COLORADO
Department of Health Care Policy & Financing

SYNAGIS® INFORMATION SHEET

This information sheet does not need to be faxed or submitted with the Prior Authorization Request (PAR) Form as it is intended to provide information only. Refer to the Synagis® 2024-2025 Provider Bulletin on the Bulletins web page for more information.

The 2024-2025 Synagis® (palivizumab) season will begin October 1, 2024, and end April 1, 2025. Health First Colorado (Colorado's Medicaid program) will approve requests for a maximum of five (5) doses at a dosing interval of no fewer than 26 days between injections. Requests for doses exceeding the five (5) dose maximum or beyond the season end date will be **DENIED**. Providers should be aware that the Colorado Respiratory Syncytial Virus (RSV) season typically has a later onset (i.e., starts closer to the end of December) and should schedule their Synagis® doses accordingly. Area virology trend reporting is available on the Centers for Disease Control and Prevention (CDC) website.

Effective October 1, 2024, Health First Colorado will begin accepting PARs for Synagis®. All requests for Synagis® (palivizumab) require prior authorization. All requests for administration in the home should be submitted for payment through the pharmacy benefit, which must be submitted on the Health First Colorado Synagis® Pharmacy Benefit PAR Form located below. **No other forms will be accepted**. The form may be faxed to 1-800-424-5881. All Synagis® pharmacy benefit PARs must be signed by the prescribing physician, even if submitted by an agent of the prescriber. Pharmacy benefit PARs for office administration will be considered if the prescriber can attest to a documented home health service access issue for the member. **All other requests for administration in the provider's office or facility should be submitted through the ColoradoPAR Program. Visit the ColoradoPAR Program web page for information on how to a submit a medical PAR for Synagis®.**

The Department of Health Care Policy & Financing (the Department) is continuing use of coverage criteria based on the recommendations of the American Academy of Pediatrics (AAP) 2014 for RSV prophylactic therapy and the 2024 Advisory Committee on Immunization Practices (ACIP) and AAP Recommendations for nirsevimab. 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 Department has reviewed the guidelines and evidence and 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 Health First Colorado Synagis® Pharmacy Benefit PAR Form below will be **DENIED**. For additional clinical consideration after a pharmacy benefit denial, contact the Prime Therapeutics Pharmacy Call Center at 1-800-434-5725 to request an expanded (pharmacist) review. Members or providers may appeal Synagis® prior authorization denials through the normal appeals process.

Dispensing and Prior Authorization of Synagis® Immune Globulin

- No more than one (1) 50-mg vial will be allowed per month through the pharmacy benefit. As an example, if 100 mg is needed, use a 100-mg vial and not two (2) 50-mg vials. The chart below provides details regarding the pharmacy coverage guidelines.

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

Reminder: The provider must retain copies of all documentation for six (6) years (10 C.C.R. 2505-10, Section 8.040.2).

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SYNAGIS® PHARMACY BENEFIT* PRIOR AUTHORIZATION REQUEST FORM

Phone: 1-800-424-5725 **Fax:** 1-800-424-5881 **Request Date:** / /

*Pharmacy Benefit is defined as being administered in the client's home.
For doses not administered in the patient's home (example: physician's office), visit the ColoradoPAR Program web page for information on how to submit a PAR to the Colorado PAR Program.

CLIENT INFORMATION

LAST NAME:

FIRST NAME:

MEDICAID ID NUMBER:

DATE OF BIRTH: – –

GENDER: ☐ Male ☐ Female

CURRENT WEIGHT: kg

UNITS PER MONTH: ☐ 0 OR ☐ 1 X 50MG X 100MG

NUMBER OF MONTHS REQUESTED (NO MORE THAN 5):

TODAY'S DATE:

DATES OF SERVICE: FROM: TO:

PROVIDER INFORMATION

PHYSICIAN LAST NAME:

PHYSICIAN FIRST NAME:

STREET ADDRESS:

CITY: **STATE:** **ZIP:**

PHONE NUMBER: – –

FAX NUMBER: – – –

NPI NUMBER:

DEA NUMBER: –

Health First Colorado will approve Synagis® PARs for clients under the age of two (2), at the start of the current RSV season, who meet one of the following conditions. **Requests will be approved for a maximum of five (5) doses, at a dosing interval of no fewer than 26 days between refills.** Requests will be accepted beginning October 1, 2024. Providers must attest to the Synagis® administration location.

