group health Cooperative of eau claire	DEPARTMENT:	Utilization Management
	SUBJECT:	Synagis
	PRODUCT LINE:	All
	POLICY NUMBER:	058
	ORIGINAL POLICY EFFECTIVE DATE:	10/10/07
KMTSJ, Inc.	LAST REVISED DATE:	04/25/17
	LAST REVIEWED DATE:	3/6/2023

SCOPE: To ensure Group Health Cooperative of Eau Claire consistently and correctly administers Synagis benefits to all members according to their policy specifics.

POLICY: It is the policy of Group Health Cooperative of Eau Claire to review requests for Synagis injections for prior authorization according to evidence based medical criteria.

PROCEDURE: Prior authorization required: YES

- Synagis (palivizumab) is not part of the Medicaid provider-administered drug carve-out policy; therefore, the Medicaid HMO should reimburse providers for Synagis.

- Group Health Cooperative of Eau Claire considers Synagis (palivizumab) prophylaxis medically necessary when one of the following conditions is met:
    1. Early preterm infants:
        a) Infants born before 29 weeks, 0 days gestation, who are younger than 12 months of age at the start of RSV season (November). For infants born during the RSV season, fewer than five monthly doses will be needed.
        b) Synagis prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone.
    2. Chronic lung disease (CDL) of prematurity:
        a) Infants younger than one year of life, **and** born before 32 weeks, 0 days gestation, **and** diagnosed with chronic lung disease of prematurity (formerly known as broncho-pulmonary dysplasia or BPD), **and** required greater than 21% oxygen for at least 28 days after birth.
        b) Infants in the second year of life with CLD who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroids, or diuretic therapy) during the 6 month period prior to the start of their second RSV season.
    3. Hemodynamically significant congenital heart disease:
        a) Infants in the first year of life who have hemodynamically significant congenital heart disease:
            - ✓ Cyanotic heart disease,
            - ✓ Moderate to severe pulmonary hypertension, or
            - ✓ Acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures.
        b) Children younger than 2 years who undergo cardiac transplantation during the RSV season.

    4. Immunocompromised state:
        a) Synagis prophylaxis is considered medically necessary for children younger than 24 months who will be profoundly immunocompromised during the RSV season (ie: severe combined immunodeficiency or severe acquired immunodeficiency, acute myeloid leukemia, acute lymphoblastic leukemia, hematopoietic stem cell transplant recipients.)
    5. Anatomic pulmonary abnormalities or neuromuscular disorders:

a) In the first year of life, Synagis is considered medically necessary for children with anatomic pulmonary abnormalities or neuromuscular disease that impairs the ability to clear secretions from the upper airways because of ineffective cough.

6. Cystic fibrosis:
   a) Synagis prophylaxis is considered medically necessary for infants with cystic fibrosis and clinical evidence of CLD or nutritional compromise during the first year of life.
   b) Continued use of Synagis in the second year is considered medically necessary for infants with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life), abnormalities on a chest xray or CT, or with weight for length less than the 10th percentile.

Dosing of Synagis (palivizumab):

- RSV season runs November through March.
- 5 monthly doses of Synagis of 15 mg/kg is considered medically necessary during RSV season for infants who meet the criteria above. For infants born during the RSV season, fewer than 5 monthly doses are needed (ie: if an infant is born in January and meets criteria, 3 doses would be approved to end in March.)
- A post-operative dose of Synagis is considered medically indicated after cardiac bypass or ECMO for infants and children younger than 24 months who are receiving Synagis.

ASSOCIATED CODES: 90378 Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50mg, each

Reference source, if applicable: American Academy of Pediatrics, CDC

APPROVED: _____ _____DATE: 3/6/2023

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision

03/22/2013	Carol E. Ebel, RN HM Mgr	This is a continuation of the archived P & P.
02/15/2014	Lynne Komanec, RN HM Manager	Reviewed with no changes
01/16/2015	Susan Fox, RN	Major Revision
4/28/2016	Betsy Kelly, RN	Reviewed with no changes
04/25/2017	Michele Bauer, MD, CMO	Reviewed with no changes aside from reformatting
02/18/2019	Michele Bauer, MD, CMO	No changes
3/22/2020	Michele Bauer, MD, CMO	No changes
3/25/2021	Michele Bauer, MD, CMO	Reviewed. No changes.
3/14/2022	Michele Bauer, MD, CMO	Reviewed. No changes.
3/6/2023	Dakota Rau, PharmD	Reviewed. No changes.