COLORADO
Department of Health Care Policy & Financing

Special Provider Bulletin – Synagis® Vaccine Benefit

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Synagis® (Palivizumab) Vaccine Benefit

Synagis® is used to prevent a serious lower respiratory tract disease caused by Respiratory Syncytial Virus (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 2023-2024 Synagis® season starts October 1, 2023, and will end April 1, 2024.

Health First Colorado (Colorado's Medicaid program) will accept Prior Authorization Requests (PARs) for Synagis® effective October 1, 2023.

The Synagis® season will begin earlier than in years prior due to the atypical RSV activity seen across Colorado in recent years.

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 Centers for Disease Control and Prevention (CDC) virology reporting and AAP guidance.

The Colorado RSV season typically has a later onset (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 is used by the Department based on the 2023 Advisory Committee on Immunization Practices (ACIP) and AAP recommendations for nirsevimab, 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.

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 Requests (PARs) Submission Methods

Follow the most appropriate submission process of the two described below.

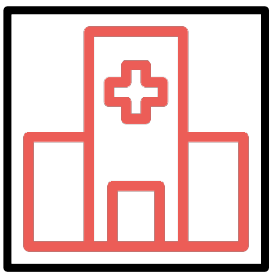
Pharmacy Benefit Prior Authorization Requests (PARs)

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

Submit PARs to Magellan via the Synagis® PAR Form (Fax: 800-434-5881), located on the Provider Forms web page under the Synagis® Prior Authorization 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, through the online PAR portal, Atrezzo®. "Medical Benefit" is defined as being administered in the practitioner's office or hospital outpatient setting.



Note: As indicated above, 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 Current Procedural Terminology (CPT) code available this season is for the Healthcare Common Procedure Coding System (HCPCS) description of 50 milligrams (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:
  - 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.

Review the provider resources available on the ColoradoPAR Program web page for additional information on how to submit a PAR using Atrezzo. Providers may also contact Acentra Health for additional 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.

Prior Authorization Requests (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. Five (5) 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 Respiratory Syncytial Virus (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 disease 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) has been administered.
- If Synagis® is initiated for the season and less than five (5) doses were administered, the infant should receive one (1) dose of nirsevimab if it is available. 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 ***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*** born within 12 months of 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*** 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 ***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 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 the patient cannot access home health services.

Visit the Provider Forms web page 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, 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 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 any 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 (1) 50-mg vial (National Drug Code [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. Electronically submitted claims must use CPT code 90378 and the NDC of the medication administered to the member.

- 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 Prior Authorization Requirement (PAR) for pediatric long-term home health is currently suspended. However, the agency can still 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 any home health policy questions.

Gainwell Technologies Contacts

Provider Services Call Center
1-844-235-2387

Gainwell Technologies Mailing Address
P.O. Box 30
Denver, CO 80201

Magellan Rx Management Contacts

Pharmacy Call Center
Phone: 1-800-424-5725
Fax: 1-800-424-5881

Acentra Health

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720-689-6340

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