For infants in the first year of life: (Check ***at least*** one of the following **AND** indicate diagnosis code)

- ☐ Any infant up to 12 months of age, born before 29 weeks 0 days gestation
- ☐ For infants born before 32 weeks 0 days gestation **AND** Chronic Lung Disease (CLD) of prematurity with greater than 21% oxygen use for at least 28 days after birth — ICD 10-CM Code:
- ☐ An infant with cystic fibrosis with clinical evidence of CLD **AND/OR** nutritional compromise — ICD 10-CM Code:
- ☐ An infant with neuromuscular disease or pulmonary abnormality **AND** is unable to clear secretions from the upper airways — ICD 10-CM Code:
- ☐ An infant who undergoes cardiac transplantation during the RSV season — ICD 10-CM Code:
- ☐ Infants with hemodynamically significant heart disease (acyanotic heart disease) defined as having one or more of the following: — ICD 10-CM Code:
  - ☐ Infants receiving medication to control congestive heart failure and will require cardiac surgical procedures
  - ☐ Infants with moderate to severe pulmonary hypertension
- ☐ An infant with cyanotic heart defects **AND** in consultation with a pediatric cardiologist **AND** ***both*** of the following:
  - ☐ Requirement of >21% oxygen for at least 28 days after birth — ICD 10-CM Code:
  - ☐ Continues to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy)
- ☐ An infant who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) — ICD 10-CM Code:

Revision Date: 09/09/2024

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Phone: 1-800-424-5725 **Fax:** 1-800-424-5881 **Request Date:** ☐☐ / ☐☐ / ☐☐☐☐

*Pharmacy Benefit is defined as being administered in the client's home.
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For children in the second year of life: (Check ***at least*** one of the following **AND** indicate diagnosis code)

- ☐ For children born before 32 weeks 0 days gestation **AND** Chronic Lung Disease (CLD) of prematurity **AND** Requirement of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid or diuretic therapy) ICD 10-CM Code: _____
- ☐ A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) ICD 10-CM Code: _____
- ☐ Children with manifestation of severe lung disease: (Choose one of the following **AND** add Diagnosis code):
  - ☐ 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** ICD 10-CM Code: _____
  - ☐ Weight for length less than the 10th percentile. ICD 10-CM Code: _____
- ☐ A child who undergoes cardiac transplantation during the RSV season

Has the member received prior doses of Synagis®? ☐Yes ☐No

If yes, what date was the last dose received? _____

Has the member received Beyfortus® (nirsevimab)? ☐Yes ☐No

If no, provider attests that Beyfortus® is not available at the initiation of Synagis® treatment and upon Beyfortus® availability Synagis® will be discontinued. ☐Yes ☐No

Provider attests that Synagis® will be administered in the patient's home or long-term care facility. ☐Yes ☐No

If no, doses administered in a physician's office or clinic must be billed through the medical benefit unless a patient cannot access home health services.

Provider attests home health services are not available to the patient. ☐Yes ☐No

If no, visit the ColoradoPAR Program web page for information on how to submit a medical PAR for Synagis®.

Prescriber Signature (Required)_____ **Date** _____

By signature, the Prescriber confirms the criteria information above is accurate and verifiable in-patient records.

Fax This Form To:
HEALTH FIRST COLORADO PRIOR AUTHORIZATIONS
FAX NUMBER: 1-800-424-5881 (FORMS NEED TO BE FAXED FOR APPROVAL)
PA HELP DESK: 1-800-424-5725

Revision Date: 09/09/2024