

About Human Respiratory Syncytial Virus (RSV) Infection Prophylaxis

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. Two products are currently available to help prevent RSV infections in young children.

Nirsevimab (BEYFORTUS) is a one-time intramuscular injection to prevent severe RSV infections in newborns and children under one year old who are born during or entering their first RSV season. Children up to 24 months old who remain at high risk of severe RSV infection through their second RSV season may also receive BEYFORTUS. BEYFORTUS is available through the Texas Vaccines for Children (TVFC) Program and is given by TVFC providers. An RSV vaccine (ABRYSVO) is also available to be administered to pregnant individuals at 32 to 36 weeks gestation for the prevention of severe RSV infections in their infants after delivery up to 6 months of age. Children who have received BEYFORTUS or who were exposed to ABRYSVO in utero should not receive additional medications for RSV prevention during the same RSV season.

Palivizumab (SYNAGIS) is a monthly intramuscular injection for infants and children up to 24 months old at the RSV season start who are at high-risk for severe RSV infections. Patients receive up to five (5) monthly doses of SYNAGIS during the RSV season. SYNAGIS is available under the pharmacy benefit and requires prior authorization. Patients who receive BEYFORTUS at any time during the RSV season should not receive SYNAGIS injections.

Initiating Prophylaxis with SYNAGIS

The provider's office sends a completed **Medicaid SYNAGIS Prior Authorization Request Form** to a preferred pharmacy listed at the top of the form. The prior authorization request should include the SYNAGIS prescription (bottom of the form), and any supporting clinical information.

The pharmacy faxes both the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits and the completed SYNAGIS form to the NAVITUS Prior Authorization Department at 1-855-668-8553.

If the request is approved, both the pharmacy and provider are notified. The dispensing pharmacy fills the prescription and ships an individual dose of SYNAGIS, in the name of the patient, directly to the provider. The pharmacy also mails an initiation packet containing information about SYNAGIS to the patient's family. Approvals are limited to one (1) monthly dose and five (5) total fills during the member's local RSV season.

The providers office administers the SYNAGIS injection. 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. Providers may request a reconsideration or appeal of the decision.

Subsequent Doses of SYNAGIS

Patients can receive one (1) dose of SYNAGIS per month, up to five (5) doses during the state-identified local RSV season. Depending on the date of the initial dose, a patient may not receive all five (5) injections before the season ends.

For subsequent doses within the local RSV season, the pharmacy does NOT need to request re-authorization. However, the pharmacy must verify the patient has NOT been hospitalized with an RSV infection and has not received BEYFORTUS (nirsevimab) during the current local RSV season. Based on the 2019 American Academy of Pediatrics guidance, prophylactic SYNAGIS injections should NOT continue if a patient is hospitalized for RSV. **The pharmacy must submit each SYNAGIS claim with a Submission Clarification Code (SCC) of 11 to show this has been verified.**

Contact

Dispensing pharmacy should fax both the Texas Standard Prior Authorization Request Form for Prescription Drug Benefits and this completed SYNAGIS prior authorization form to NAVITUS at 1-855-668-8553.

Providers with questions should call the Texas Provider Hotline at 1-877-908-6023.

Dispensing Pharmacy FAX completed form to PRIOR AUTHORIZATION for approval: 1.855.668.8553

Providers please FAX completed form to preferred pharmacy for processing:

Preferred Pharmacies:

- Lumicera - 855.847.3558
- UHS Pharmacy Southwest - 210.358.5136
- UHS Pharmacy South - 210.358.5505
- UHS Pharmacy Downtown - 210.358.9650
- AcariaHealth - 877.252.2444
- UHS Pharmacy Pavilion - 210.358.8689
- UHS Pharmacy TX Diabetes - 210.358.7470
- UHS Outpatient Pharmacy - 210.358.4747

