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® 2021-2022 Provider Bulletin for more information.

The 2021-2022 Synagis® (palivizumab) season will begin August 17, 2021 and end April 15, 2022. Health First Colorado will approve requests at a dosing interval of no fewer than 26 days between injections. Requests for doses exceeding 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 August 17, 2021, 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. The form can be found in the Provider Services Forms section of the Department's website. **No other forms will be accepted**. The form can be faxed to 1-800-424-5881 or completed by calling the Pharmacy Prior Authorization Helpdesk at 1-800-424-5725. All Synagis® Pharmacy PARs must be signed by the prescribing physician, even if submitted by an agent of the prescriber. **All requests for administration in the provider's office or facility should be submitted through the Colorado PAR Program. Please visit https://hcpf.colorado.gov/par for information on how to a submit a medical PAR for Synagis®.**

The Department is continuing use of coverage criteria based on the recommendations of the American Academy of Pediatrics (AAP) 2014 for Respiratory Syncytial Virus (RSV) prophylactic therapy. These recommendations have been updated since the 2009 AAP guidelines. 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 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 Health First Colorado Synagis® Pharmacy Benefit PAR Form online will be **DENIED**. To request additional clinical consideration after a pharmacy benefit denial, first contact Magellan Rx Management Pharmacy Call Center (1- 800-434-5725) for a home administration (pharmacy benefit) and request an expanded (pharmacist) review. For office/outpatient administration (medical benefit), please visit https://hcpf.colorado.gov/par to submit a medical prior authorization for Synagis®.
Members or providers may appeal Synagis® prior authorization denials through the normal appeals process.

Dispensing and Prior Authorization of Synagis® Immune Globulin

- Please note that no more than one (1) 50mg vial will be allowed per month through the pharmacy benefit. As an example, if 100mg is needed use a 100mg vial and not two (2) 50mg 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 client's home
For doses not administered in the patient's home (ex. physician's office), please visit https://hcpf.colorado.gov/par **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® prior authorization requests for clients under the age of two, at the start of the current RSV season, who meet one of the following conditions**. Requests will be approved at a dosing interval of no fewer than 26 days between refills.** Requests will be accepted beginning August 17, 2021. 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: _____

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

*Pharmacy Benefit is defined as being administered in client's home
For doses not administered in the patient's home (ex. physician's office), please visit https://hcpf.colorado.gov/par **for information on how to submit a PAR to the Colorado PAR Program**

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? ☐ Yes ☐ No

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

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

If no, for doses not administered in the patient's home (ex. physician's office), please visit **https://hcpf.colorado.gov/par** 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: 01/04/2022