COLORADO
Department of Health Care Policy & Financing

Special Provider Bulletin – Synagis® Vaccine Benefit

Reference: B2500529

Sept 2025

Table of Contents

Prevention of Respiratory Syncytial Virus (RSV)

Nirsevimab

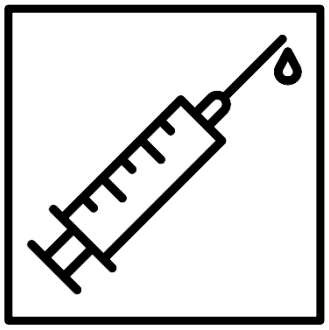
Nirsevimab is a covered benefit for members under two (2) years of age without cost-sharing, effective August 3, 2023.

Clesrovimab

Effective June 26, 2025, clesrovimab is a covered benefit for infants aged less than eight (8) months who are born during or entering their first Respiratory Syncytial Virus (RSV) season. There is no cost-sharing for this benefit.

Nirsevimab and clesrovimab will be referred to, collectively, as “long-acting monoclonal antibodies.” Children who should receive a long-acting monoclonal antibody but have not yet done so, may receive a long-acting monoclonal antibody at any time during the RSV season.

All infants eligible for a long-acting monoclonal antibody should receive a long-acting monoclonal antibody. Palivizumab should be administered to eligible high-risk patients only if a long-acting monoclonal antibody is unavailable. An infant should receive one (1) dose of a long-acting monoclonal antibody if Palivizumab was administered initially for the season and less than five (5) doses were administered. No further Palivizumab should be administered. Members may not receive Palivizumab after receiving a long-acting monoclonal antibody in the same season.



Improve health care equity, access and outcomes for the people we serve while saving Coloradans money on health care and driving value for Colorado.

Current Procedural Terminology (CPT) codes 90380 or 90381 should be used in nirsevimab claims as well as either administration code 96380 or 96381. CPT code 90382 should be used in clesrovimab claims as well as administration code 96380 or 96381. Do not report immunization administration codes 90461–90462 or 90471–90472 for the injection of nirsevimab or clesrovimab.

Visit the Provider Rates and Fee Schedule web page under the Immunization Rate Schedule section to locate the rates.

Providers must enroll in the Vaccines for Children (VFC) program to receive these long-acting monoclonal antibody products and to receive reimbursement for administering a product to Health First Colorado (Colorado's Medicaid program) members.

Synagis® (Palivizumab) Vaccine Benefit

All infants eligible for a long-acting monoclonal antibody should receive a long-acting monoclonal antibody. Synagis® (Palivizumab) should be administered to eligible high-risk patients only if a long-acting monoclonal antibody is unavailable. Infants who receive a long-acting monoclonal antibody should not also receive Palivizumab. An infant should receive one (1) dose of a long-acting monoclonal antibody if Palivizumab was administered initially for the season and less than five (5) doses were administered. No further Palivizumab should be administered.

Synagis® is used to prevent a serious lower respiratory tract disease caused by RSV in pediatric members at high risk for RSV disease. Synagis® is administered by intramuscular injections at 15 milligrams (mg) per kilogram (kg) of body weight once a month during expected periods of RSV frequency in the community. Requests for Synagis® that do not meet the American Academy of Pediatrics (AAP) indications will be denied. Members may appeal this decision and must follow the normal member appeal process.

Time Spans

The 2025-2026 Synagis® season starts October 1, 2025, and will end April 1, 2026. Health First Colorado will accept Prior Authorization Requests (PARs) for Synagis® effective October 1, 2025.

A maximum of five (5) doses will be approved. The Department of Health Care Policy & Financing (the Department) will continue to monitor RSV reporting and reassess Health First Colorado member needs based on the Centers for Disease Control and Prevention (CDC) virology reporting and AAP guidance.

The Colorado RSV season typically has a later onset than other states (i.e., starts closer to the end of December). Visit the CDC website for area virology trend reporting. Providers should schedule the member's Synagis® doses accordingly.

