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Oregon Health Authority

Policy Update: RSV Antivirals - Palivizumab

Month/Year of Review: September 2014 **Date of Last Review:** September 2013

Current PA: Prior authorization (PA) criteria are currently in place for palivizumab to align prescribing with American Academy of Pediatric (AAP) Guidelines and to allow for geographic variations of respiratory syncytial virus (RSV) activity.

Research Questions:

- Is there any new evidence on the effectiveness of palivizumab on important outcomes such as mortality and hospitalizations due to RSV?
- Is there any new evidence about harms associated with palivizumab treatment?
- Are there subpopulations of patients who benefit more from palivizumab prophylaxis?

Conclusions:

- There is insufficient evidence that palivizumab lowers mortality rates or subsequent wheezing after an infection in infants and children receiving palivizumab prophylaxis.[1,2]
- New AAP guidelines recommend lowering the gestational age of preterm infants who should be candidates for palivizumab prophylaxis. The determination of which infants and children are considered high risk, in addition to prematurity, and who should receive palivizumab are the following: premature infants with chronic lung disease (CLD), infants with congenital heart disease (CHD), patients with cyanotic heart defects, those undergoing cardiac transplant, neuromuscular disease or congenital anomaly and those who are immunocompromised. [1,2]

Recommendations:

- Amend the current PA criteria to align recommendations with those of the AAP guideline (Appendix 1).
- Continue to allow for geographic variations in RSV activity.

Reason for review:

The AAP released a revised guidance in July of 2014 for palivizumab prophylaxis among infants and young children. Review of the guidelines and analysis of data published since the last update will be included.

Previous Conclusions and Recommendation:

- A policy evaluation of the palivizumab prior authorization (PA) criteria in Oregon Fee-for-Service patients was done in September of 2013 to assess palivizumab use outside of the recommended PA criteria and to determine if there was any unintended harm as a result of the policy. Results of the evaluation showed that

palivizumab was used within the established parameters of the PA criteria. This resulted in decreased palivizumab utilization and costs. No hospitalizations or emergency room visits were associated with palivizumab claims.[3]

- The decision was made to continue the palivizumab PA criteria for the 2013-2014 RSV season (Appendix 2).

Background:

Palivizumab is a humanized mouse immunoglobulin (IgG1) monoclonal antibody which is indicated for prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.[1,2,4] Data demonstrating reduced RSV hospitalizations with palivizumab immunoprophylaxis, comes from two randomized controlled trials.[5,6] The Impact-RSV trial included children born prematurely(≤35 weeks) or with bronchopulmonary dysplasia (BPD).[5] Palivizumab prophylaxis demonstrated a significant reduction in risk of RSV hospitalizations compared to placebo, 4.8% vs. 10.6%, respectively.[5] The Cardiac Synagis Study Group found that in children with hemodynamically significant CHD palivizumab prophylaxis also showed significant reductions in RSV hospitalization rates compared to placebo, 5.3% vs. 9.7%, respectively. [6] Conclusive data regarding reductions in mortality and subsequent wheezing following an infection due to palivizumab prophylaxis is lacking. [1,2,7,8]

Methods:

A Medline literature search beginning July 2013 and ending July 2014 for new systematic reviews and randomized controlled trials (RCTs) that evaluated palivizumab effectiveness and/or harms was performed. The Agency for Healthcare Research and Quality (AHRQ), Cochrane Collection, National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, Clinical Evidence, Up To Date, Dynamed, and the Canadian Agency for Drugs and Technologies in Health (CADTH) resources were manually searched for high quality and relevant systematic reviews. The FDA website was searched for safety alerts, and the AHRQ National Guideline Clearinghouse (NGC) was searched for updated and recent evidence-based guidelines. The primary focus of the evidence is on high quality systematic reviews and evidence based guidelines for this class update. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources. Data that is observational and/or at a high risk of bias due to study design does not meet the inclusion criteria for our analysis as outlined in the policy and procedures (i.e. Ambrose 2014, Hall 2013, Hasegawa 2013 and Winterstein 2013).[9-12]

New Guidelines:

AAP Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

In July 2014 the AAP updated treatment guidelines for use of palivizumab in those individuals at increased risk of RSV infection.[1,2] The goal of the updated guidelines is to streamline evidence so that those at highest risk receive prophylaxis. Recommendations are based on an analysis of the data by the Committee on Infectious Diseases (COID). Updates to the data are in the following area:

