Policy Statement—Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections

TARGET POPULATION	Decidable (Y or N)
Eligibility	
Inclusion Criterion	
· Pediatric patients who are at increased risk of severe disease	
Exclusion Criterion	

RECOMMENDATIONS

Recommendation

* Criteria 1. Infants with CLD (Page 4, Column 1, Paragraph 3)

Conditional: 1.1 Infants with CLD

IF	**Decidable**	**Vocab**
Chronological Age **Value:** < 24 months		
CLD **Value:** TRUE		
Receives medical therapy **Value:** TRUE		
Onset of RSV **Value:** If Southeast Florida - July 1 If Location = North-central orsouthwest Florida - 9/15Else 11/1		

THEN	**Executable**	**Vocab**
should receive a maximum of 5 doses.		

Evidence Quality: Quality of Evidence = IThe efficacy of palivizumab has been evaluated in 2 multicenter, placebo controlled, randomized clinical trials, both of which used a primary endpoint of reduction in hospitalization attributable to RSV infection. The RSV-IMpact trial evaluated children 24 months of age or younger with CLD who required continuing medical therapy (supplemental oxygen, bronchodilator, or diureticorcorticosteroidtherapywithin the previous 6 months)

and children born at 35 weeks' gestation or less who were 6 months of age or younger at the start of the RSV season.4 Prophy4 laxis resulted in a 55% overall decrease in the rate of RSV-related hospitalization (10.6% and 4.8% in recipients of placebo versus palivizumab, respectively [P .001]).

Strength of Recommendation: Strength of Recommendation = A

Reason: The primary benefit of immuno prophylaxis is a decrease in the rate of RSV associated hospitalization.

Logic: If (Chronological Age < 24 months) AND (CLD = TRUE AND Receives medical therapy =TRUE) AND (Onset of RSV <= 6 months) Then May benefit from prophylaxisReceive a maximum of 5 doses

Conditional: 1.2 Severe CLD

IF	**Decidable**	**Vocab**
Conditional 1.1		
Value: TRUE		
Received Synagis Prior Year		
Value: TRUE		
Severe CLD		
THEN	**Executable**	**Vocab**
may benefit from prophylaxis during a second RSV season.		
Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists (AI).		

Evidence Quality: Quality of Evidence = III(Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.)"Data are limited regarding the effectiveness of palivizumab during the second year of life."

Strength of Recommendation: Strength = C

Reason: The primary benefit of immuno prophylaxis is a decrease in the rate of RSV associated hospitalization. Patients with the most severe CLD who continue to require medical therapy may benefit from prophylaxis during a second RSV season.

Logic: If Conditional 1.1 = TRUE AND Received Synagis Prior Year = TRUE AND

Severe CLD Then May benefit from prophylaxis during a second RSV season. Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists (AI).

Recommendation

* Criteria 2. Infants Gestational Age < 32 weeks (Page 4, Column 2, Paragraph 2)

Conditional: 2.1 Infants born at 28 weeks' gestation or earlier may benefit from prophylaxis during the RSV season whenever that occurs during the first 12 months of life.

IF	**Decidable**	**Vocab**
Gestational Age		
Value: <= 28 Weeks		
Chronological Age		
Value: < 12 Months		
Onset of RSV		
Value: TRUE		

THEN	**Executable**	**Vocab**
May benefit from prophylaxis		
Receive maximum of 5 doses		
Receive all 5 doses		

Evidence Quality:

Strength of Recommendation:

Reason:

Logic: If (Gestational Age <= 28 Weeks) AND (Chronological Age < 1 year) AND (Onset of RSV) Then May benefit from prophylaxis Receive maximum of 5 doses Receive all 5 doses

Conditional: 2.2 Infants born at 29 to 32 weeks' gestation (31 weeks 6 days) may benefit most from prophylaxis up to 6 months of age.

IF

Decidable	Vocab

Gestational Age

Value: >= 29 weeks AND <= 32 weeks

Chronologial Age

Value: <= 6 months

Onset of RSV

Value: If Location = Southeast FloridaThen July 1ElseIf Location = North-central orsouthwest FloridaThen September 15ElseThen November 1

CLD

THEN

Executable	Vocab

May benefit from prophylaxis

Receive maximum of 5 doses

Receive all 5 doses

Evidence Quality:

Strength of Recommendation:

Reason:

Logic: If (Gestational Age >= 29 weeks AND Gestational Age <= 31 weeks 6 days) AND (Chronologial Age < 6 months) AND (Onset of RSV =TRUE) Then May benefit from prophylaxis Receive maximum of 5 doses Receive all 5 doses

Recommendation

* Criteria 3. Infants Gestational Age > 32 & < 35 weeks (Page 4, Column 2, Paragraph 3)

Conditional: 3.1 Prophylaxis may be considered for infants from 32 through less than 35 weeks' gestation (defined as 32 weeks 0 days through 34 weeks 6 days) who are born less than 3 months before the onset or during the RSV season and for whom at least 1 of the 2 risk factors is present.

