Subject: Synagis

Objective:

I. To ensure that Tuality Health Alliance (THA) providers utilize standard clinical practice guidelines when requesting and dispensing Synagis (palivizumab for high risk infant patients).

II. To ensure a consistent utilization review process for authorization of Synagis.

Policy:

I. Synagis (palivizumab) is covered for the prevention of Respiratory Syncytial Virus (RSV); RSV season begins November 1 and ends March 31.

II. THA members receive Synagis (palivizumab) through the THA Formulary program.

III. Synagis (palivizumab) dosing will be based on the 2014 American Academy of Pediatrics Guidelines for the use of palivizumab for prophylaxis of RSV available online - *http://pediatrics.aappublications.org/content/134/2/415*

IV. Prior Authorization requests that meet the above criteria will be approved for five fills, until the patient no longer meets criteria based on age during RSV season, or until the completion of RSV season, whichever is less.

V. THA's contracted specialty pharmacy must be utilized for dispensing Synagis.

VI. Synagis (palivizumab) is not medically necessary for the treatment of RSV infections.

VII. Synagis (palivizumab) is administered intramuscularly once a month during the RSV season.

VIII. Prophylaxis start date is approximately November 1.

IX. During the RSV season, Synagis (palivizumab) may be considered medically necessary at the recommended American Academy of Pediatrics guideline doses when any of the following criteria are met:

1. Infants born before 29 weeks, O days gestations that are younger than 12 months at the start of the RSV season, fewer than 5 monthly doses will be needed. Synagis is not recommended for otherwise healthy infants born at or after 29, 0 days gestation.
2. Premature infants within the first 12 months of life who develop chronic lung disease (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

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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.

3. Children 12 months or younger with hemodynamically significant congenital heart disease (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.
4. Infants 12 months or younger with hemodynamically significant CHD and acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension.
5. Children under the age of 2 years undergoing cardiac transplantation during the RSV season.
6. Infants with neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airway during the first year of live.
7. Children under the age of 24 months who are profoundly immunocompromised during the RSV season.
8. Infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year.

X. Any request for Synagis (palivizumab) that does not meet the guidance outlined by the AAP Guidelines will be denied as not meeting criteria and not a covered benefit for THA members.

References: American Academy of Pediatric Guidelines 2014

Formulated:	September 2001
Reviewed:	January 2014 January 2016
Revised	December 2009 December 2011 April 2018