- Palivizumab pharmacokinetics
- Seasonality of RSV circulation
- Overall declining incidence of hospitalizations for bronchiolitis in the United States
- Statistically significant but clinically minimal reduction in wheezing episodes among recipients of palivizumab prophylaxis
- Reports of little benefit of palivizumab prophylaxis among patients with cystic fibrosis or Down syndrome
- Reports describing palivizumab resistant isolates from hospitalized patients who received prophylaxis
- Independently conducted cost analyses demonstrating high cost versus limited benefit from palivizumab prophylaxis

Recommendations for the consideration of palivizumab prophylaxis are for the following groups:

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- Infants born before 29 weeks, 0 days' gestations that are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed
- Premature infants within the first 12 months of life who develop CLD of prematurity, defined by a gestational age of <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth. These same infants may be candidates for prophylaxis in the second year of life if they continue to require medical support (chronic corticosteroid therapy, diuretic therapy or supplemental oxygen) during the 6-month period before the start of the RSV season
- Children 12 months or younger with hemodynamically significant CHD, specifically those with acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension
- Infants with cyanotic heart defects, 12 months or younger, if recommended by a pediatric cardiologist
- Infants with CHD with lesions corrected by surgery and still requiring medication for CHF born within 12 months of onset of the RSV season
- Children under the age of 2 years undergoing cardiac transplantation during the RSV season
- Infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway during the first year of life
- Children under the age of 24 months who are profoundly immunocompromised during the RSV season
- Infants with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life and in those of their second year of life if manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable) or weight or length less than the 10^{th} percentile

In general palivizumab prophylaxis is not recommended in the second year of life based on the prematurity alone. Clinicians in Alaska may utilize RSV season surveillance data to determine needs of infant prophylaxis. Those patients receiving prophylaxis and who experience a RSV hospitalization should no longer continue to receive palivizumab. Even in areas of unpredictable onset and offset of RSV season, like Florida, only 5 doses of palivizumab are recommended. Palivizumab has not been shown to impact primary asthma prevention or reduction in subsequent episodes of wheezing.

Limitations to the guidelines include recommendations that were made on data that is subject to a high chance of bias due to study design and lack of grading of the evidence that was used within the guideline.

New FDA Safety Alerts:

In March of 2014 the Food and Drug Administration approved labeling changes to the Synagis ® package insert that recommends that children undergoing cardio-pulmonary bypass should receive an additional dose of palivizumab as soon as possible, post-procedure. This recommendation is based on evidence that palivizumab serum levels are decreased after cardio-pulmonary bypass.[4] Additionally, language stating palivizumab provides passive immunity was also added.[4]

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References:

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2. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014; 134(2):e620-e638. doi: 10.1542/peds.2014-1666.
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5. Impact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. Pediatrics. 1998;102:531-537.
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11. Hall C, Weinberg G, Blumkin A, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. Pediatrics. 2013:132(2):e341-8. doi:10.1542/peds.2013-0303.
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APPENDIX 1:
Recommended PA Criteria

Synagis (palivizumab)

Goal(s):

- Promote safe and effective use of Synagis.

Length of Authorization: Based on individual factors; may extend up to 5 months (5 doses).

Approval Criteria		
1. What is the diagnosis being treated?	Record ICD9 code and reject/internal error code	
2. Has the patient been receiving monthly palivizumab prophylaxis and been hospitalized for a breakthrough RSV infection?	**Yes:** Pass to RPH: DENY (Medical Appropriateness).	**No:** Go to #3
3. Is the request for immunoprophylaxis between the months of November and March?	**Yes:** Go to #5	**No:** Go to #4
4. Is the request for immunoprophylaxis starting in October due to an early onset* of the RSV season in the region from which the patient resides (see below)? * Onset is defined as 2 consecutive weeks where % positive is ≥10% (data is provided by the Oregon's Weekly Respiratory Syncytial Virus Surveillance Report from the Oregon Public Health Division based on regions. Weekly updates are found at: https://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/Pages/disease.aspx?did=40)	**Yes:** Go to #5	**No:** Pass to RPH: DENY (Medical Appropriateness). Prophylaxis is indicated only during high viral activity.
5. Is the current age of the patient < 24 months at start of RSV season?	**Yes:** Go to #6	**No:** Pass to RPH: DENY (Medical Appropriateness). Synagis not recommended for patients ≥24 months old.