IF

Decidable	Vocab

Gestational Age

Value: >= 32 weeks and <= 35 weeks

Chronological Age

Value: < 90 days

Attends Childcare

Value: TRUE

Other children < 5 years in household.

Value: TRUE

Onset of RSV Season

Value: If Location = Southeast FloridaThen July 1ElseIf Location = North-central orsouthwest FloridaThen September 15ElseThen November 1

THEN	**Executable**	**Vocab**
Prophylaxis may be considered		
Receive prophylaxis only until they reach 3 months of age		
Receive a maximum of 3 monthly doses;		

Evidence Quality:

Strength of Recommendation:

Reason: Epidemiologic data suggest thatRSV infection is more likely to oc-cur and more likely to lead to hos-pitalization for infants in thisgestational-age group when atleast 1 of the following 2 risk fac-tors is present:

Logic: If (Gestational Age >= 32 weeks AND Gestational Age <= 35 weeks) AND (Chronological Age <= 90 Days) AND (Onset of RSV Season) AND (Attends Childcare =TRUE OR Other children < 5 years in household =TRUE) Then Prophylaxis may be considered Receive prophylaxis only until they reach 3 months of age Receive a maximum of 3 monthly doses

Recommendation

* Criteria 4. Infants with congenital abnormalities of the airway or neuromuscular disease.

Conditional: 4.1 Immunoprophylaxis may be considered for infants who have either significant congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory tract secretions.

IF	**Decidable**	**Vocab**
Chronological Age		

Value: < 1 Year

Congenital abnormalities of the airway

Value: TRUE

Neuromuscular condition

THEN

Immunoprophylaxis may be considered

Receive a maximum of 5 doses of palivizumab during the first year of life

Executable	Vocab

Evidence Quality:

Strength of Recommendation:

Reason:

Logic: If Chronological Age < 1 Year AND (Congenital abnormalities of the airway = TRUE) OR Neuromuscular condition =TRUE) Then Immunoprophylaxis may be considered Receive a maximum of 5 doses during the first year of life

Recommendation

* Criteria 5. Infants and children with CHD:

Conditional: 5.1 Infants and children with CHD: Children who are 24 months of age or younger with hemodynamically significant cyanotic or acyanotic CHD may benefit from palivizumab prophylaxis.5

IF

Decidable	Vocab

Chronological Age

Value: <= 24 Months

CHD

Value: TRUE

CHD Medication

Value: TRUE

Pulmonary hypertension

Value: TRUE

Cyanotic heart disease

Value: TRUE

THEN

Executable	Vocab

may benefit from palivizumab prophylaxis

Evidence Quality:

Strength of Recommendation:

Reason:

Logic: If (Chronological Age <= 24 months) AND (CHD = TRUE) AND (CHD Medication =TRUE OR Pulmonary hypertension =TRUE OR Cyanotic heart disease =TRUE) Then may benefit from palivizumab prophylaxis

Conditional: 5.2 After surgical procedures that use cardiopulmonary bypass

IF	**Decidable**	**Vocab**
Conditional 5.1		
Value: TRUE		
Surgical procedure that use cardiopulmonary bypass		
Value: TRUE		
THEN	**Executable**	**Vocab**
a postoperative dose of palivizumab (15 mg/kg) should be administered as soon as the patient is medically stable (AI).		

Evidence Quality:

Strength of Recommendation:

Reason: a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that use cardiopulmonary bypass

Logic: If Conditional 5.1 =TRUE AND Surgical procedure that use cardiopulmonary bypass Then A postoperative dose of palivizumab (15 mg/kg) should be administered as soon as the patient is medically stable (AI).

Conditional: 5.3 Infants with CHD not at increased risk

IF	**Decidable**	**Vocab**
with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonicstenosis,uncomplicatedaortic stenosis, mild coarctation of the aorta,andpatentductusarteriosus);		
with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure;		

with mild cardiomyopathy who are not receiving medical therapy for the condition.

