Alabama Medicaid Agency
Synagis® Prior Authorization Criteria

1. Has the patient received Beyfortus® (nirsevimab) in the current RSV season?
   - ❒Yes (If yes, deny)
   - ❒ No (If no, go to #2)
2. Is the infant's gestational age less than 29 weeks, 0 days and chronological age[1] less than 12 months old?
   - ❒ Yes (If yes, go to # 7)
   - ❒ No (If no, go to # 3)
3. Is the patient 12 months of age[1] or younger with a diagnosis[2] of pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough? Supporting documentation* of diagnosis code (ICD-10) must be included.
   - ❒ Yes (If yes, go to #7)
   - ❒ No (If no, go to # 4)
4. Is the patient 12 months of age[1] or younger with a diagnosis of Chronic Lung Disease[2] (CLD) of prematurity defined as gestational age less than 32 weeks, 0 days and required supplemental oxygen >21% for at least the first 28 days after birth[3]?
   - ❒ Yes (If yes, go to #7)
   - ❒ No (If no, go to #5)
5. Is the patient 24 months of age[1] or younger with a diagnosis of Chronic Lung Disease[2] (CLD) of prematurity defined as gestational age less than 32 weeks, 0 days and has received supplemental oxygen >21% for at least the first 28 days after birth[3] ***and*** continues to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season? Supporting documentation* of diagnosis code (ICD-10) and medical therapy must be included.
   - ❒ Yes (If yes, indicate treatment below and go to #7)
   - ❒ No (If no, go to #6)
6. Is the patient 12 months of age[1] or younger with a diagnosis of hemodynamically significant cyanotic or acyanotic Congenital Heart Disease (CHD) with one of the following:
   (a) acyanotic heart disease[2] and receiving medication to control congestive heart failure and will require cardiac surgical procedures, **or**
   (b) moderate to severe pulmonary hypertension[2], **or**
   (c) cyanotic heart defects[2] and palivizumab decision made in consultation with a pediatric cardiologist?
   Supporting documentation* of diagnosis/ICD10 code as well as medications (if applicable) must be included.
   - ❒ Yes (If yes, go to #7)
   - ❒ No (If no, deny)
7. Is the patient currently an outpatient and has not been enrolled as an inpatient within 2-weeks of the date the Synagis® is requested? Infants discharged on or after October 1st of the Synagis® season should receive their first dose in the inpatient setting. Enter discharge date (if applicable)_____
   - ❒ Yes (If yes, approve request)
   - ❒ No (If no, deny)

(**NOTE:** If discharge date does not reflect a 2 week period, approval may be given to be effective 2 weeks post hospital discharge)

One of criteria 2 through 6 and the final criterion must be met before approval can be granted. A copy of the hospital discharge summary from birth or documentation of the first office visit with pertinent information (gestational age, diagnosis, etc.) is required on all Synagis® PA requests. RSV prophylaxis approval will terminate March 31. RSV season is defined by the Alabama Medicaid Agency as October 1 through March 31.**

NOTE: Approval authorizes only one dose (based on patient weight) every twenty-eight days up to a five (5) dose maximum or through March 31. A dose is defined as the calculated dosage [patient weight (kg) X 15mg/kg ÷ 100 mg/ml of Synagis®]. The results of the calculation will be the number of mls the patient needs. Use the appropriate combination of vials to get the correct dose. No dose may be given after March 31.** Requests for more than one dose in a 28 day period cannot be approved. If the patient received a dose in an inpatient setting, approval will only be given for 4 doses. Retroactive requests must be submitted and billed within 6 months of the dispense date. Letters will be faxed to both prescriber and dispensing pharmacy notating approval or denial.

If approved, each monthly subsequent dose will require submission of the recipient's current weight and last injection date and may be faxed to Kepro utilizing the PA approval letter by the prescribing physician or dispensing pharmacy. Subsequent doses will be denied if child experiences a breakthrough RSV hospitalization.

Supporting documentation is supplemental information submitted to support the patient meeting the criteria. Supporting documentation may include copies of hospital discharge notes, progress notes, pharmacy profiles, etc., and must include all medications, frequency of medication dosing, and diagnosis(es) with indications of severity of illness. A periodic review of medical records will be conducted by the Alabama Medicaid Agency or designees. Stamps/copies of physician's signatures will not be accepted.

****Medicaid will closely monitor the CDC surveillance information and coordinate with our state pediatric infectious disease/pulmonary specialist leaders in early 2024 to determine if changes or an extension of the 2023-2024 season is warranted.***

[1]Chronological age at the start of the RSV Season
[2]Please refer to Appendix A of the Synagis® Prior Authorization Instruction Worksheet for acceptable diagnosis codes for all applicable diagnoses as well as acceptable medications used in CHD.
[3]Infants for which documentation indicates weaning was attempted and failed in the 1st 28 days after birth may be approved.