# ALERT

September 26, 2025

TO: All Providers

RE: RSV Prevention in Children Criteria for the 2025-2026 Season

#### Beyfortus®:

- Beyfortus® (nirsevimab), a long-acting monoclonal antibody product, was approved by the U.S. Food and Drug Administration (FDA) on July 17, 2023, for use in newborns and infants to protect against (medically attended) respiratory syncytial virus (RSV).<sup>1</sup>
- 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<sup>®</sup> as indicated in its FDA package insert.<sup>2</sup>
- Beyfortus® will be administered and dispensed through the Vaccines for Children Program (VFC)³, administered through Alabama Department of Public Health (ADPH). Therefore, Beyfortus® will not be eligible for billing through the Alabama Medicaid Pharmacy Program.
- Procedure Codes 90380 and 90381 have been assigned to Beyfortus<sup>®</sup>. Medicaid VFC providers should refer to Appendix A, Section A.6 of the Provider Billing Manual located at <a href="www.medicaid.alabama.gov">www.medicaid.alabama.gov</a> for filing claims related to VFC products.
- Per the FDA label, children who have received Beyfortus<sup>®</sup> should not receive Synagis<sup>®</sup> for the same RSV season.<sup>4</sup>
- Questions on Beyfortus® administration through the VFC program should be directed to ADPH at (800) 469-4599, or <a href="https://www.alabamapublichealth.gov/immunization/vaccines-for-children.html">https://www.alabamapublichealth.gov/immunization/vaccines-for-children.html</a>.

### **Enflosia<sup>™</sup> and Other VFC-Approved Products:**

- Enflosia<sup>™</sup> (clesrovimab-cfor), a preventative monoclonal antibody product, was approved by the FDA on June 9, 2025, for prevention of RSV in neonates (newborns) and infants who are born during, or entering, their first RSV season.<sup>5</sup>
- The ACIP of the CDC has voted to recommend Enflosia<sup>™</sup> (clesrovimab-cfor) as an option for the
  prevention of RSV lower respiratory tract disease in infants younger than 8 months of age who are born
  during, or entering, their first RSV season. The ACIP also voted to include Enflosia<sup>™</sup> in the VFC Program.<sup>5</sup>
- Enflosia<sup>™</sup>, and other products approved, administered, and dispensed through the VFC Program will be managed through ADPH, and therefore not eligible for billing through the Alabama Medicaid Pharmacy Program.

### **ALABAMA MEDICAID AGENCY**

# ALERT

Procedure Code 90382 has been assigned to Enflosia<sup>TM</sup>. Medicaid VFC providers should refer to Appendix
A, Section A.6 of the Provider Billing Manual located at <a href="www.medicaid.alabama.gov">www.medicaid.alabama.gov</a> for filing claims related to VFC products.

#### Synagis®:

- Synagis® (palivizumab) has been voluntarily discontinued and will no longer be manufactured, distributed, or available for purchase after December 31, 2025.<sup>6</sup> As in prior RSV seasons, requests for prior authorization (PA) will be reviewed through the Agency PA vendor, Acentra Health. Approvals will be effective October 1, 2025 March 31, 2026.
- Questions regarding Synagis<sup>®</sup> criteria can be directed to the Agency's PA contractor, Acentra Health, at 1-800-748-0130. Criteria, forms, and instructions for Synagis can be found on the Agency webpage, <a href="https://medicaid.alabama.gov/content/9.0">https://medicaid.alabama.gov/content/9.0</a> Resources/9.4 Forms Library/9.4.13 Pharmacy Forms.aspx.
- Prescribers must prescribe Synagis<sup>®</sup> through a specialty pharmacy. CPT Code 90378 remains discontinued for the 2025-2026 season.

1https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers

<sup>2</sup>https://publications.aap.org/redbook/resources/25379

<sup>3</sup>https://www.alabamapublichealth.gov/immunization/vaccines-for-children.html

4https://products.sanofi.us/bevfortus/bevfortus.pdf

<sup>5</sup>https://www.cdc.gov/acip/vaccine-recommendations/index.html

6https://view.na.sobi.com/?qs=9713b41b18c474b225f1031f963d36014b69f952c7c5be78af7f8900b5782d84e56dc 8ead77a3c7f182bb33896620c515757d35ce23541a9b73aa73634f19af5ceee6279732eece0445d85a6031ade04