SmartPA Criteria Proposal

Drug/Drug Class:	RSV Prophylaxis – Pediatric Clinical Edit *(formerly the Synagis Clinical Edit)*
First Implementation Date:	October 1, 2003
Revised Date:	December 7, 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 agents for pediatric RSV prophylaxis

Why Issue Selected: Respiratory syncytial virus (RSV) is a common cause of respiratory illness with a typical season in Missouri of November through April. In most cases, the virus causes mild cold-like symptoms and can be managed with supportive care. However, some patients, especially infants and the elderly, are at risk of more severe illness. Severe RSV disease is the most common reason for hospitalization in infants under one year of age in the United States.

Synagis® (palivizumab) was FDA approved in June 1998 for the prevention of RSV infection in high-risk pediatric patients. Synagis was the first monoclonal antibody approved to provide passive immunity for an infectious disease. The American Academy of Pediatrics (AAP) recommends limiting the usage of Synagis to certain preterm infants and infants with certain chronic illnesses.

In July 2023, the FDA approved Beyfortus™ (nirsevimab) for the prevention of RSV in infants born during or entering their first RSV season regardless of risk status as well as in children up to 24 months of age who are at risk of severe RSV disease through their second RSV season. Shortly after FDA approval, the CDC's Advisory Committee on Immunization Practices (ACIP) unanimously approved the inclusion of Beyfortus in the CDC's Vaccines for Children (VFC) program. The AAP published recommendations for use of Beyfortus in August 2023 that are consistent with the recommendations by ACIP. Beyfortus administration will be provided through the VFC program.

In May 2023, the FDA approved Arexvy (respiratory syncytial virus vaccine, adjuvanted) and Abrysvo™ (respiratory syncytial virus vaccine) for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older. Later in August 2023, the FDA approved an additional indication for Abrysvo for maternal administration at 32 to 36 weeks gestation to prevent RSV in infants from birth through 6 months of age. ACIP will meet in late September 2023 to establish recommendations for use of Abrysvo for newborn RSV prevention. Maternal Abrysvo administration will be provided through maternal coverage programs.

MO HealthNet will continue to assess and review guidance for RSV prophylaxis administration and will evaluate the Missouri RSV season on a month-to-month basis, dependent on RSV virology. For RSV prophylaxis for pediatric patients, MO HealthNet will require Beyfortus administration through the VFC program and will only approve Synagis if Beyfortus is unavailable.

Program-Specific Information:

Date Range FFS 11-01-2022 to 4-30-2023 (typical RSV Season)			
Drug	**Claims**	**Spend***	**Avg Spend per Claim***
BEYFORTUS 50 MG/0.5 ML SYRINGE	0	-	-
BEYFORTUS 100 MG/ML SYRINGE	0	-	-
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

**Vaccines provided by the VFC program do not accrue any cost to MO HealthNet.*

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

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

Setting & Population

- Drug class for review: agents for pediatric RSV prophylaxis
- Age range: All appropriate MO HealthNet participants ≤ 24 months of age

Approval Criteria

- Claim is for Synagis:
  - Claim is during RSV Season (MO HealthNet will announce the current season based on local RSV levels) **AND**
  - Reason of medical necessity required as to why Beyfortus administration through the VFC program cannot be utilized **AND**
  - For prematurity:
    - Participant age at RSV season is ~~**> 6 months but**~~ ≤ 12 months and born ≤ 28 weeks gestation **OR**
    - Participant age at RSV season is > 3 months but ≤ 6 months and born ≤ 32 weeks gestation **OR**
    - Participant age at RSV season is ≤ 3 months and born ≤ 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
- For Synagis:
    - 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

Default Approval Period

Two doses of Synagis (45 days)

References

- Abrysvo (respiratory syncytial virus vaccine) [package insert]. New York, NY: Pfizer Inc.; August 2023.
- Beyfortus (nirsevimab-alip) [package insert]. Swiftwater, PA: Sanofi Pasteur, Inc.; July 2023.
- Synagis (palivizumab) [package insert]. Waltham, MA: Sobi Inc.; November 2021.
- IPD Analytics. Infectious Diseases: Respiratory Syncytial Virus (RSV). Accessed September 13, 2023.
- 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. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection | Pediatrics | American Academy of Pediatrics (aap.org).
- 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
- American Academy of Pediatrics. ACIP and AAP Recommendations for the Use of the Monoclonal Antibody Nirsevimab for the Prevention of RSV Disease. August 15, 2023. ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics.