Texas Medicaid
Respiratory Syncytial Virus (RSV) Season
2019 - 2020 | Synagis® Prior Authorization Request Form

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.

The information and form contained in this document should be used to obtain prior authorization for clients who meet the specified criteria. The start of RSV season varies based on a client'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 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 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 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. 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 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. Based on the 2014 American Academy of Pediatrics guidance, prophylactic Synagis® injections should not continue if a patient is hospitalized for RSV, therefore patients who are hospitalized for RSV while being treated with Synagis® may not be approved for subsequent doses.

Subsequent Dosage

Patients can receive one dose of Synagis® 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. 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 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 provider

Contact

Dispensing pharmacy should fax the completed prior authorization form to NAVITUS at 1-855-668-8553.
Providers with questions should call the NAVITUS Texas Provider Hotline at 1-877-908-6023.

Dispensing Pharmacy FAX completed form to NAVITUS for approval: 1.855.668.8553

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Providers please FAX completed form to **preferred pharmacy** for processing:

Preferred Pharmacies: ☐ Lumicera - 855.847.3558 ☐ Avella Pharmacy - 877.480.1746

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)?

☐ No ☐ 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?

☐ No ☐ 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*.)

☐ 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	☐ **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: _____
☐ 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 ** Please refer to page 3 for definition*	☐ **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: _____ ☐ Chronic systemic corticosteroids ☐ > 21% Supplemental oxygen ☐ Diuretics ☐ Long-Term Mechanical Ventilator
	☐ **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: _____
☐ 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.	☐ **12-1**: ≤ 28 6/7 weeks gestational age at birth: ICD-10-CM code: _____
	☐ **12-2**: Chronic lung disease (CLD) of prematurity‡: ICD-10-CM code: _____
	☐ **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: _____
	☐ **12-4**: Active diagnosis of hemodynamically significant congenital heart disease (CHD): ICD-10-CM code: _____ **AND any of the below:** ☐ Moderate to severe pulmonary hypertension ☐ Acyanotic heart disease, on medication to control congestive heart failure, and will require cardiac surgery ☐ Cyanotic heart disease (with consultation from a pediatric cardiologist) (**NOTE:** This excludes infants with hemodynamically **insignificant** heart disease - refer to page 3 for the list)
	☐ **12-5**: Diagnosis of cystic fibrosis with clinical evidence of CLD and/or nutritional compromise ICD-10-CM code: _____

Rx: Synagis® (palivizumab) injection 50mg and/or 100mg vials ☐ 50mg ☐ 100mg vials

Dose (mg): _____ **Quantity (QS for weight based dose):** _____ **Refills:** _____

Sig: Inject 15mg/kg one time per month **Current Weight**: _____ ☐ kg or ☐ lbs. **Date Weight Obtained:** _____

☐ Syringes 1mL 25G 5/8" ☐ Syringes 3mL 20G 1" ☐ 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	• Infants born < 32 weeks, 0 days' gestational age who require >21% oxygen for at least 28 days after birth.
Hemodynamically **significant** heart disease	• Congestive Heart Failure (CHF) requiring medication • Moderate to severe pulmonary hypertension • Unrepaired cyanotic congenital heart disease
*Severe lung disease	• 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	• 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 NOT 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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