Region	Counties
NW Oregon- SW Washington	Benton, Clackamas, Clatsop, Columbia, Lane, Lincoln, Linn, Marion, Multnomah, Polk, Tillamook, Washington, Yamhill
Central Oregon	Crook, Deschutes, Grant, Harney, Jefferson, Wheeler
Columbia Gorge – NE Oregon	Baker,, Gilliam, Hood River, Morrow, Sherman, Umatilla, Union, Wasco, Wallowa
Southern Oregon	Coos, Curry, Douglas, Jackson, Josephine, Klamath, Lake, Malheur

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6. **GROUP A** Does the patient have CLD (chronic lung disease) of prematurity ICD9 7485x or 7486x **and** in the past 6 months has required medical treatment with at least one of the following: a. diuretics b. chronic corticosteroid therapy c. supplemental oxygen therapy	**Yes:** Go to #18	**No:** Go to #7
7. GROUP B Has the patient received a cardiac transplant during the RSV season?	**Yes:** Go to #18	**No:** Go to #8
8. GROUP C Is the child profoundly immunocompromised during the RSV season (i.e. solid organ transplant or hematopoietic stem cell transplantation)?	**Yes:** Go to #18	**No:** Go to #9
9. GROUP D Does the infant have cystic fibrosis and manifestations of severe lung disease or weight or length less than the 10th percentile?	**Yes:** Go to #18	**No:** Go to #10
10. **GROUP** E Is the request for a second season of palivizumab prophylaxis for a child born <32 weeks, 0 days gestation who required at least 28 days of oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of start of second RSV season?	**Yes:** Go to #18	**No:** Got to #11
11. Will the patient be < 12 months at start of RSV season?	**Yes:** Go to #12	**No:** Pass to RPH: DENY (Medical Appropriateness).
12. GROUP F Was the infant born before 29 weeks, 0 days gestation?	**Yes:** Go to #18	**No:** Go to #13
13. GROUP G Does the infant have pulmonary abnormalities of the airway or neuromuscular disease compromising handling of secretions?	**Yes:** Go to #18	**No:** Go to #14
14. GROUP H Does the patient have hemodynamically significant congenital heart disease (CHD) ICD9 746xx or 747xx **and** at least one of the following: a. Acyanotic heart disease who are receiving treatment to control congestive heart failure and will require cardiac surgical procedures **or** b. Have moderate to severe pulmonary hypertension **or** c. History of lesions adequately corrected by surgery AND still requiring medication for congestive heart failure	**Yes:** Go to #18	**No**: Go to #15

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15. <u>GROUP I</u> Does the patient have chronic lung disease (CLD) of prematurity defined as gestational age <32 weeks, 0 days and requirement for >21% oxygen for at least the first 28 days after birth?	**Yes:** Go to #18	**No:** Go to #16
16. <u>GROUP J</u> Does the patient have cyanotic heart defects and immunoprophylaxis is recommended?	**Yes:** Go to #18	**No:** Go to #17
17. GROUP K Does the patient have cystic fibrosis with clinical evidence of CLD and/or nutritional compromise?	**Yes:** Go to #18	**No:** Pass to RPH: DENY (Medical Appropriateness).
18. Is the request for more than 5 doses within the same RSV season or for dosing <28 days apart?	**Yes:** Pass to RPH: DENY (Medical Appropriateness). Prophylaxis is indicated for 5 months maximum and doses should be administered ≥28 days apart. **May approve for the following on a case by case basis:** **a. > 5 doses.** **b. Prophylaxis for a second/subsequent RSV season.**	**No:** Go to #19
19. Has the patient had a weight taken within the last 30 days?	**Yes:** Document weight and date and go to #20 Weight:_____ Date: _____	**No:** Pass to RPH: obtain recent weight so accurate dose can be calculated.
20. Approve palivizumab for a dose of 15mg/kg. Document number of doses received in hospital and total number approved according to **BIRTH DATE** and **GROUP** based on start of RSV season: - Immunoprophylaxis between <u>November - March</u> refer to **Table 1** - Immunoprophylaxis starting in <u>October</u> based on above (#4) refer to **Table 2** Total number of doses approved for RSV season:_____ Number of doses received in the hospital:_____		

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Table 1. Maximum number of doses to approve for RSV prophylaxis for ALL groups – Beginning **NOVEMBER 1st**

MONTH OF BIRTH	ALL GROUPS
November 1 – March 31	5
April	5
May	5
June	5
July	5
August	5
September	5
October	5
November	5
December	4
January	3
February	2
March	1

* Infant may require less doses than listed based on age at the time of discharge from the hospital. Subtract number of doses given in hospital from total number of approved doses.