Dosage

Dosage is a maximum of five (5) doses at a dosing interval of no fewer than 26 days between injections.

Coverage and Reimbursement

Coverage criteria used by the Department is based on the 2023 Advisory Committee on Immunization Practices (ACIP) and AAP recommendations for nirsevimab and clesrovimab, as well as the AAP 2014 for RSV prophylactic therapy. The AAP did not change recommendations for RSV after a review of new data in 2017, and the recommendations were reaffirmed in 2019.

Providers should bill less than the reimbursement maximum per unit if the 50-mg vial is split between two (2) members. No more than one (1) 50-mg vial will be allowed per month under the pharmacy benefit. For example, if 100 mg is needed, use a 100-mg vial rather than two (2) 50-mg vials.

Product Availability

Providers are advised that in August of 2025, the manufacturer of Synagis® announced their intention to discontinue the product at the end of 2025.

Dispensing Guide (For Pharmacy Administration Only)

Weight	Dosage	Dispense Units
Up to 3.3 kg	Up to 49.5 mg	1 x 50-mg vial
3.4 kg to 6.6 kg	51 mg to 99 mg	1 x 100-mg vial
6.7 kg to 10 kg	100.5 mg to 150 mg	1 x 100-mg vial + 1 x 50-mg vial
10.1 kg to 13.3 kg	151.5 mg to 199.5 mg	2 x 100-mg vials
13.4 kg to 16.6 kg	201 mg to 249.5 mg	2 x 100-mg vials + 1 x 50-mg vial
16.7 kg to 20 kg	250.5 mg to 300 mg	3 x 100-mg vials

Prior Authorization Request (PARs) Submission Methods

Follow the most appropriate submission process of the two (2) described below.

Pharmacy Benefit PARs

Synagis® administered in the home or at a long-term care facility is billed via the pharmacy benefit and requires a Prior Authorization Request (PAR) be submitted to Prime Therapeutics. Pharmacy benefit PARs for in-office or clinic administration will be considered if home health services are not available to a patient. Refer to Appendix P - Pharmacy Benefit Prior Authorization Procedures and Criteria located on the Pharmacy Resources web page under the Prior Authorization Policies section to see the PARs that will be approved only for members meeting the criteria. Contact the Prime Therapeutics Pharmacy Call Center at 800-434-5725 to request additional clinical consideration after a denial and an expanded (pharmacist) review.

Fax PARs to Prime Therapeutics at 800-434-5881 via the Synagis® PAR Form, located on the Provider Forms web page under the Synagis® Prior Authorization Request Form drop-down.

Medical Benefit PARs

Synagis® administered in a doctor's office, hospital or clinician's office as a medical benefit requires that a PAR be submitted to the Department's Utilization Management (UM) vendor Acentra Health's online PAR portal, Atrezzo®. "Medical Benefit" is defined as being administered in the practitioner's office or hospital outpatient setting.

Note: Synagis® may be billed through the pharmacy benefit if the patient cannot access home health services for administration in the patient's home with an approved pharmacy benefit PAR.

The only CPT code available this season is for the Healthcare Common Procedure Coding System (HCPCS) description of 50 mg.

- Calculate the billing unit need based on a 50-mg dosage. Requested items per month will be equal to how many 50 mg are required per dose.

  For example:

Dose	Units Per Month
50-mg dose	1 unit/month
100-mg dose	2 units/month
150-mg dose	3 units/month
200-mg dose	4 units/month

- Be sure to use CPT code 90378 (includes both 50-mg and 100-mg vials). Providers will not be required to enter the National Drug Code (NDC) on the prior authorization, only the CPT code.

Visit the ColoradoPAR Program web page to review the provider resources for information on how to submit a PAR using Atrezzo®. Providers may also contact Acentra Health for assistance at:

- Acentra Health Customer Service: 720-689-6340
- Acentra Health Provider Issue email: COProviderIssue@kepro.com

Contact the Department's UM Team at HCPF_UM@state.co.us with questions about the PAR process or with escalated concerns regarding Synagis® PARs.

