Palivizumab (Synagis®)

Goal(s):

- Promote safe and effective use of palivizumab in high-risk infants and children. Prophylaxis against RSV should cover up to 5 months during high viral activity season, usually spanning from November through March in Oregon.

Length of Authorization:

- Based on individual factors; may extend up to 5 months (5 total doses)

Requires PA:

- Synagis (Palivizumab) pharmacy and physician-administered claims

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Has the patient been receiving monthly palivizumab prophylaxis and been hospitalized for a breakthrough RSV infection?	**Yes:** Pass to RPh; deny for medical appropriateness.	**No:** Go to #3
3. Is the request for RSV prophylaxis to be administered during the typical high viral activity season from November through March?	**Yes:** Go to #5	**No:** Go to #4
4. Is the request for prophylaxis starting in October due to interseasonal increase in RSV activity with season onset designated by the OHA*? * Data 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. Not recommended for patients ≥24 months old.

Approval Criteria		
6. **GROUP A** Does the patient have the CLD (chronic lung disease) of prematurity ICD10 Q331through Q339 **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:** Go 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

Approval Criteria		
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) ICD10: P293, Q209, Q220-Q223, Q225, Q229-Q234, Q238, Q240-Q246, Q248-Q249, Q250-Q256, Q278-Q279,Q282-Q283,Q288-Q289, Q2560-Q2565,Q2568-Q2569, Q2570-Q2572, Q2579,Q2731-Q2732 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
15. **GROUP I** 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. **GROUP J** 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.

Approval Criteria		
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 15 mg/kg. Document number of doses received in hospital and total number approved according to month of birth (refer to Table 1): Total number of doses approved for RSV season:_____ Number of doses received in the hospital:_____ Prior to each refill, the patient's parent/caregiver and prescriber must comply with all case management services, including obtaining current weight for accurate dosing purposes throughout the approved treatment period as required by the Oregon Health Authority.		

Table 1. Maximum Number of Doses for RSV Prophylaxis

MONTH OF BIRTH	ALL GROUPS
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 5 doses.
- Approval for more than 5 doses or additional doses after March 31 will be considered on a case-by-case basis. Results from clinical trials indicate that Synagis® trough concentrations greater than 30 days after the 5th dose are well above the protective concentration. Therefore, 5 doses will provide more than 20 weeks of protection.

P&T/DUR Review: *2/22 (KS); 11/16 (DE); 9/14; 5/11; 5/12*
Implementation: *4/1/22; 1/1/17; 3/30/12*