TEXAS Health and Human Services

Form 1321
January 2024

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. The provider should then send this form and any required supporting clinical information to a Texas Medicaid-enrolled pharmacy for dispensing.
2. The pharmacy faxes 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. A pharmacist can use the prescription section on this form for dispensing Synagis.
3. The Texas Prior Authorization Call Center will notify the pharmacy and provider if approved. 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 submitted information does not meet the prior authorization criteria, the request will be denied, and 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 Texas Prior Authorization Call Center representative 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 or 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. Therefore, patients who receive Beyfortus at the beginning or any time during RSV season are not approved for start or continuation of Synagis therapy.

RSVpreF (Abrysvo) is approved for use in pregnant people to protect newborns and infants in the first six months after birth against lower respiratory tract disease (LRTD) and severe LRTD caused by RSV. Abrysvo must be administered at 32 weeks and zero days through 36 weeks and six days gestational age of pregnancy. Most infants will not need protection from both Abrysvo and Synagis. Therefore, patients whose mothers have received Abrysvo vaccine during pregnancy, are not approved for SYNAGIS prophylaxis therapy.

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 five 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.

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 (all questions must be answered)

Name of Pharmacy	National Provider Identifier (NPI)	Area Code and Phone No.	Area Code and Fax No.

Section II — Patient Demographics (all questions must be answered)

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

Has the patient received a Beyfortus injection during the current RSV season? (Verification is required)

Yes No If yes, date:

Has Abrysvo been given to the patient's mother during 32 through 36 weeks gestational age of pregnancy? (Verification is required)

Yes No If yes, date:

Has patient received a Synagis prophylactic injection during hospitalization since the start of the current 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 (all questions must be answered)

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 im munocompromised 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.

(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
- ☐ Greater than 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.

12-4: 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.

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 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, zero days' gestational age who require more 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.

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 treatment or referral for tobacco dependence treatment. 877 administration. Offer tobacco dependent parents tobacco dependence - 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, zero days' gestation or later are no longer universally recommended to receive prophylaxis with Synagis. Infants born at 29 weeks, zero 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 newborns whose mothers are vaccinated with Abrysvo during 32 to 36 gestational weeks of pregnancy.

References

- "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Syncytial Virus Infection." *Pediatrics* 134.2 (2014): 415-420. Respiratory Web. Aug. 11, 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