PRIOR AUTHORIZATION CRITERIA
SYNAGIS (*palivizumab*)

Medication Class:	**MONOCLONAL ANTIBODY**	
Review Date:	11/29/2019	
Available Through:	**X Medical Benefit**	□ Pharmacy Benefit
Available Dosage Forms:	**Dosage Forms And Strengths** Single-dose liquid solution vials: 50 mg per 0.5 mL and 100 mg per 1 mL	
Usual Dose:	**General Dosing Information** **Respiratory Syncytial Virus (RSV) Prevention** 15 mg/kg body weight, administered intramuscularly prior to commencement of the RSV reason and remaining doses administered monthly throughout the RSV season	
Duration of Approval:	Up to 5 monthly doses or until end of season (ask Clinical Pharmacist for end of season date)	
Treatment Cost:	$3,400 per 100 mg dose	
Brand Name:	SYNAGIS	
Generic Name:	palivizumab	
INDICATION:	**Requires Diagnosis AND**	
RSV Prevention	**Synagis may be medically necessary for members <u><24 months of age</u> at the start of the RSV season if:** 1. At least ONE of the following criteria are met: **a.** Active diagnosis of chronic lung disease (CLD) of prematurity (defined as born ≤31 6/7 weeks gestational age who require >21% oxygen for at least 28 days after birth) **AND** required treatment with one of the following therapies within the 6 months prior to RSV season: **i.** >21% supplemental oxygen **ii.** Medical support (i.e., chronic corticosteroid therapy, diuretic therapy, bronchodilator, or long-term ventilation) **OR** b. Hemodynamically Significant Congenital Heart Disease and patient has undergone a cardiac transplantation during the RSV season **OR**	

NOTE: *Intolerance or previous trial/failure of traditional therapy must be must be supplied for review through physician chart note, or through patient's pharmacy history.*

*Medical PA requests are reviewed by FirstCare for in-office administration only. For outpatient home administration, PA requests must go through pharmacy benefit, and submitted via PBM: http://www.firstcare.com/FirstCare/media/First-Care/PDFs/RX_FirstCare_Prior-Authorization-List.pdf

	c. Cystic Fibrosis with severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length <10th percentile on pediatric growth chart **OR** d. Immunocompromised due to one of the following: i. Received or will receive a solid organ transplant, hematopoietic stem cell transplant, chemotherapy during the RSV season OR ii. Other condition that leaves infant profoundly immunocompromised (provide ICD-10) **Synagis may be medically necessary for members <u><12 months of age</u> at the start of the RSV if:** 1. At least ONE of the following criteria are met: a. Premature infants (without other indications) defined as: born prematurely at or before ≤28 6/7 weeks gestation **OR** b. Active diagnosis of chronic lung disease (CLD) of Prematurity defined as born before ≤31 6/7 weeks gestation who require >21% oxygen for at least the first 28 days after birth **OR** c. Severe Congenital Pulmonary Abnormality or Neuromuscular Disorder that impairs ability to clear secretions from the upper airway due to an ineffective cough **OR** d. Cystic Fibrosis and clinical evidence of CLD and/or nutritional compromise (i.e. failure to thrive) **OR** e. Hemodynamically significant congenital heart disease, defined as: i. Acyanotic heart disease, requiring medication to control congestive heart failure, and will require a cardiac surgical procedure OR ii. Moderate to severe pulmonary hypertension iii. Cyanotic congenital heart disease (with consultation from a pediatric cardiologist) **OR** f. Meets any of the criteria for members <u><24 months of age</u> at the start of RSV season

NOTE: *Intolerance or previous trial/failure of traditional therapy must be must be supplied for review through physician chart note, or through patient's pharmacy history.*

*Medical PA requests are reviewed by FirstCare for in-office administration only. For outpatient home administration, PA requests must go through pharmacy benefit, and submitted via PBM: http://www.firstcare.com/FirstCare/media/First-Care/PDFs/RX_FirstCare_Prior-Authorization-List.pdf

	Coverage is NOT medically necessary for any member, regardless of age, who has already experienced a breakthrough RSV hospitalization during the CURRENT season. As of August 15, 2019, there has been no change in AAP guidelines for the 2019-2020 season.

NOT COVERED

FirstCare considers SYNAGIS experimental and investigational for all other indications because its effectiveness for these indications has not been established.

CPT-Codes/HCPCS Codes/ICD-10 Codes

90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each
S9562	Home injectable therapy, palivizumab, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

REFERENCES:

1. "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.
2. Synagis® (palivizumab) [prescribing information]. Gaithersburg, MD: Medimmune, LLC. 2014.
3. American Academy of Pediatrics Red Book 2015: 667-676.
4. FDA label for Synagis® : https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/palimed102302LB.pdf. Accessed 03/19/2018

WEBSITES FOR ADDITIONAL INFORMATION

DOCUMENT HISTORY

New	*11/29/19*	Initial document development

NOTE: *Intolerance or previous trial/failure of traditional therapy must be must be supplied for review through physician chart note, or through patient's pharmacy history.*

*Medical PA requests are reviewed by FirstCare for in-office administration only. For outpatient home administration, PA requests must go through pharmacy benefit, and submitted via PBM: http://www.firstcare.com/FirstCare/media/First-Care/PDFs/RX_FirstCare_Prior-Authorization-List.pdf