Alabama Medicaid Agency
Synagis® Prior Authorization Instruction Worksheet

A new respiratory syncytial virus (RSV) long-acting monoclonal antibody product, Beyfortus® (nirsevimab), was approved by the US Food and Drug Administration (FDA) on July 17, 2023, for the 2023-2024 RSV season[1]. On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) voted unanimously in favor of recommending use of Beyfortus®[2]. Beyfortus® will be administered and dispensed through the Vaccines for Children Program (VFC) administered through the Alabama Department of Public Health[3]. Therefore, Beyfortus® will not be eligible for billing through the Medicaid pharmacy program. Procedure codes 90380 and 90381 have been assigned to Beyfortus®. Medicaid VFC providers should refer to Appendix A, section A.6 of the Provider Billing Manual located at www.medicaid.alabama.gov for filing claims related to VFC products[4].

Based on guidance from the American Academy of Pediatrics (AAP), if Beyfortus® is not available or not feasible to administer, high risk infants who are recommended to receive Synagis® (palivizumab) in the first or second year of life should receive Synagis® until Beyfortus® becomes available. Per the FDA label, children who have received Beyfortus® should not receive Synagis® for the same RSV season[5].

Synagis® is FDA approved for the prevention of respiratory syncytial virus (RSV) in selected infants and children. Synagis® requires prior authorization (PA) for reimbursement through the Alabama Medicaid Agency. The approval time frame for Synagis® will begin October 1 and will be effective through March 31 of the following year. Synagis® should be administered monthly; a total of up to five doses will be allowed per recipient from October 1 through March 31. There are no circumstances that will allow for approval of a sixth dose.*

For approval of requests, the recipient must meet gestational and chronological age requirements. In order to meet chronological age requirements, the recipient must be the required age at the start of the RSV season.

Prescribers - not the pharmacy, manufacturer, or any other third-party entity - are to submit requests for Synagis® on a separate PA form (Form 351) **directly** to Kepro and may be accepted beginning September 1 (for an October 1 effective date). A copy of the hospital discharge summary from birth or documentation of the first office visit with pertinent information (gestational age, diagnosis, etc.) must be included on all Synagis® PA requests. The first dose for newborns must be administered while infant is still inpatient/in the hospital prior to discharge. Prescribers must prescribe Synagis® through a specialty pharmacy. CPT code 90378 has been discontinued for the 2023-2024 season.

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Letters will be faxed to both the prescriber and the dispensing pharmacy notating approval or denial. If approved, each monthly subsequent dose will require submission of the recipient's current weight, date patient weighed, and last injection date, and must be faxed to Kepro utilizing the PA approval letter by the prescribing physician or dispensing pharmacy. Subsequent doses will be denied it the child experiences a breakthrough RSV hospitalization. This information will also be required each month and included on the PA approval letter.

The following outlines the instructions and additional information for completing the Synagis® PA form (Form 351). Questions regarding the Synagis® PA process can be directed to Kepro at 1-800-748-0130.

Patient Information

- Complete Patient Information Section to include Patient Name, Medicaid Recipient ID #, date of birth, and phone number with area code.

Prescriber Information

- Complete Prescriber Information Section to include Prescriber name, NPI, License #, phone and fax number with area code, and address (optional).
- The prescriber **MUST** sign and date the PA form attesting the information on the submitted form and supplemental information is accurate information. Stamped or copied signatures will not be accepted.

Drug/Clinical Information

- Synagis® has been approved by Alabama Medicaid for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) as outlined by the American Academy of Pediatrics (AAP) recommendations for the prevention of RSV.
- The patient must meet the most current AAP guidelines, the gestational age, chronological age, and must be an outpatient with no in-patient stay for at least two weeks prior to the date of the medication request. In order to meet chronological age requirements, the recipient must be the required age at the start of the RSV season.
- Supporting documentation (see definition below in glossary section) **MUST** be submitted for **any** accepted diagnosis codes (ICD-10).
- See Appendix A of the Synagis® PA Instruction Worksheet for a list of acceptable diagnosis codes (ICD-10) and acceptable medications used in Congenital Heart Disease (CHD).
- A copy of the hospital discharge summary from birth or documentation of the first office visit with pertinent information (gestational age, diagnosis, etc.) must be included with the PA submission.
- If a dose was administered in an inpatient setting, the date the dose was administered must be included on the PA request form.

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- See Synagis® Prior Authorization Criteria for specific requirements for approval.
- Required fields within this section of the PA form include:
  - Drug requested
  - NDC#/J Code
  - Strength
  - Quantity per month
  - Number of doses requested
  - Current weight of recipient (in kg) and date
  - Gestational age (in weeks and days)
  - ICD-10 Code
  - Chronological age
- Other fields within this section of the PA form are to be completed/marked if applicable.

Pharmacy Information

- Complete the pharmacy information to include the dispensing pharmacy name, the NPI # (if known), phone and fax number.

PA Approval Timeframes

- Approval may be given for up to 5 doses or through the end of RSV season (March 31), whichever comes first.*

Prior Treatment Trials

- Prior treatment trials do not apply to Synagis®.

Stable Therapy

- Stable therapy does not apply to Synagis®. A new PA must be submitted for each defined Synagis® season.

Electronic Prior Authorization (PA)

- Not Applicable

Verbal PA Requests

- Not Applicable. Questions on the Synagis® PA process should be directed to Kepro at 1-800-748-0130.

Glossary:

- **Chronic Lung Disease (CLD)**: also known as bronchopulmonary dysplasia (BPD): during the first year of life for preterm infants, CLD of prematurity is defined as an infant whose gestational age is less than 32 weeks, 0 days and has a requirement of >21% oxygen for at least the first 28 days after birth. During the 2nd year of life, infants must meet this definition of CLD of prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 month period before the start of the RSV season. *Note:* CLD *does not* include croup, URI, bronchitis,

bronchiolitis, asthma, or wheezing. Infants for which documentation indicate weaning was attempted and failed in the 1st 28 days after birth may be approved.

- **Hemodynamically significant cyanotic or acyanotic Congenital Heart Disease (CHD):** children with acyanotic heart disease who are receiving medication to control congestive heart failure, have moderate to severe pulmonary hypertension, or have cyanotic heart disease. Decisions regarding prophylaxis with Synagis® in children with CHD should be made on the basis of the degree of physiologic cardiovascular compromise.
- **Medical Justification:** an explanation of the reason the drug is required in a particular patient and any additional information needed. Medical justification may include supporting documentation from the patient chart or peer-reviewed literature to support the physician's request for the drug.
- **Supporting Documentation:** supplemental information submitted to support the patient meeting the criteria. Supporting documentation may include copies of hospital discharge notes, progress notes, pharmacy profiles, etc.

*****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] https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers

[2] https://publications.aap.org/redbook/resources/25379

[3] Advisory Committee on Immunization Practices, Vaccines for Children Program (cdc.gov)

[4] Questions on Beyfortus® administration through the VFC program should be directed to the Alabama Department of Public Health at (800) 469-4599, or https://www.alabamapublichealth.gov/immunization/vaccines-for-children.html

[5] https://products.sanofi.us/beyfortus/beyfortus.pdf