TEXAS Health and Human Services

Children with Special Health Care Needs (CSHCN) Services Program
Palivizumab (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 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 formulary year-round if the patient meets the criteria for approval. Prior authorization for Synagis is required monthly. The start of RSV season varies based on a patient's county of residence. Refer to txvendordrug.com for the schedule.

Initial Dosage

1. The provider or provider's agent may utilize 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 this form and the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits to the CSHCN Services Program at 512-776-7238. The prescription section on this form can be utilized by a pharmacist for dispensing.
3. If approved, the CSHCN Services Program will notify the provider. The dispensing pharmacy may then fill the prescription and ship an individual dose of the medication, in the name of the CSHCN 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 authorizations 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.

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.

Nirsevimab (Beyfortus) – 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.

Abrysvo (Pfizer Inc.) is approved for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth through 6 months. Most infants younger than 8 months who are clinically eligible do not need further immunization with nirsevimab or palivizumab if they were born 14 or more days after Abrysvo is properly administered to the mothers at the start or anytime during the RSV season.

Subsequent Dosage

I. For each subsequent dose, the pharmacy must complete the required section on the approval letter and fax it back to the CSHCN Services Program. 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/administering provider of the total number of doses per season (typically five monthly doses per season).

c. Verify the number of vials needed is consistent with the correct dose.

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

Submittal

Fax form to 512-776-7238 or mail form to mailing address provided on the Form 1325 instructions.

Providers with questions should call the CSHCN Services Program at 800-252-8023 and select option 2.

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			
Date of Birth (MMDDYY)	CSHCN ID	Patient Area Code and Phone No.	Gestational Age weeks and / 7th day
Address of Patient (Street, City, State, ZIP Code)			County of Residence

Has the patient received a nirsevimab injection during the current RSV season? ◯ Yes ◯ No If yes, Date: _____

If No, explain why nirsevimab was not administered.

☐ Birth hospital did provide nirsevimab administration.
☐ Primary care physician is not enrolled in Vaccines for Children program.
☐ Parent or legally authorized representative refused nirsevimab administration.
☐ Patient too ill to receive immunization.
☐ Patient did not schedule follow-up appointment.
☐ Other, explain below:

Has Abrysvo been given to the patient's mother during pregnancy (between 32 weeks through 36 weeks of gestational age)? ◯ Yes ◯ No

If yes, Date(s): _____

Has the patient received a Synagis prophylactic injection during hospitalization since the start current of the RSV season? ◯ Yes No

If yes, number of shots: _____ Dose (mg): _____ Date(s): _____

Has the patient been hospitalized due to RSV at any time since the start of the current RSV season? ◯ Yes ◯ No

If yes, date of diagnosis: _____

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

Diagnosis and conditions must be clearly documented in the patient's medical record.

☐ Patients who are **younger than 20 months** of chronological age entering their first or second RSV season can qualify for up to five monthly doses of Synagis, based on the diagnosis listed to the right.	☐ **20-1:** 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 8 - 19 months** of chronological age at the start of their second RSV season can qualify, for up to five monthly doses of Synagis, based on the diagnosis or conditions listed to the right. *Refer to Page 3 for definition.*	☐ **19-2:** 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 — Greater than 21% Supplemental oxygen Diuretics — Long-Term Mechanical Ventilator ☐**19-3:** Diagnosis of cystic fibrosis with severe lung disease, or cystic fibrosis with weight for length less than the 10th percentile: ICD-10-CM code: ☐ 19-4: American Indian and Alaska Native children.

☐ Patients who are **younger than 12 months** of chronological age at the start of the RSV season can qualify, for up to five monthly doses of Synagis, based on the criteria listed to the right.	☐ **12-5**: ≤ 28 6/7 weeks gestational age at birth: _____ ICD-10-CM code:
	☐ **12-6**: Chronic lung disease (CLD) of prematurity: _____ ICD-10-CM code:
	☐ **12-7**: Severe congenital abnormality of the airway **OR** severe neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough: ICD-10-CM code: ☐
	12-8: 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 pages 3 and 4 for list)
	12-9: 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.

Name of Prescriber	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 512-776-7238.

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

Category	Subcategories
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 the second year of life based on of 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

- The CSHCN Services Program 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.
- Patients who receive Beyfortus during the RSV season no longer need Synagis prophylaxis therapy.
- Synagis prophylaxis therapy is not needed for a newborn whose mother is vaccinated with Abrysvo during 32 to 36 gestational weeks of pregnancy. Most infants younger than 8 months do not need nirsevimab or palivizumab for that if they were born 14 or more days after their mother was properly vaccinated with Abrysvo.

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.
- Beyfortus (nirsevimab-nilp) Highlights of Prescribing Information
- Product package insert, ABRYSVO- respiratory syncytial virus vaccine, Pfizer Laboratories Div Pfizer Inc
- Frequently Asked Questions About RSVpreF (Abrysvo) Vaccine for Pregnant People, National Center for Immunization and Respiratory Diseases; Web. Last update, Nov. 13, 2023
- Red Book Online, February 21, 2024 - publications.aap.org/redbook/book/755/chapter/14080939/Respiratory-Syncytial-Virus?autologincheck=redirected