

PROTOCOLS
MedStar Family Choice

Subject: Synagis (palivizumab)

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Purpose: To define the process for the Prior Authorization of Synagis (palivizumab) for members of MedStar Family Choice

Scope: All members of MedStar Family Choice.

Policy: It is the policy of MedStar Family Choice to provide Synagis (palivizumab) therapy to appropriate members as a pharmacy benefit.

Background: In most years, RSV season in Maryland begins in November and continues until March. Synagis prophylaxis administration should begin on or around November 1 and end on or before March 31 in most years. A maximum of 5 doses will be authorized as recent data has shown that 5 doses will afford 20 weeks of protection and the average RSV season in the continental USA is 17 weeks long.

MedStar Family Choice will require prior authorization for Synagis (palivizumab). Authorization will be given in accordance with the most recent edition of the American Academy of Pediatrics Red Book Guideline in 2009. Much of this Protocol is excerpted word-for-word from the Red Book.

Reference: <http://aapredbook.aappublications.org/cgi/content/full/2009/1/3.110>

Synagis (palivizumab) will be approved when the following criteria are met:

Premies:

- Infants < 28 (28 weeks, 6 days) weeks Gestational Age and < 12 months of age

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(Maximum of 5 doses. Treatment continues through to the end of RSV season, i.e., past 12 mo of age)

- Infants ≥ 29 (29 weeks, 0 days) and < 32 weeks Gestational Age (31 weeks, 6 days or less) and < 6 mo of age at the start of RSV season (November)
(Maximum of 5 doses. Treatment continues through to the end of RSV season, i.e., past 6 mo of age)
- Infants ≥ 32 (32 weeks, 0 days) and < 35 (34 weeks, 6 days) and younger than 3 months of age (90 days) at the start of RSV season or who are born during RSV season (Nov thru Mar) **AND** have at least one of the two following risk factors:
 - 1) infant attends child care, defined as a home or facility where care is provided for any number of infants or young toddlers in the child care facility; **or**
 - 2) infant has a sibling younger than 5 years of age.

Infants in this gestational age category should receive prophylaxis only until they reach 3 months of age and should receive a maximum of 3 monthly doses; many will receive only 1 or 2 doses until they reach 3 months of age. Once an infant has passed 3 months of age (90 days of age), the risk of hospitalization attributable to RSV lower respiratory tract disease is reduced. Administration of palivizumab is not recommended after 3 months of age.

- Infants ≥ 35 weeks Gestational Age are not candidates for prophylaxis unless they have other conditions as outlined below.

Co-Morbid Conditions:

Congenital abnormalities of the airway or neuromuscular disease: Immunoprophylaxis may be considered for infants born before 35 weeks of gestation who have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions. Infants and young children in this category should receive a maximum of 5 doses of palivizumab during the first year of life.

Congenital heart disease: Children who are 24 months of age or younger with hemodynamically significant cyanotic or acyanotic congenital heart disease may benefit from palivizumab prophylaxis. Children younger than 24 months of age with congenital heart disease who are most likely to benefit from immunoprophylaxis include:

Infants who are receiving medication to control congestive heart failure
Infants with moderate to severe pulmonary hypertension
Infants with cyanotic heart disease

The following groups of infants are **not** at increased risk of RSV and generally should **not** receive immunoprophylaxis:

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- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition

Dates for initiation and termination of prophylaxis should be based on the same considerations as for high-risk infants with CLD.

Chronic Lung Disease: Palivizumab prophylaxis may be considered for infants and children younger than 24 months of age who receive medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the RSV season. Maximum of 5 doses a season and this group may benefit from prophylaxis during the second year of life.

Immunocompromised children: Palivizumab prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised patients cannot be made, infants and young children with severe immunodeficiencies (eg, severe combined immunodeficiency or advanced acquired immunodeficiency syndrome) may benefit from prophylaxis.

Patients with cystic fibrosis: Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. Whether RSV infection exacerbates the chronic lung disease of cystic fibrosis is not known. In addition, insufficient data exist to determine the effectiveness of palivizumab use in this patient population. Therefore, a recommendation for routine prophylaxis in patients with cystic fibrosis cannot be made.

RSV Infection: If an infant or child who is receiving palivizumab immunoprophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should continue until a maximum of 3 doses have been administered to infants in the 32 to less than 35 weeks' gestation group (defined as 32 weeks, 0 days through 34 weeks, 6 days) or until a maximum of 5 doses for infants with congenital heart disease, CLD, or preterm birth before 32 weeks' gestation. This recommendation is based on the observation that high-risk infants may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than one RSV strain often co-circulates in a community.

In some cases, MSFC may request clinical records, laboratory results or other information as part of the prior authorization process.

Procedure: Requests for Synagis (palivizumab) therapy should be forwarded along with the supporting clinical information to QRM in accordance with the MedStar Family Choice, Pharmacy and Therapeutics Prior Authorization Policy.

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Requests for off-label uses of Synagis (palivizumab) may be submitted to the Medical Director of MedStar Family Choice for individual consideration.

Procedure: Requests for off-label Synagis (palivizumab) therapy should be forwarded along with the supporting clinical information to QRM in accordance with the MedStar Family Choice, Pharmacy and Therapeutics Prior Authorization Policy.

Requests for off-label uses should include the patient's clinical information and any supporting information from the medical literature including studies, abstracts, etc., relevant to the request.

APPROVED DOSES

	5 dose regimen	5 dose regimen	3 dose regimen	5 dose regimen
Month of Birth	≤ 28 week, 6 days GA and < 12 mo of age at start of season	29 weeks, 0 days through 31 weeks, 6 days GA and < 6 mo of age at start of season	32 weeks, 0 days through 34 weeks, 6 days GA with one or more risk factor(s)	< 24 mo of age with CLD, CHD, airway, neuromuscular
January	(May be 2 nd season for some if still < 12 mo old)		(Should receive 1 dose every 30 days until 90 days old)	
February				
March				
April	5	0 (> 6 mo old)	0 (> 90 days old)	
May	5	5	0	
June	5	5	0	
July	5	5	0	
August	5	5	1	
September	5	5	2	
October	5	5	3	
November	5	5	3	5
December	4	4	3	4
January	3	3	3	3
February	2	2	2	2
March	1	1	1	1
April	0	0	0	0