COLORADO
Department of Health Care Policy & Financing

Special Provider Bulletin – Synagis® Vaccine Benefit

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Synagis® (Palivizumab) Vaccine Benefit

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Synagis® (Palivizumab) Vaccine Benefit

Synagis® is used to prevent 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 15mg 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 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 2022-2023 Synagis season will begin October 4, 2022 and end April 28, 2023.

Effective October 4, 2022, Health First Colorado (Colorado's Medicaid program) will begin accepting Prior Authorization Requests (PARs) for Synagis®.

Due to the atypical RSV activity currently seen across Colorado, the Synagis® season will begin earlier than in years prior. A maximum of five (5) doses will be approved. The Department will continue to monitor RSV reporting and reassess Health First Colorado member needs based on CDC virology reporting and AAP guidance.

The Colorado RSV season typically has a later onset (i.e. starts closer to the end of December). Area virology trend reporting is available on the Centers for Disease Control and Prevention (CDC) website. Providers should schedule the member's Synagis® doses accordingly.

Dosage

Maximum of five (5) doses, at a dosing interval of no fewer than 26 days between injections.

Coverage and Reimbursement

The Department of Health Care Policy & Financing (the Department) uses coverage criteria based on the American Academy of Pediatrics (AAP) 2014 for Respiratory Syncytial Virus (RSV) prophylactic therapy. The AAP did not change recommendations for RSV after review of new data in 2017 and they were reaffirmed in 2019.

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

Please follow the most appropriate submission processes described below.

Home Administration (Limited to Members Approved for Home Health)

Pharmacy Synagis® claims (claims billed through a pharmacy for home administration), prior authorization will only be approved for members meeting the criteria listed in Appendix P, available on the Pharmacy Resources web page under the Prior Authorization Policies section. To request additional clinical consideration after a denial, contact Magellan Rx Management Pharmacy Call Center (1-800-434-5725) for a home administration (pharmacy benefit) and request an expanded (pharmacist) review.

Submit PARs to Magellan via the Synagis® Pharmacy Benefit Prior Authorization Request Form (Fax: 1-800-434-5881) available on the Provider Forms web page under Synagis® Pharmacy Prior Authorization Form drop-down.

For all Physician's Office or Outpatient Facility Synagis® PAR requests

Synagis® administered in a doctor's office, hospital, or clinician's office as a medical benefit requires that a Prior Authorization Request (PAR) be submitted to the Department's Utilization Management (UM) Vendor, Keystone Peer Review Organization (KEPRO), through their online PAR portal, Atrezzo. "Medical Benefit" is defined as being administered in the practitioner's office or hospital outpatient setting (not given in the member's home).

The only dose available this season is the 50 mg Vial (National Drug Code (NDC) 60574-4114-01). (Please note that the Current Procedural Terminology (CPT) code for the 100mg vial will no longer be accepted.)

- Calculate need based on 50 mg vial – Requested items per month will be equal to how many vials are required per dose (Example: 50mg dose: 1 vial/month, 100mg dose: 2 vials/month, 150mg dose: 3 vials/month, 200mg dose: 4 vials/month)
- Be sure to use CPT Code 90378. Providers will not be required to enter the NDC on the prior authorization, only the CPT code.

The submitted PAR requests may be backdated to October 4, 2022. 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 Kepro for additional assistance at:

Kepro Customer Service: 720-689-6340
Kepro Provider Issue email: coproviderissue@kepro.com

Email the Department's UM Team at hcpf_UM@state.co.us for questions about the PAR process, or for 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 provides more than six (6) months of protective serum concentration.
- Synagis® is not recommended for controlling outbreaks of health care associated disease.
- Synagis® is not recommended for prevention of health care 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.

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

a. Infants born before 29 weeks 0 days gestation
b. 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
c. 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
d. Infants who undergo cardiac transplantation during the RSV season
e. 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)
f. Infants with neuromuscular disease or pulmonary abnormality AND an inability to clear secretions from the upper airways
g. Infants who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)
h. Infants with cystic fibrosis with clinical evidence of CLD AND/OR nutritional compromise

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

a. 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)
b. Children who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)
c. 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.
d. 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.

The Synagis® Pharmacy Benefit Prior Authorization Request Form is available on the Provider Forms web page.

Guidelines

The use of coverage criteria based on the recommendations of the American Academy of Pediatrics (AAP) 2014 for Respiratory Syncytial Virus (RSV) prophylactic therapy is being continued. These recommendations have been unchanged in 2017 after reviews of new data by the Committee on Infectious Diseases and the Subcommittee on Bronchiolitis and also reaffirmed the policy statement in February of 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 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 15mg 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® Pharmacy Benefit Prior Authorization Request Form online 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 claims

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

Medical - Professional or Institutional Claims

Providers administering Synagis® in an office or outpatient setting must use Current Procedural Terminology (CPT) code 90378 and National Drug Codes (NDC) 60574411401 (50 MG/0.5ML vial) 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 NDC 60574411401.

- 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 50mg 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.

Synagis® and Home Health Agencies

The PAR requirement for Pediatric Long-Term Home Health is currently suspended If the member is currently receiving Home Health services, the agency is able to administer the Synagis® injections in compliance with Colorado Rules and Regulations. 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.

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

Keystone Peer Review Organization (Kepro)

Kepro Customer Service
720-689-6340

Kepro Provider Issue Email
coproviderissue@kepro.com