



**Texas Medicaid
Respiratory Syncytial Virus (RSV) Season
2021 - 2022 | SYNAGIS Prior Authorization Request Form**

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 (1) dose per month, up to five (5) doses. Access to SYNAGIS is available on the Texas Medicaid formulary year-round as long as the patient meets the criteria for approval.

The information and form contained in this document should be used to obtain prior authorization for patients who meet the specified criteria. The start of RSV season varies based on a patient's county of residence. A county table and local RSV season dates are available on the Navitus website at <https://www.navitus.com/texas-medicaid-star-chip/synagis.aspx> or on the Texas Vendor Drug Program website at www.TxVendorDrug.com/formulary/prior-authorization/synagis.

Initial Dosage

The provider or provider's agent will send a completed **Medicaid SYNAGIS Prior Authorization Request Form** to one (1) of the preferred pharmacies listed at the top of the form. The prior authorization request should include (1) preferred pharmacy, (2) patient demographics, (3) patient diagnosis, (4) SYNAGIS prescription (bottom of the form), and (5) any supporting clinical information the prescriber feels necessary to include.

The pharmacy faxes both the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits and the completed form to the NAVITUS Prior Authorization Department at 1-855-668-8553.

If the information submitted demonstrates medical necessity, the request is approved, and both the pharmacy and provider are notified via approval letters. The dispensing pharmacy fills the prescription and ships an individual dose of SYNAGIS, in the name of the Medicaid patient, directly to the provider. An initiation packet that contains information about SYNAGIS is to be mailed by the pharmacy to the patient's family.

The physician, or provider under the direct supervision of the physician, administers 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. The pharmacy is reimbursed for the drug and dispensing fees.

If the information submitted does not demonstrate medical necessity then the request is denied and both the pharmacy and provider are notified of the denial via denial letters. 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. Based on the 2019 American Academy of Pediatrics guidance, prophylactic SYNAGIS injections should not continue if a patient is hospitalized for RSV. Patients who are hospitalized for RSV while being treated with SYNAGIS may not be approved for subsequent doses because the rate of RSV re-hospitalization is very low.

Subsequent Dosage

Patients can receive one (1) dose of SYNAGIS per month, up to five (5) doses. Depending on the date of the initial dose, a patient may not receive all five (5) injections before the end of season. Prior to dispensing a subsequent dose, the pharmacy must contact the prescriber to:

- Verify that the patient has not experienced a breakthrough RSV hospitalization
- Obtain the patient's updated weight
- Verify that the patient was administered all previously dispensed SYNAGIS doses
- Pharmacies should maintain a log of the information obtained from the injecting/administering provider

For each subsequent dose, the pharmacy must complete the required section on the SYNAGIS Subsequent Dose prior authorization form that was included in the approval letter and fax it to NAVITUS at 1-855-668-8553.

Contact

Dispensing pharmacy should fax both the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits and this completed prior authorization form to NAVITUS at 1-855-668-8553.

Providers with questions should call the Texas Provider Hotline at 1-877-908-6023.

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Providers please FAX completed form to preferred pharmacy for processing:

Preferred Pharmacies: Lumicera - 855.847.3558 Walmart Pharmacy - 866.537.0877

If Other Pharmacy - Name of Pharmacy:		Pharmacy Phone:	Pharmacy Fax:	
Patient Name:		Medicaid ID:	DOB:	
Patient Address:			Patient Phone:	
County of Residence/Zip:		Gestational Age:	& / 7 weeks	
Has the patient received a SYNAGIS prophylaxis injection since the start of the current RSV season (including during hospitalization)? <input type="checkbox"/> No <input type="checkbox"/> Yes – If Yes, number of injections: _____ Dose (mg): _____ Date(s) of Injection(s): _____				
Has the patient been hospitalized 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 _____				
PATIENT DIAGNOSIS AT THE START OF RSV SEASON (Diagnoses/conditions must be clearly documented in the patient's medical record.)				
<input type="checkbox"/> Patients who are younger than 24 months chronological age can qualify, for up to 5 monthly doses of SYNAGIS, based on diagnosis listed to the right		<input type="checkbox"/> 24-1: Profoundly immunocompromised during the RSV season (e.g., solid organ or hematopoietic stem cell transplant, chemotherapy or other condition that leaves the infant profoundly immunocompromised): ICD-10-CM code: _____		
<input type="checkbox"/> Patients who are between 12 - 24 months chronological age at the start of the RSV season can qualify, for up to 5 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"/> 24-2: Active diagnosis of chronic lung disease (CLD) of prematurity [†] AND required any of the following therapies within the 6 months prior to the current RSV season (check all that apply): ICD-10-CM code: _____ <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 younger than 12 months chronological age at the start of the RSV season can qualify, for up to 5 monthly doses of SYNAGIS, based on criteria listed to the right.		<input type="checkbox"/> 24-3: Diagnosis of cystic fibrosis with severe lung disease* or cystic fibrosis with weight for length less than (<) the 10 th percentile: ICD-10-CM code: _____		
		<input type="checkbox"/> 12-1: Less than or equal to (\leq) 28 6/7 weeks gestational age at birth: ICD-10-CM code: _____		
		<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 (NOTE: This excludes infants with hemodynamically insignificant heart disease - refer to page 3 for the list)		
		<input type="checkbox"/> 12-5: Diagnosis of cystic fibrosis with clinical evidence of CLD and/or nutritional compromise ICD-10-CM code: _____		
SYNAGIS Prescription (to be completed by the prescriber)				
Rx: SYNAGIS (palivizumab) injection 50mg and/or 100mg vials		<input type="checkbox"/> 50mg		<input type="checkbox"/> 100mg vials
Dose (mg): _____		Quantity (QS for weight based dose): _____		Refills: _____
Sig: Inject 15mg/kg one time per month		Current Weight: _____ <input type="checkbox"/> kg or <input type="checkbox"/> lbs.		Date Weight Obtained: _____
<input type="checkbox"/> Syringes 1mL 25G 5/8"		<input type="checkbox"/> Syringes 3mL 20G 1"		<input type="checkbox"/> Epinephrine 1:1000 amp Sig: Inject 0.01mg/kg as directed.
Prescriber Name (PRINT):			License Number:	
PHONE:		FAX:		NPI:
ADDRESS:		CITY:		STATE: ZIP:
Prescriber Signature:			Date: / /	

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Category	Subcategories
‡Chronic Lung Disease (CLD) of Prematurity	<ul style="list-style-type: none"> Infants born less than (<) 32 weeks, 0 days' gestational age who require greater than (>) 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 insignificant 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	
4) Children in their second year of life on the basis of a history of prematurity alone	
NOTE: Tobacco smoke exposure is <u>NOT</u> an indication for SYNAGIS administration. Tobacco dependent parents should be offered tobacco dependence treatment or referral for tobacco dependence treatment. 1-877-YES-QUIT (1-877-937-7848, YesQuit.org) is the Quitline operated in Texas.	

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, on the basis of chronic lung disease, congenital heart disease, or another condition, may qualify to receive prophylaxis.
- SYNAGIS is not recommended in the second year of life on the basis of prematurity alone.
- Monthly prophylaxis should be discontinued 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.

For questions, please call Navitus Customer Care at 1-877-908-6023.

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