

## Synagis Standard Prior Authorization Addendum (Medicaid and CHIP)

### About

Human Respiratory Syncytial Virus (RSV) causes mild symptoms in most people but can also cause severe illnesses, such as pneumonia or bronchiolitis in some infants and children. Palivizumab (Synagis®) is available for the prevention of RSV infection in infants and children who are at high-risk for severe illnesses from RSV. Patients should receive one dose per month, up to five doses. Access to Synagis® is available on the Texas Medicaid formulary year-round as long as the patient meets the criteria for approval. The start of RSV season varies based on a patient's county of residence (refer to [txvendordrug.com/formulary/prior-authorization/synagis](http://txvendordrug.com/formulary/prior-authorization/synagis)).

Requests should be submitted on the Texas Standard Prior Authorization Form for Prescription Drug Benefits (NOFR002), developed by the Texas Department of Insurance (TDI). Additional information can be provided with the Synagis Standard Prior Authorization Addendum Form or prescribers can call 800-310-6826.

### Initial Dosage

1. The provider or provider's agent may fax both the [Texas Standard Prior Authorization Request Form for Prescription Drug Benefits \(TDI Form NOFR002\) \(PDF\)](#) and this form to the OptumRx Pharmacy Prior Authorization Call Center at 1-866-940-7328. The prescription section on this form can be utilized by a pharmacist for dispensing Synagis®.
2. If the information submitted demonstrates medical necessity, the request is approved, and both the member and provider are notified. The dispensing pharmacy fills the prescription and ships an individual dose of the medication, in the name of the patient, directly to the provider. The pharmacy mails an initiation packet containing information about Synagis® to the patient's family.
3. The physician, or the provider under the direct supervision of the physician, administers the drug. The administering provider may only bill for an injection administration fee and any medically necessary office-based evaluation and management services provided at the time of injection. The pharmacy is reimbursed for the drug and dispensing fees.
4. If the information submitted does not meet the prior authorization criteria, the request will be denied, and both the member and provider will be notified. Prescribing providers may request a reconsideration of a denied prior authorization for patients with RSV infection risks not identified on this form. The reconsideration process may require additional supporting documents, such as pertinent diagnostic, lab tests, or hospital records. Reconsideration requests may be faxed to the OptumRx Pharmacy Prior Authorization Call Center at 866-940-7328. The requesting provider may call for a discussion or reconsideration at 800-310-6826, following the prompts for Peer-to-Peer, Monday through Friday from 8 am to 5 pm. Requests for a Peer-to-Peer discussion should be made within 7 days of an adverse determination notice.

Prophylactic Synagis® injections should not continue if the patient is hospitalized for RSV, based on the 2019 American Academy of Pediatrics guidance. Patients hospitalized for RSV while being treated with Synagis® should not receive subsequent doses because the rate of RSV re-hospitalization is very low.

### Subsequent Dosage

Patients can receive one dose per month, up to 5 doses. Depending on the date of the initial dose, a patient may not receive all five injections before the end of season.

### Contact

**Please fax both completed forms (Texas Standard Prior Authorization Request Form for Prescription Drug Benefits (TDI Form NOFR002) AND Synagis Standard Prior Authorization Addendum) to OptumRx Pharmacy Prior Authorization Help Desk at 866-940-7328.**

Providers with questions should call the OptumRx Pharmacy Prior Authorization Help Desk at 800-310-6826.

**Section I — Dispensing Pharmacy Information**

Name of Pharmacy	National Provider Identifier (NPI)	Area Code and Telephone No.	Area Code and Fax No.																	
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**Section II — Patient Demographics**

Name of Patient	Medicaid ID	Date of Birth (MMDDYY)	Gestational Age																			
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Address of Patient (Street, City, State, ZIP Code)		Patient Phone No. with Area Code		County of Residence																		
Has patient received a Synagis prophylactic injection during hospitalization since the start current of the RSV season?																						
<input type="checkbox"/> No <input type="checkbox"/> Yes   If yes, number of shots: _____ Dose (mg): _____ Date(s): _____																						
Has the patient been hospitalization due to RSV at any time since the start of the current RSV season?																						
<input type="checkbox"/> No <input type="checkbox"/> Yes   If yes, date of diagnosis: _____																						

**Section III — Patient Diagnosis at the start of the RSV season**

(Clearly document diagnosis/conditions in the patient's medical record.)

