TEXAS Health and Human Services

Wellpoint

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Texas Medicaid

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 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 the county where a patient lives.

- For patients enrolled in managed care (Medicaid or CHIP), the treating provider should contact the patient's MCO for 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 and this form to Wellpoint at 844-474-3341. A pharmacist can use the prescription section on this form to dispense Synagis.
3. Wellpoint notifies 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 with 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 more supporting documents, such as pertinent diagnostics, 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 rehospitalization 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 patients 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

1. For each subsequent dose, the pharmacy must complete the required section on the approval letter and fax it to Wellpoint. Wellpoint may contact the prescribing provider for 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. Doses typically are 5 monthly 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 needed for up to five monthly doses per treatment course. 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 Wellpoint at 833-731-2162.

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
Patient's Street Address, City, State, ZIP Code		County of Residence	Patient Area Code and Phone No.

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 through 36 weeks of gestational age? ◯ 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 because of 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

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

☐ Patients younger than 20 months chronological age entering their first or second RSV season can qualify for up to five monthly doses of Synagis based on 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 **between 8 - 19 months** chronological age **entering their second RSV season** can qualify for up to five monthly doses of Synagis based on the diagnosis or conditions listed to the right.

Note: Diagnosis of profoundly immunocompromised during RSV season, as described in **20-1**, is acceptable for this age group.

*Refer to Page 3 for definition

☐ **19-2:** Active diagnosis of chronic lung disease (CLD) of prematurity **and** required any of the following therapies within the six months before 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** 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.

Note: Diagnosis of profoundly immunocompromised during RSV season, as described in **20-1**, is acceptable for this age group.

☐ **12-5:** 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.

☐ **12-6 :** Diagnosis of cystic fibrosis with clinical evidence of CLD, nutritional compromise or both

ICD-10-CM code:

☐ **12-7 :** Chronic lung disease (CLD) of prematurity

ICD-10-CM code:

☐ **12-8 :** 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:

☐ **12-9 :** Patient was born before 29 weeks, 0 days (≤ 28 6/7 weeks) of gestational age.

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
Prescriber Street Address, City, State and ZIP Code	Area Code and Phone No.	Area Code and Fax No.
Physician Signature		**Date**

Fax the completed prior authorization form to 844-474-3341.

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) that requires 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 administration. Offer tobacco dependent parents tobacco dependence treatment or referral for tobacco dependence treatment. The Quitline operated in Texas, YesQuit.org, is 877-937-7848 (877-YES-QUIT).

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. 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. 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
- Red Book Online, February 21, 2024 - https://publications.aap.org/redbook/book/755/chapter/14080939/Respiratory-Syncytial-Virus?autologincheck=redirected