Texas Medicaid

Synagis Standard Prior Authorization Request

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 to prevent 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.

- For patients enrolled in Medicaid fee-for-service (FFS): prior authorization for Synagis is required monthly.
- For patients enrolled in managed care (Medicaid or CHIP): the treating provider should contact the patient's MCO to obtain instructions for prior authorization processes. Using this form for patients enrolled in managed care will cause unnecessary delays in access to treatment.

For Initial Treatment

1. The provider or provider's agent may use the prescription section of this form (Section IV) to write for a Synagis prescription plus refills. This form, along with all the required supporting clinical information should be sent to a Texas Medicaid-enrolled pharmacy for dispensing.
2. The pharmacy faxes both the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits (TDI Form NOFR002) and this form (HHS Form 1321) to the Texas Prior Authorization Call Center at 866-469-8590. The prescription section on this form can be used by a pharmacist for dispensing Synagis.
3. If approved, the Texas Prior Authorization Call Center will notify both the pharmacy and provider. The dispensing pharmacy may then fill the prescription and ship 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.
4. 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. Medicaid reimburses the pharmacy for the drug and dispensing fees.
5. If the information submitted does not meet the prior authorization criteria, the request will be denied, and both the pharmacy 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 diagnostics, lab tests, or hospital records. The prescribing provider must complete and fax the reconsideration request form (HHS Form 1322) to **866-617-8864**. A representative from the Texas Prior Authorization Call center will provide further information on the reconsideration process.

Prophylactic Synagis injections should not continue if the patient is hospitalized for RSV, based on the 2019 American Academy of Pediatrics (AAP) 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.

Beyfortus (nirsevimab – monoclonal antibody – AstraZeneca/Sanofi) is administered as a one-time intramuscular dose for the prevention of severe RSV infections in newborns and babies under one year, born during or entering their first RSV season, as well as children up to 24 months who remain at risk of severe RSV disease through their second RSV season. The Texas Vaccine for Children Program (TVFC) provides this medication. Prophylactic Synagis therapy should not be administered to clinically eligible patients once Beyfortus is administered anytime during the season.

Subsequent Dosage

1. For each subsequent dose, the pharmacy must complete the required section on the approval letter and fax it to the Texas Prior Authorization Call Center. Pharmacy staff may contact the prescribing provider to obtain the following necessary information:
    a. Verify the patient has not experienced a breakthrough RSV hospitalization.
    b. Maintain a log of the information obtained from the injecting or administering provider of the total number of doses per season (typically 5 monthly doses per season).
    c. Verify the number of vials needed is consistent with the correct dose.
2. For patients enrolled in managed care, only one prior authorization approval is necessary for up to five monthly doses per treatment course, and a month-to-month approval is not required. For subsequent doses it is still required to verify clinically appropriate indications for continuing monthly treatment.

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Subsequent dosage of Synagis should not be continued if Beyfortus is administered to infants during the season.

Contact

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 Phone No.	Area Code and Fax No.

Section II — Patient Demographics

Name of Patient	Medicaid ID	Date of Birth (MMDDYY)	Gestational Age
			weeks and / 7th day

Address of Patient (Street, City, State, ZIP Code)	Patient Phone No. with Area Code	County of Residence

Has patient received a Beyfortus injection during the current of the RSV season?

☐ No ☐ Yes If yes, Date _____ _____ _____

Has patient received a Synagis prophylactic injection during hospitalization since the start of the current RSV season?

☐ No ☐ 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?

No Yes If yes, date of diagnosis:

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

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

☐ 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.

☐ **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:

☐ 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.

(Please refer to Page 3 for definition.)

☐ **24-2:** Active diagnosis of chronic lung disease (CLD) of prematurity**# AND r**equired any of the following therapies within the six months prior to the current RSV season (check all that apply):

☐ 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 five 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 (**Note:** This excludes infants with hemodynamically insignificant heart disease - refer to pages 3 and 4 for list.)
	☐ **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: _____ ☐ (kg) or ☐ (lbs.)

☐ Syringes 1ml 25G 5/8 ☐ Syringes 3ml 20G 1 ☐ 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 Phone 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	• 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	• 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.	

Category	Subcategories
4. Children in the second year of life-based on a history of prematurity alone. **Note**: Tobacco smoke exposure is not 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.	

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.