peds.2014-1665. Available at: <http://pediatrics.aappublications.org/content/134/2/415.full.pdf+html?sid=c5cf7568-4302-4ccd-9c71-ea785e33e241>. Accessed August 6, 2014.
- 2 American Academy of Pediatrics. Technical Report. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. DOI: 10.1542/peds.2014-1666. Available at: <http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1666>. Accessed July 29, 2014.
- 3 Synagis [package insert]. Gaithersburg, MD; MedImmune; March 2014.