Patient Name:		Medicaid ID:	DOB:
Patient Address:		Patient Phone:	
County of Residence/Zip:		Gestational Age:	& / 7 weeks
PREVIOUS RSV TREATMENTS PATIENT RECEIVED			
Did the patient's birthing parent receive ABRYVVO (RSV vaccine) injection between 32-36 weeks gestation of their pregnancy with the patient? <input type="checkbox"/> No <input type="checkbox"/> Yes – If Yes, Date of Injection: _____			
Has the patient received a BEYFORTUS prophylactic injection since the start of the current RSV season? <input type="checkbox"/> No <input type="checkbox"/> Yes – If Yes, Date of Injection: _____			
Has the patient received a SYNAGIS prophylactic injection since the start of the current RSV season (including during hospitalization)? <input type="checkbox"/> No <input type="checkbox"/> Yes – If Yes, number of doses received: _____ 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? <input type="checkbox"/> No <input type="checkbox"/> 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.)			
<input type="checkbox"/> 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	<input type="checkbox"/> 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: _____		
<input type="checkbox"/> 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 <i>* Please refer to page 3 for definition</i>	<input type="checkbox"/> 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: _____ <input type="checkbox"/> Chronic systemic corticosteroids <input type="checkbox"/> Greater than (>) 21% supplemental oxygen <input type="checkbox"/> Diuretics <input type="checkbox"/> Long-Term Mechanical Ventilator		
	<input type="checkbox"/> 24-3: Diagnosis of cystic fibrosis with severe lung disease* or cystic fibrosis with weight for length less than (<) the 10 th percentile: ICD-10-CM code: _____		
<input type="checkbox"/> 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.	<input type="checkbox"/> 12-1: Less than or equal to (≤) 28 6/7 weeks gestational age at birth: ICD-10-CM code: _____ <input type="checkbox"/> 12-2: Chronic lung disease (CLD) of prematurity [†] : ICD-10-CM code: _____ <input type="checkbox"/> 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: _____ <input type="checkbox"/> 12-4: Active diagnosis of hemodynamically significant congenital heart disease (CHD): ICD-10-CM code: _____ AND any of the below: <input type="checkbox"/> Moderate to severe pulmonary hypertension <input type="checkbox"/> Acyanotic heart disease, on medication to control congestive heart failure, and will require cardiac surgery <input type="checkbox"/> Cyanotic heart disease (NOTE: This excludes infants with hemodynamically insignificant heart disease - refer to page 3 for the list)		
	<input type="checkbox"/> 12-5: Diagnosis of cystic fibrosis with clinical evidence of CLD and/or nutritional compromise ICD-10-CM code: _____		
SYNAGIS Prescription (to be completed by the prescriber) – continued on next page			
Rx: SYNAGIS (palivizumab) injection 50mg and/or 100mg vials		<input type="checkbox"/> 50mg	<input type="checkbox"/> 100mg vials
Dose (mg): _____	Quantity (QS for weight based dose): _____	Refills: _____	
Sig: Inject 15mg/kg one time per month	Current Weight: _____ <input type="checkbox"/> kg or <input type="checkbox"/> lbs.	Date Weight Measured: _____	
<input type="checkbox"/> Syringes 1mL 25G 5/8"	<input type="checkbox"/> Syringes 3mL 20G 1"	<input type="checkbox"/> Epinephrine 1:1000 amp	Sig: Inject 0.01mg/kg as directed.

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Prescriber Name (PRINT):		License Number:	
PHONE:	FAX:	NPI:	
ADDRESS:	CITY:	STATE:	ZIP:
Prescriber Signature:			Date: / /

Category	Subcategories
‡Chronic Lung Disease (CLD) of Prematurity	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Congestive Heart Failure (CHF) requiring medication • Moderate to severe pulmonary hypertension • Unrepaired cyanotic congenital heart disease
*Severe lung disease	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 <u>NOT</u> 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.
- Patients who receive BEYFORTUS during the RSV season no longer need SYNAGIS prophylactic therapy.
- SYNAGIS prophylactic therapy is not needed for a newborn who was exposed in utero when their birthing parent received ABRYVVO vaccination during 32 to 36 weeks gestation of their pregnancy.

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 Customer Care at 1-877-908-6023.

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