<input type="checkbox"/> Patients who are <b>younger than 24 months</b> chronological age can qualify, for up to five monthly doses of Synagis, based on diagnosis listed to the right.	<input type="checkbox"/> <b>24-1:</b> Profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplant, chemotherapy or other condition that leaves the infant profoundly immunocompromised):  _____ ICD-10-CM code: _____
	<input type="checkbox"/> <b>24-2:</b> Active diagnosis of chronic lung disease (CLD) of prematurity <sup>#</sup> , <b>AND</b> required any of the following therapies within the six months prior to the current RSV season (check all that apply): <input type="checkbox"/> Chronic systemic corticosteroids <input type="checkbox"/> Greater than 21% Supplemental oxygen <input type="checkbox"/> Diuretics <input type="checkbox"/> Long-Term Mechanical Ventilator
<input type="checkbox"/> Patients who are <b>between 12 - 24 months</b> chronological age at the start of the RSV season can qualify, for up to five monthly doses of Synagis, based on the diagnosis or conditions listed to the right.  <i>Please refer to Page 3 for definition.</i>	<input type="checkbox"/> <b>24-3:</b> Diagnosis of cystic fibrosis with severe lung disease*, or cystic fibrosis with weight for length less than the 10th percentile:  _____ ICD-10-CM code: _____
	<input type="checkbox"/> <b>12-1:</b> ≤ 28 6/7 weeks gestational age at birth: _____ ICD-10-CM code: _____
<input type="checkbox"/> Patients who are <b>younger than 12 months</b> chronological age at the start of the RSV season can qualify, for up to five monthly doses of Synagis, based on criteria listed to the right.	<input type="checkbox"/> <b>12-2:</b> Chronic lung disease (CLD) of prematurity#: _____ ICD-10-CM code: _____
	<input type="checkbox"/> <b>12-3:</b> Severe congenital abnormality of airway <b>OR</b> severe neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough:  _____ ICD-10-CM code: _____

	<input type="checkbox"/> <b>12-4:</b> Active diagnosis of hemodynamically significant congenital heart disease (CHD): <hr/> ICD-10-CM code: <b>AND any of the below</b> <input type="checkbox"/> Moderate to severe pulmonary hypertension. <input type="checkbox"/> Acyanotic heart disease, on medication to control congestive heart failure, and will require cardiac surgery <input type="checkbox"/> Cyanotic heart disease <b>(Note:</b> This excludes infants with hemodynamically insignificant heart disease - refer to pages 3 and 4 for list.)
	<input type="checkbox"/> <b>12-5:</b> Diagnosis of cystic fibrosis with clinical evidence of CLD, nutritional compromise or both <hr/> ICD-10-CM code:

**Section IV — Synagis Prescription (to be completed by prescriber)**

<b>Rx:</b> Synagis (palivizumab) Injection	Quantity: _____	Dose (mg): _____	Refills: _____
<b>Sig:</b> Inject 15mg/kg one time per month	Current Weight: _____	<input type="checkbox"/> (kg) or <input type="checkbox"/> (lbs.)	
<input type="checkbox"/> Syringes 1ml 25G 5/8*	<input type="checkbox"/> Syringes 3ml 20G 1*	<input type="checkbox"/> Epinephrine 1:1000 amp.	Sig: Injected 0.01 mg/kg as directed.
Prescriber Name	License No.	NPI	
Address of Prescriber (Street, City, State and ZIP Code)	Area Code and Telephone No.	Area Code and Fax No.	
Physician Signature			Date

**Fax the completed prior authorization from to 866-940-7328.**

Category	Subcategories
#Chronic Lung Disease (CLD) of Prematurity	<ul style="list-style-type: none"> <li>• Infants born less than 32 weeks, 0 days' gestational age who require greater than 21% oxygen for at least 28 days after birth.</li> </ul>
Hemodynamically significant heart disease	<ul style="list-style-type: none"> <li>• Congestive heart failure (CHF) requiring medication</li> <li>• Moderate to severe pulmonary hypertension</li> <li>• Unrepaired cyanotic congenital heart disease</li> </ul>
*Severe lung disease	<ul style="list-style-type: none"> <li>• Previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable</li> </ul>
<b>The following groups of infants are NOT AT INCREASED risk of RSV and generally should not receive immunoprophylaxis:</b>	
1. Hemodynamically <i>insignificant</i> heart disease.	<ul style="list-style-type: none"> <li>• Secundum atrial septal defect</li> <li>• Small ventriculoseptal defect</li> <li>• Pulmonic stenosis</li> <li>• Uncomplicated aortic stenosis</li> <li>• Mild coarctation of the aorta</li> <li>• Patent ductus arteriosus</li> </ul>
2. Congenital heart disease adequately corrected by surgery which does not continue to require medication for congestive heart failure.	
3. Mild cardiomyopathy that does not require medical therapy for the condition.	

Category	Subcategories
4. Children in the second year of life on the basis of a history of prematurity alone.	<p><b>Note:</b> Tobacco smoke exposure is <u>not</u> an indication for Synagis administration. Offer tobacco dependent parents tobacco dependence treatment or referral for tobacco dependence treatment. 877-YES-QUIT (877-937-7848, YesQuit.org) is the Quitline operated in Texas.</p>

#### Additional Information

- Texas Medicaid has adopted the updated guidance published in 2014 by the American Academy of Pediatrics.
- Infants born at 29 weeks, 0 days' gestation or later are no longer universally recommended to receive prophylaxis with Synagis. Infants born at 29 weeks, 0 days' gestation or later, based on chronic lung disease, congenital heart disease, or another condition, may qualify to receive prophylaxis.
- Synagis is not recommended in the second year of life based on prematurity alone.
- Discontinue monthly prophylaxis in any child who experiences a breakthrough RSV hospitalization.

#### References

- "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection." *Pediatrics* 134.2 (2014): 415-420. Web. 11 Aug. 2015.
- Synagis® (palivizumab) [prescribing information]. Gaithersburg, MD: Medimmune, LLC. 2014.
- Epinephrine 1:1000 (1mg/ml) [prescribing information]. Lake Forest, IL: Hospira. 2008.