PARs Criteria and Guidelines

Prior authorization is required for pharmacy and medical benefit requests and will be approved as follows:

- No more than five (5) doses per season are allowed. Five doses provide more than six (6) months of protective serum concentration.
- Synagis® is not recommended for controlling outbreaks of healthcare-associated disease.
- Synagis® is not recommended for prevention of healthcare-associated RSV disease.
- Infants born later in the season may require fewer than five (5) doses to complete therapy to the end of the season.
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
- Synagis® is not recommended to prevent wheezing, nosocomial diseases or treatment of RSV.
- Synagis® is not routinely recommended for patients with a diagnosis of Down syndrome unless they also have a qualifying indication listed below.
- Synagis® should not be administered if Beyfortus® (nirsevimab-alip) or Enflonsia® (clesrovimab) has been administered.
- An infant should receive one (1) dose of nirsevimab or clesrovimab, if available, if Synagis® is initiated for the season and less than five (5) doses were administered. No further Synagis® should be administered.

In the first year of life, Synagis® is recommended for:

- Infants born before 29 weeks, 0 days gestation.
- Infants born before 32 weeks, 0 days gestation and with Chronic Lung Disease (CLD) of prematurity and requirements of >21% oxygen for at least 28 days after birth.
- Infants with hemodynamically significant heart disease (acyanotic heart disease who are receiving medication to control Congestive Heart Failure (CHF) and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension) and were born within 12 months of the onset of the RSV season.
- Infants who undergo cardiac transplantation during the RSV season.
- Infants with cyanotic heart defects and in consultation with a pediatric cardiologist and have requirements of >21% oxygen for at least 28 days after birth and continue to require medical intervention (supplemental oxygen, chronic corticosteroid or diuretic therapy).
- Infants with neuromuscular disease or pulmonary abnormality and an inability to clear secretions from the upper airways.
- Infants who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation or are receiving chemotherapy).
- Infants with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise.

In the second year of life, Synagis® is recommended for:

- Children born before 32 weeks, 0 days gestation and with CLD of prematurity and requirements of >21% oxygen for at least 28 days after birth and continue to require medical intervention (supplemental oxygen, chronic corticosteroid or diuretic therapy).

- Children who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation or are receiving chemotherapy).
- Children with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) or weight-for-length less than the 10th percentile.
- Children who undergo cardiac transplantation during the RSV season.

Additional PAR Instructions

- All pharmacy Synagis® PARs must be signed by the prescribing physician, even if submitted by a home health agency or long-term care facility.
- Members or providers may appeal Synagis® prior authorization denials through the normal member appeals process.
- Synagis® given in a doctor's office, hospital or dialysis unit is to be billed directly by those facilities as a medical benefit. Synagis® may be a pharmacy benefit only if the medication is administered in the member's home or long-term care facility, or when administered in a doctor's office because the patient cannot access home health services.

Visit the Provider Forms web page under the Synagis® Prior Authorization Request Form drop-down to access the Synagis® PAR Form.

Guidelines

The use of coverage criteria based on the recommendations of the American Academy of Pediatrics (AAP) 2014 for RSV prophylactic therapy is being continued alongside the 2023 Advisory Committee on Immunization Practices (ACIP) and AAP recommendations for nirsevimab. The AAP 2014 recommendations were unchanged in 2017 after reviews of new data by the Committee on Infectious Diseases (COID) and the Subcommittee on Bronchiolitis, and the policy statement was reaffirmed in February 2019.

Per the AAP, "Evidence of these falling rates of RSV hospitalizations, along with new data about which children are at highest risk of RSV hospitalization, guided the AAP recommendation that Palivizumab prophylaxis be limited to infants born before 29 weeks gestation, and to infants with certain chronic illnesses like congenital heart disease or chronic lung disease."

