SmartPA Criteria Proposal

Drug/Drug Class:	Synagis Clinical Edit
First Implementation Date:	October 1, 2003
Proposed Date:	July 18, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Synagis® (palivizumab) injection

Why Issue Selected: Synagis® (palivizumab) injection was FDA approved in June 1998 for the prevention of infection in high-risk pediatric patients due to respiratory syncytial virus (RSV), the most common cause of pneumonia and bronchiolitis in infancy and early childhood. Synagis is the first monoclonal antibody approved to provide passive immunity for an infectious disease. Severe RSV disease is the most common reason infants under 1 year of age are hospitalized in the United States. The American Academy of Pediatrics (AAP) recommends limiting the usage of Synagis to certain preterm infants and infants with certain chronic illnesses.

Synagis is typically reserved for use during the RSV Season (November through April). However, the atypical RSV season that followed the COVID-19 pandemic led the AAP to publish guidance in August of 2021 urging Synagis administration to eligible infants where RSV activity approaches the typical fall-winter season levels. This guidance was updated for the 2022-2023 season as well, stating that widespread and intense RSV circulation may lead to a period of disease activity lasting more than the typical 6-month duration. In October 2022, the five-week average of positive RSV cases in Missouri reached its highest point since the summer of 2021.

MO HealthNet will continue to assess and review guidance for out-of-season Synagis administration and will evaluate the need for additional doses on a month-to-month basis, dependent on RSV virology.

Program-Specific Information:

Date Range FFS 11-01-2022 to 4-30-2023 (typical RSV Season)			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
SYNAGIS 50 MG/0.5 ML VIAL	699	$1,168,358.71	$1,671.47
SYNAGIS 100 MG/1 ML VIAL	1412	$4,754,897.01	$3,367.49

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Synagis® (palivizumab) injection
- Age range: All appropriate MO HealthNet participants ≤ 24 months of age

Approval Criteria

- Claim is during RSV Season **(MO HealthNet will announce the current season based on local RSV levels)** **AND**
- For prematurity:
  - Participant aged ≤ 12 months and born ≤ 28 weeks gestation **OR**
  - Participant aged ≤ 6 months and born between 29 and 32 weeks gestation **OR**
  - Participant aged ≤ 3 months and born between 32 and 35 weeks gestation **AND**
    - Enrolled in childcare **OR**
    - Has siblings that are < 5 years of age **OR**
- For chronic lung disease:
  - Participant aged < 12 months and born < 32 weeks gestation with chronic lung disease **AND**
    - required more than 21% oxygen for 28 days following birth **AND**
    - currently requiring medical therapy (oxygen on a continuous basis, bronchodilator, diuretic, corticosteroid or ventilator dependent) **OR**
  - Participant aged < 24 months and born < 32 weeks gestation with chronic lung disease **AND**
    - required more than 21% oxygen for 28 days following birth **AND**
    - required continued medical therapy throughout the past 6 months (oxygen on a continuous basis, bronchodilator, diuretic, corticosteroid or ventilator dependent) **OR**
- For congenital heart disease:
  - Participant aged ≤ 24 months with hemodynamically significant cyanotic and acyanotic congenital heart disease **AND**
    - Receiving medication to control CHF (digoxin, beta blockers, calcium channel blockers, ACE inhibitors, nitroglycerin, anti-coagulants, diuretics, or supplemental oxygen) **OR**
    - Moderate to severe pulmonary hypertension **OR**
    - Cyanotic heart disease **OR**
- For congenital abnormality of the airway or neuromuscular disease that impairs ability to clear secretions: Participant aged < 12 months **OR**
- For severe immunodeficiencies that may benefit from prophylaxis as determined by clinical consultant review: Participant aged ≤ 24 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Therapy exceeds 5 doses per RSV season
- **Evidence of a different RSV preventative product within the last 6 months**

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

SmartPA Clinical Proposal Form

Default Approval Period

Max of 5 doses per RSV season

References

- Synagis® (palivizumab) [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); November 2021.
- Clinical Pharmacology. Palivizumab – Synagis. Accessed May 16, 2022.
- American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics 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 Aug;134(2):e620-38. doi: 10.1542/peds.2014-1666. PMID: 25070304.
- IPD Analytics. Infectious Diseases: Respiratory Syncytial Virus (RSV). Accessed May 16, 2022.
- American Academy of Pediatrics. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. Last Updated November 17, 2022. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season (aap.org)
- Centers for Disease Control and Prevention. Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity in Parts of the Southern United States. June 10, 2021. CDC-HAN-443-Increased-Interseasonal-RSV-Activity-06.10.21.pdf