THEN

are not at increased risk of RSV and generally should not receive immunoprophylaxis

Executable	**Vocab**

Evidence Quality:

Strength of Recommendation:

Reason:

Logic: If with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonicstenosis,uncomplicatedaortic stenosis, mild coarctation of the aorta,andpatentductusarteriosus); OR with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure OR with mild cardiomyopathy who are not receiving medical therapy for the condition. Then are not at increased risk of RSV and generally should not receive immunoprophylaxis

Recommendation

* Criteria 6. Immunocompromised children

Conditional: 6.1 Immunocompromised

IF

Severe immunodeficiency

Value: TRUE

Decidable	**Vocab**

THEN

May benefit from prophylaxis

Executable	**Vocab**

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

Strength of Recommendation:

Reason:

Logic: If Severe immunodeficiency Then May benefit from prophylaxis

Recommendation

* Criteria 7. Patients with cystic fibrosis

Imperative: 7.1 A recommendation for routine prophylaxis in patients with cystic fibrosis cannot be made

IF

Inclusion Criterion:

· Pediatric patients who are at increased risk of severe disease

Exclusion Criterion:

THEN

Executable	Vocab

Evidence Quality: insufficient data exist to determine the effectiveness of palivizumab use in this patient population.31. Giusti R. North American Synagis Prophylaxis survey. Pediatr Pulmonol. 2009;44(1): 96–98

Strength of Recommendation:

Reason:

Logic:

Cost:

Recommendation

* Criteria 8. Special situations

Conditional: 8.1) Breakthrough RSV infection

IF

Decidable	Vocab
Qualifes for prophylaxis	
is receiving palivizumab immuno prophylaxis	
Breakthrough RSV infection	

THEN

Executable	Vocab
Continue until a maximum number of doses have been administered	

	3 doses have been administered to infants in the 32 weeks' 0 days' through 34 weeks' 6 days' gestational-age group o Maximum of 5 doses have been administered to infants with CHD, CLD, or preterm birth before 32 weeks' gestation.		

Evidence Quality:

Strength of Recommendation:

Reason: This recommendation is based on the observation that infants at high risk may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than 1 RSV strain often cocirculates in a community (CIII).

Logic: If Is receiving palivizumab immuno prophylaxis =TRUE AND Breakthrough RSV infection = TRUE Then Continue until a maximum number of doses have been administered 3 doses have been administered to infants in the 32 weeks' 0 days' through 34 weeks' 6 days' gestational-age group Maximum of 5 doses have been administered to infants with CHD, CLD, or preterm birth before 32 weeks' gestation.

Conditional: 8.2) Hospitalized infants who qualify for prophylaxis during the RSV season s

IF

Decidable	Vocab
Hospitalized	
Onset of RSV	

Value: If Location = Southeast FloridaThen July 1ElseIf Location = North-central orsouthwest FloridaThen September 15ElseThen November 1

THEN

Executable	Vocab
receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge(CIII).	

Evidence Quality:

Strength of Recommendation:

Reason:

Logic: If Conditional 1.1 - 5.3 = TRUE AND Hospitalized = TRUE AND Onset of RSV = TRUE Then receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge(CIII).

Conditional: 8.3) Hospitalized during course

IF

Decidable	Vocab
is receiving palivizumab immuno prophylaxis	
hospitalized	
date when the next monthly dose is due should receive that dose as scheduled w	

THEN

Executable	Vocab
eceive that dose as scheduled while they remain in the hospital (AI).	

Evidence Quality:

Strength of Recommendation:

Reason:

Logic:

Imperative: 8.4) Infection control

IF

Inclusion Criterion:

· Pediatric patients who are at increased risk of severe disease

Exclusion Criterion:

THEN

Executable	Vocab
RSVisknowntobetransmittedin the hospital setting and to cause serious disease in infants at high risk. Among hospitalized infants, the major means of reducing RSV transmissionisstrictobservance of infection-control practices, including prompt initiation of precautions for RSV-infected infants.32 If an RSV outbreak occurs .32 If in a high-risk unit (eg, PICU or NICU or stem cell transplantation unit), primary emphasis should be placed on proper infectioncontrolpractices,especiallyhand hygiene. No data exist to support palivizumab use in controlling outbreaks of health care–associateddisease,andpalivizumabuse is not recommended	

for this purpose (CIII).

Evidence Quality:

Strength of Recommendation:

Reason:

Logic:

Cost:

Imperative: 8.5 Palivizumab does not interfere with response to vaccines.

IF

Inclusion Criterion:

· Pediatric patients who are at increased risk of severe disease

Exclusion Criterion:

THEN

Executable	Vocab

Evidence Quality:

Strength of Recommendation:

Reason:

Logic:

Cost: