

Texas Vendor Drug Program
Synagis Standard PA Addendum (Medicaid)

About

Human Respiratory Syncytial Virus (RSV) causes respiratory tract infections and serious lung disease in infants and children. Palivizumab (Synagis®) is available with prior authorization for high-risk patients.

Prior authorization for Synagis is required monthly for patients enrolled in fee-for-service (FFS) Medicaid. Use Form 1321 to obtain prior authorization for FFS patients meeting the specified criteria. The start of RSV season varies based on a patient's county of residence (refer to www.txvendordrug.com/formulary/prior-authorization/synagis).

For patients enrolled in Medicaid managed care, the treating provider must contact the appropriate health plan to obtain instructions for Synagis prior authorization processes. The provider may utilize the Prescriber MCO Assistance Chart at www.txvendordrug.com/resources/managed-care to obtain plan contact information. Using this form for patients not enrolled in FFS will cause unnecessary delays in access to treatment. Forms received outside the RSV season will not be processed (refer to the RSV season schedule at www.txvendordrug.com/formulary/prior-authorization/synagis).

Initial Dosage

The provider or provider's agent will send a prescription for Synagis with refills with supporting clinical information on Form 1321 to a Medicaid-enrolled pharmacy.

The pharmacy faxes both the [Texas Standard Prior Authorization Request Form for Prescription Drug Benefits \(TDI Form NOFR002\) \(PDF\)](#) and Form 1321 to the Texas Prior Authorization Call Center at 866-469-8590.

If the information submitted demonstrates medical necessity, approve the request, and notify both the pharmacy and provider. The dispensing pharmacy fills the prescription and ships an individual dose of the medication, in the name of the Medicaid patient, directly to the provider. The pharmacy mails an initiation packet that contains information about Synagis to the patient's family.

The physician or provider under the direct supervision of the physician administers the Synagis. 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. Reimburse the pharmacy for the drug and dispensing fees.

If the information submitted does not meet the prior authorization criteria, the request is denied, and both the pharmacy and provider will be notified. Prescribing providers may request a reconsideration of denied prior authorizations for infants and children younger than 24 months if there is additional information on RSV risks not included on the PA form **and** the prescription was written by or in consultation with an appropriate pediatric sub-specialist. This includes sub-specialist consultations that may have occurred upon discharge from the hospital with a recommendation reflected in the discharge summary. Supporting documents, such as the sub-specialist consultation notes, pertinent diagnostic or lab tests, and hospital records, may be required during the reconsideration process.

Prophylactic Synagis injections should not continue if the patient is hospitalized for RSV, based on 2014 American Academy of Pediatrics guidance. Patients hospitalized for RSV while being treated with Synagis may not be approved for subsequent doses.

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. For each monthly dose, the pharmacy receives an approval letter from Texas Prior Authorization Call Center. The pharmacy must complete the table provided on the approval letter no sooner than one week before billing for the subsequent dose. Pharmacy staff must contact the prescriber to:

- Verify patient has not experienced a breakthrough RSV hospitalization
- Obtain patient's updated weight

- Verify patient was administered all previously dispensed Synagis doses
- Maintain a log of the information obtained from the injecting/administering provider

Contact

Fax the completed [Texas Standard Prior Authorization Request Form for Prescribing Drug Benefits \(TDI Form NOFR002\) \(PDF\)](#) and Form 1321 to 866-469-8590.

Providers with questions should call the Texas Prior Authorization Call Center at 877-728-3927.

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 younger than 24 months chronological age can qualify, for up to five monthly doses of Synagis, based on diagnosis listed to the right	<input type="checkbox"/> 24-1: 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"/> 24-2: Active diagnosis of chronic lung disease (CLD) of prematurity [#] , AND 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"/> > 21% Supplemental oxygen <input type="checkbox"/> Diuretics <input type="checkbox"/> Long-Term Mechanical Ventilator
<input type="checkbox"/> Patients who are between 12 - 24 months 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"/> 24-3: 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"/> 12-1: ≤ 28 6/7 weeks gestational age at birth: _____ ICD-10-CM code: _____
<input type="checkbox"/> Patients who are younger than 12 months 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"/> 12-2: Chronic lung disease (CLD) of prematurity#: _____ ICD-10-CM code: _____
	<input type="checkbox"/> 12-3: Severe congenital abnormality of airway OR 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"/> 12-4: Active diagnosis of hemodynamically significant congenital heart disease (CHD): _____ ICD-10-CM code: AND any of the below <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 (with consultation from a pediatric cardiologist) (NOTE: This excludes infants with hemodynamically insignificant heart disease - refer to pages 3 and 4 for list)
	<input type="checkbox"/> 12-5: Diagnosis of cystic fibrosis with clinical evidence of CLD, nutritional compromise or both _____ ICD-10-CM code:

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

Rx: Synagis (palivizumab) Injection Quantity: _____ Dose (mg): _____ Refills: _____		
Sig: 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 866-469-8590.

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