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Objective:

- I. To ensure Tuality Health Alliance (THA) providers utilize standardized clinical practice guidelines when requesting and dispensing Synagis for their high risk infant patients.
- II. To ensure a consistent medical review process for the review and decision making for Synagis authorizations.

Guideline:

- I. Synagis (palivizumab) is covered for the prevention of respiratory syncytial virus (RSV).
- II. Oregon Health Plan members receive Synagis (palivizumab) through the High Cost Injectable program, Cura Scripts.
- III. RSV season is from November 1 through March 31.
- IV. Synagis (palivizumab) dosing will be based on the 2009 AAP modified guidelines.

Procedures:

- I. Synagis may be considered medically necessary at the recommended guideline doses during the RSV season when any of the following criteria are met.
 - A. Infants less than 24 months of age with chronic lung disease (CLD).
 1. Requires use of supplemental oxygen, corticosteroid therapy, assisted ventilation or CPAP via tracheostomy currently or within the preceding six months before the anticipated RSV season.
 2. A maximum of 5 doses can be approved during the RSV season.
 - B. Infant is less than 24 months of age and is considered by a cardiologist or intensivist to have hemodynamically significant Congenital Heart Disease (CHD).
 1. Children with CHD receiving medication to control CHF and those with moderate to severe pulmonary hypertension.

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2. A maximum of 5 doses can be approved during the RSV season.
 - C. Infants less than 12 months of age at the beginning of the RSV season and born less than 28 weeks gestation.
 1. A maximum of 5 months (5 doses) can be approved during the RSV season.
 2. Continue the Synagis for 5 doses and do not stop if child reaches the age of 12 months.
 - D. Infants less than 6 months of age at the beginning of the RSV season and was born at 29 weeks, 0 days gestation to less than 32 weeks (<31 weeks, 6 days) gestation.
 1. Approve for a maximum of 5 months.
 2. These children continue throughout the RSV season and do not stop if they reach 6 months of age. (See Table 1 for number of doses {months}).
 - E. Infants less than 3 months of age at the beginning of the RSV season or born during the RSV season AND was born at 32 weeks, 0 days gestation to less than 35 weeks (< 34 weeks, 6 days) gestation AND has one of the following 2 risk factors:
 1. Risk factors:
 - a. Infant attending child care where care is provided for any number of infants or young toddlers in the home or facility.
 - b. The infant lives with an individual (e.g. older sibling) < 5 years of age. Note: This does NOT include siblings of the same age from multiple births for which Synagis is being requested.
 2. Approve for a maximum of 3 months.
 3. These infants only receive prophylaxis until they reach 3 months of age (90 days). (See Table 1 for number of doses {months}).
- II. Synagis (palivizumab) is not indicated for:
- A. Infants with congenital heart disease, except for infants with hemodynamically insignificant lesions, who meet criteria because of prematurity or CLD. The efficacy and safety of Synagis (palivizumab) in these children has not been established.
 - B. Premature infants 32-35 weeks gestation with no risk factors.
 - C. Children over 2 years of age.
- III. Synagis (palivizumab) is not medically necessary for the treatment of RSV

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infections.

- IV. Synagis (palivizumab) has not been evaluated in randomized trials in immunocompromised children. Therefore, Synagis (palivizumab) in these patients is considered investigational due to the lack of scientific evidence supporting health outcomes.
- V. Synagis (palivizumab) is administered intramuscularly once a month during the RSV season. (November – March)
- VI. Prophylaxis start date is approximately November 1.

Reference: American Academy of Pediatric Guidelines 2009.
Express Scripts Prior Authorization Policy: Synagis 9/21/2011

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THA Plan Director

THA Medical Director

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TABLE 1. Maximum Number of Palivizumab Doses for RSV Prophylaxis of Preterm Infants Without CLD, Based on Birth Date, Gestational Age, and Presence of Risk Factors (Shown for Areas Beginning Prophylaxis on November 1st)

Month of Birth	Maximum No. of Doses for Season Beginning Nov 1		
	≤28 wk 6 d Gestation and <12 mo of Age at Start of Season	29 wk 0 d Through 31 wk 6 d Gestation and <6 mo of Age at Start of Season	32 wk 0 d Through 34 wk 6 d and With Risk Factor ^a
Nov 1–Mar 31 of previous RSV season	5 ^b	0 ^c	0 ^d
Apr	5	0 ^c	0 ^d
May	5	5	0 ^d
Jun	5	5	0 ^d
Jul	5	5	0 ^d
Aug	5	5	1 ^e
Sep	5	5	2 ^e
Oct	5	5	3 ^e
Nov	5	5	3 ^e
Dec	4	4	3 ^e
Jan	3	3	3 ^e
Feb	2	2	2 ^e
Mar	1	1	1 ^e

If the infant is discharged from the hospital during RSV season, fewer doses may be required.

^a Risk factors: infant attends child care or has sibling younger than 5 years.

^b Some of these infants may have received 1 or more doses of palivizumab in the previous RSV season if discharged from the hospital during that season; if so, they still qualify for up to 5 doses during their second RSV season.

^c Zero doses because infant will be older than 6 months at the start of RSV season.

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^d Zero doses because infant will be older than 90 days of age at start of RSV season.

^e On the basis of the age of patients at the time of discharge from the hospital, fewer doses may be required, because these infants will receive 1 dose every 30 days until the infant is 90 days of age.