The guidelines and evidence have been reviewed by the Department, and the Department agrees with the AAP statement. Synagis® is used to prevent serious lower respiratory tract disease caused by RSV in pediatric members at high-risk for RSV disease. Synagis® is administered by intramuscular injections of 15 mg per kg of body weight once a month during expected periods of RSV frequency in the community. Requests for Synagis® that do not meet the AAP indications listed on the Synagis® PAR Form will be denied.

Note: A separate Synagis® PAR process exists for Child Health Plan *Plus* (CHP+) State Managed Care Network members. Contact Colorado Access at 800-511-5010 with questions regarding this process.

Billing Instructions

Pharmacy Benefit

Pharmacy claims will be limited to one (1) 50-mg vial per 26-day period. For example, to achieve a dose of 240 mg, the pharmacy must submit its claim for one 50-mg vial (NDC 60574-4114-01) and two (2) 100-mg vials (NDC 60574-4113-01).

Synagis® may only be a pharmacy benefit if the medication is administered in the member's home or long-term care facility, or when administered in a doctor's office because a patient cannot access home health services.

Medical Benefit - Professional or Institutional Claims

Providers administering Synagis® in an office or outpatient setting must use CPT code 90378 and the NDC of the medication administered to the member on the professional claim submittal via the Provider Web Portal or when submitting an 837 Professional (837P) electronic transaction.

- Providers may not ask members to obtain Synagis® from a pharmacy and take it to the practitioner's office for administration.
- Reimbursement is based on one (1) unit increments of 50 mg of Synagis®.
- Synagis® given in a doctor's office, hospital or dialysis unit is to be billed directly by those facilities as a medical benefit. Synagis® may only be a pharmacy benefit if the medication is administered in the member's home or long-term care facility, or when administered in a doctor's office because a patient cannot access home health services.

Contact Christina Winship at Christina.Winship@state.co.us with medical benefit Synagis® questions.

Synagis® and Home Health Agencies

Home administration of Synagis® is limited to members approved for home health, including those newly enrolled or members already receiving home health services. This means that members cannot get Synagis® via home health unless they would otherwise qualify for home health. The agency must administer the Synagis® injections in compliance with Colorado Rules and Regulations. The number of visits the home health agency provides for the sole purpose of administering Synagis® should equal the number of Synagis® doses for which the physician or allowed practitioner has ordered. The home health agency will bill for administration, not for Synagis® itself. Synagis® will be billed through the pharmacy. These visits cannot exceed five (5) standard Registered Nurse (RN) visits.

Contact HomeHealth@state.co.us with home health policy questions.

Vaccine Counseling for RSV Monoclonal Antibody (MAB) Guidance and Preventive Medicine Counseling Codes

Health First Colorado covers vaccine counseling visits in which healthcare providers talk to families about the importance of vaccination. Providers should bill Current Procedural Terminology (CPT) codes G0310, G0311, G0312, G0313, G0314 or G0315 for visits in which healthcare providers give counseling about the importance of vaccination. Providers should include modifier CR for all COVID-19 vaccine counseling-only visits. Providers should not bill for the vaccine counseling code and the vaccine administration code on the same date of service when vaccine administration codes are inclusive of counseling.

CPT G0310, G0311, G0312, G0313, G0314 or G0315 can be billed at only one (1) visit for each member per day, but there are no quantity limits for the number of times this education is provided to an individual member.

Keep documentation in the member's chart that shows the duration of counseling and a list of the prevention topics covered during counseling. A separate Evaluation and Management (E/M) visit code may be reported with modifier 25 if there is a separately identifiable E/M service performed outside of vaccine counseling and immunization administration.

Contact Christina Winship at Christina.Winship@state.co.us with questions.

Contacts

Billing and Claims Contact

Provider Services Call Center

Pharmacy Contacts

Prime Therapeutics Call Center

Phone: 1-800-424-5725
Fax: 1-800-424-5881

Colorado PAR Contacts

Acentra Call Center

Phone: 720-689-6340
Email: COProviderIssue@kepro.com