Table 2. Maximum number of doses to approve for RSV prophylaxis for ALL groups – Beginning **OCTOBER 1-31**

MONTH OF BIRTH	ALL GROUPS
November 1 – March 31	5
April	5
May	5
June	5
July	5
August	5
September	5
October	5
November	5
December	4
January	3
February	2
March	1

* Infant may require less doses than listed based on age at the time of discharge from the hospital. Subtract number of doses given in hospital from total number of approved doses.

Notes:

- Dose: 15 mg/kg via intramuscular injection once monthly throughout RSV season.
- The start date for Synagis is November 1 each year (or sooner when the Oregon Public Health Division has determined that RSV season onset has occurred) for a total of up to five doses.

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- Approval for more than five doses or additional doses after March 31 is considered on a case-by-case basis. Results from clinical trials indicate that Synagis trough concentrations greater than 30 days after the 5th dose will be well above the protective concentration therefore five doses will provide more than 20 weeks of protection.

DUR Board Action: 05/17/11 (DO/KK), 5/26/12 (KS), 9/23/14 (KS)
Revision(s): 3/30/12 (KS)
Initiated:

APPENDIX 2:
Previous PA Criteria (2013-2014 RSV season)

Synagis (palivizumab)

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Goal(s):

- Promote safe and effective use of Synagis.

Length of Authorization: Based on individual factors; may extend up to 5 months (5 doses).

<table>
<tr><th colspan="3">Approval Criteria</th></tr>
<tr><td>1. What is the diagnosis being treated?</td><td colspan="2">Record ICD9 code and reject/internal error code</td></tr>
<tr><td>2. Is the request for immunoprophylaxis between the months of November and March?</td><td>Yes: Go to #4</td><td>No: Go to #3</td></tr>
<tr><td>3. Is the request for immunoprophylaxis starting in October due to an early onset* of the RSV season in the region from which the patient resides (see below)?

* Onset is defined as 2 consecutive weeks where % positive is ≥10% (data is provided by the Oregon's Weekly Respiratory Syncytial Virus Surveillance Report from the Oregon Public Health Division based on regions. Weekly updates are found at: https://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/Pages/disease.aspx?did=40)

<table>
<tr><th>Region</th><th>Counties</th></tr>
<tr><td>NW Oregon- SW Washington</td><td>Benton, Clackamas, Clatsop, Columbia, Lane, Lincoln, Linn, Marion, Multnomah, Polk, Tillamook, Washington, Yamhill</td></tr>
<tr><td>Central Oregon</td><td>Crook, Deschutes, Grant, Harney, Jefferson, Wheeler</td></tr>
<tr><td>Columbia Gorge – NE Oregon</td><td>Baker,, Gilliam, Hood River, Morrow, Sherman, Umatilla, Union, Wasco, Wallowa</td></tr>
<tr><td>Southern Oregon</td><td>Coos, Curry, Douglas, Jackson, Josephine, Klamath, Lake, Malheur</td></tr>
</table>
</td><td>Yes: Go to #4</td><td>No: Pass to RPH: DENY (Medical Appropriateness). Prophylaxis is indicated only during high viral activity.</td></tr>
<tr><td>4. Is the current age of the patient < 24 months at start of RSV season?</td><td>Yes: Go to #5</td><td>No: Pass to RPH: DENY (Medical Appropriateness). Synagis not recommended for patients ≥24 months old.</td></tr>
<tr><td>5. <u>GROUP A</u>
Does the patient have the CLD (chronic lung disease) ICD9 7485x or 7486x <u>and</u> in the past 6 months has required medical treatment</td><td>Yes: Go to #12</td><td>No: Go to #6</td></tr>
</table>

