ALABAMA MEDICAID AGENCY

ALERT

September 17, 2024

TO: All Providers

RE: RSV Prevention Criteria for the 2024–2025 Season

Beyfortus®:

- Beyfortus® (nirsevimab), a long-acting monoclonal antibody product, was approved by the US Food and Drug Administration (FDA) on July 17, 2023, for use in newborns and infants to protect against (medically attended) respiratory syncytial virus (RSV).[1]
- On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) voted unanimously in favor of recommending use of Beyfortus® as indicated in its FDA package insert.[2]
- Beyfortus® will be administered and dispensed through the Vaccines for Children Program (VFC)[3], administered through Alabama Department of Public Health. 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.
- 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® in the first or second year of life should receive Synagis® until Beyfortus® becomes available.[2]
- Per the FDA label, children who have received Beyfortus® should not receive Synagis® for the same RSV season.[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 .

Synagis®:

- As a result of the recommendations for use of Beyfortus®, requests for Synagis® (palivizumab) will be reviewed on a case-by-case basis.
- As per normal criteria, **the first dose of Synagis® for newborns must be administered while still inpatient/in the hospital prior to discharge.**
- The 2024-2025 season will begin on October 1, 2024. Doses received prior to that date will not be counted towards the baby's doses for the 2024-2025 Synagis® season.

- The approval time frame for Synagis® for the 2024-2025 RSV season will be effective October 1, 2024, through March 31, 2025. Up to five doses will be allowed per baby in this time frame. There are no circumstances that will result in the approval of a sixth dose*.

- If a dose was administered in an inpatient setting, the date the dose was administered must be included on the PA request form. Subsequent doses will be denied if the baby experiences a breakthrough RSV hospitalization during the RSV season.

- Medicaid updated its prior authorization (PA) criteria for the RSV 2024-2025 season. Complete criteria can be found at: https://medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME/4.3.10_Synagis.aspx

- **Prescribers**, not the pharmacy, manufacturer or any other third-party entity are to submit requests for Synagis® on a specific prior authorization form (Form 351) **directly** to Acentra Health. Completed forms may be accepted beginning September 1, 2024 (for an October 1 effective date). The fax number for Synagis® requests is: **1-800-748-0116**.

- All signatures must meet the requirements of Alabama Medicaid Administrative Code Rule 560-X-1-.18(2)(c). Please note that stamped or copied prescriber signatures will not be accepted and will be returned to the provider.

- 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.

- If approved, each subsequent monthly dose will require submission of the baby's current weight and last injection date. Requests may be faxed to Acentra Health by the prescriber or dispensing pharmacy utilizing the original PA approval letter.

- Prescribers must prescribe Synagis® through a specialty pharmacy. CPT code 90378 remains discontinued for the 2024-2025 season.

- Medicaid is the payor of last resort. Claims must be billed to the primary payor if other third-party coverage exists. Use of NCPDP Other Coverage Codes will be reviewed, and inappropriately billed claims will be recouped.

*Medicaid will closely monitor the CDC surveillance information and coordinate with our state pediatric infectious disease/pulmonary specialist leaders in early 2025 to determine if changes or an extension of the 2024-2025 season is warranted.

Criteria
Additional questions regarding Synagis® criteria can be directed to the Agency's Prior Authorization contractor, Acentra Health at 1-800-748-0130.

[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] https://www.alabamapublichealth.gov/immunization/vaccines-for-children.html

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