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with at least one of the following: a. bronchodilators b. chronic corticosteroid therapy c. home oxygen therapy d. diuretics		
6. GROUP B Does the patient have hemodynamically significant congenital heart disease (CHD) ICD9 746xx or 747xx **and** at least one of the following: a. Receiving treatment for congestive heart failure **or** b. Have moderate to severe pulmonary hypertension **or** c. Cyanotic heart disease	**Yes:** Go to #12	**No:** Go to #7
7. Will the patient be < 12 months at start of RSV season?	**Yes:** Go to #8	**No:** Pass to RPH: DENY (Medical Appropriateness).
8. GROUP C Is the gestational age ≤ 28 weeks?	**Yes:** Go to #12	**No:** Go to #9
9. GROUP D Infants with congenital abnormalities of the airway or neuromuscular disease compromising handling of secretions?	**Yes:** Go to #12	**No:** Go to #10
10. GROUP E Will the patient be < 6 months at the start of the RSV season and the gestational age ≤ 29-31 weeks and 6 days?	**Yes:** Go to #12	**No**: Go to #11
11. GROUP F Will the patient be < 90 days at the start of the RSV season AND have a gestational age of ≤ 32-34 weeks and 6 days AND have at least one of the following risk factors: a. Daycare attendance b. Siblings less than 5 years of age	**Yes:** Go to #12	**No:** Pass to RPH: DENY (Medical Appropriateness).
12. Is the request for more than 5 doses within the same RSV season or for dosing <28 days apart?	**Yes:** Pass to RPH: DENY (Medical Appropriateness). Prophylaxis is indicated for 5 months maximum and doses should be administered ≥28 days apart. **May approve for the**	**No:** Go to #13

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	following on a case by case basis: **a. > 5 doses.** **b. Prophylaxis for a second/subsequent RSV season.**	
13. Has the patient had a weight taken within the last 30 days?	**Yes:** Document weight and date and go to #14 Weight:_____ Date: _____	**No:** Pass to RPH: obtain recent weight so accurate dose can be calculated.
14. Approve palivizumab for a dose of 15mg/kg. Document number of doses received in hospital and total number approved according to **BIRTH DATE** and **GROUP** based on start of RSV season: - Immunoprophylaxis between November - March refer to **Table 1** - Immunoprophylaxis starting in October based on above (#3) refer to **Table 2** Total number of doses approved for RSV season:_____ Number of doses received in the hospital:_____		

Table 1. Maximum number of doses to approve for RSV prophylaxis (Based on Criteria Group from Above) – Beginning **NOVEMBER 1st**

MONTH OF BIRTH	**GROUP A-D** (Child is <24 or <12 mo. old at start of season)	**GROUP E** (Child is <6 mo. old at start of season)	**GROUP F** (Child is <3 mo. old at start of season)
November 1 – March 31 of previous RSV season	5	Zero doses; infant will be older than 6 months at start of RSV season	Zero doses; infant will be older than 90 days at start
April	5	Zero doses; infant will be older than 6 months at start of RSV season	

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May	5	5	of RSV season
June	5	5	
July	5	5	
August	5	5	1*
September	5	5	2*
October	5	5	3*
November	5	5	3*
December	4	4	3*
January	3	3	3*
February	2	2	2*
March	1	1	1*

* Infant may require less doses than listed based on age at the time of discharge from the hospital. Subtract number of doses given in hospital from total number of approved doses.

Table 2. Maximum number of doses to approve for RSV prophylaxis (Based on Criteria Group from Above) – Beginning **OCTOBER 1-31**

MONTH OF BIRTH	**GROUP A-D** (Child is <24 or <12 mo. old at start of season)	**GROUP E** (Child is <6 mo. old at start of season)	**GROUP F** (Child is <3 mo. old at start of season)
November 1 – March 31 of previous RSV season	5	Zero doses; infant will be older than 6 months at start of RSV season	Zero doses; infant will be older than 90 days at start of RSV season
April	5	5	
May	5	5	
June	5	5	
July	5	5	1*
August	5	5	2*
September	5	5	3*
October	5	5	3*
November	5	5	3*
December	4	4	3*
January	3	3	3*
February	2	2	2*
March	1	1	1*

* Infant may require less doses than listed based on age at the time of discharge from the hospital. Subtract number of doses given in hospital from total number of approved doses.

Notes:

- Dose: 15 mg/kg via intramuscular injection once monthly throughout RSV season.
- The start date for Synagis is November 1 each year (or sooner when the Oregon Public Health Division has determined that RSV season onset has occurred) for a total of up to five doses.
- Approval for more than five doses or additional doses after March 31 is considered on a case-by-case basis. Results from clinical trials indicate that Synagis trough concentrations greater than 30 days after the 5th dose will be well above the protective concentration therefore five doses will provide more than 20 weeks of protection.

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