COLORADO
Department of Health Care Policy & Financing

Special Provider Bulletin – Synagis® & Seasonal Influenza Vaccines Reference: B1900438

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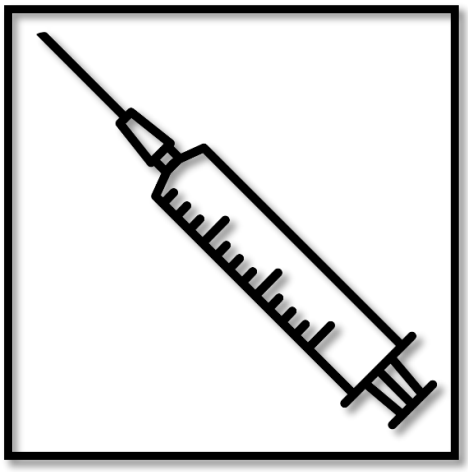
Synagis® (Palivizumab) Vaccine Benefit

Seasonal Influenza Vaccine



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 2019-2020 Synagis® season will begin December 2, 2019, and end April 30, 2020.

Effective November 18, 2019, Health First Colorado (Colorado's Medicaid Program) will begin accepting Prior Authorization Requests (PARs) for Synagis®.

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

Dosage

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

Reimbursement of Synagis®

Reimbursement for Synagis® administered in a physician's office is $1,498.30 for each 50mg/0.5mL unit. When billing, providers should calculate how much of a unit is used per member per dose.

Improving health care access and outcomes for the people we serve while demonstrating sound stewardship of financial resources.

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.

Reimbursement for pharmacy Synagis® claims (claims billed through a pharmacy for home health administration) is $1,498.30 per 50mg unit. 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

Home Administration (Limited to Members Approved for Home Health)

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 pharmacy Synagis® claims (claims billed through a pharmacy for home health 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, first contact Magellan Rx Management Pharmacy Call Center (1-800-434-5725) for a home administration (pharmacy benefit) and request an expanded (pharmacist) review. If additional consideration is needed, escalate to the state pharmacist at fax number 303-866-3590.

Physician's Office or Outpatient Facility Administration

The Department's prior authorization vendor, eQHealth Solutions, will be responsible for reviewing the medical necessity of medical PAR for Synagis®. "Medical Benefit" is defined as being administered in the practitioner's office or hospital outpatient setting (not given in the member's home). Providers will be required to submit a PAR to be reviewed by eQHealth Solutions through the PAR portal, eQSuite®. Please note that for the 19-20 season, medical PARs for Synagis® will only need the CPT code submitted on the prior authorization request with eQHealth.

Visit the Prior Authorization Website for information and training on submitting a medical PAR for Synagis®. Contact eQHealth's Provider Relations Specialist at co.pr@eqhs.org, or contact eQHealth customer service at 888-801-9355 or finally you may submit an online helpline ticket through eQSuite® for any questions or to request assistance with submitting a PAR.

Prior Authorization Requests (PARs) Criteria and Guidelines

Prior authorization is required for pharmacy and medical 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 recommend 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. Children 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. Children 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. Infants 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. Infants 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

- For all Physician's Office or Outpatient Facility Synagis® PAR requests:
  - The only dose available this Season: 50 mg Vial (NDC 60574-4114-01). (Please note the 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.
- All pharmacy Synagis® PARs must be signed by the prescribing physician, even if submitted by an infusion or long-term care facility.
- Members or providers may appeal Synagis® prior authorization denials through the normal member appeals process.

Guidelines

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 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

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.

Contact Alexandra Koloskus at Alexandra.Koloskus@state.co.us or 303-866-6814 with questions.

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® and Home Health Agencies

If a member has been approved for Synagis® injections to be delivered in the member's home by a Home Health Agency (HHA), the HHA must submit the Long-Term Home Health (LTHH) Prior Authorization Request (PAR) to the ColoradoPAR Program for the visits related to the Synagis® injections. If the member has an active LTHH PAR in place, then the agency is not required to submit a separate PAR for the Synagis® injections and should use the current approved PAR to administer the Synagis® injections. The number of visits requested by the HHA for the sole purpose of administering Synagis® should equal the number of Synagis® doses for which the member has been approved. The HHA will bill for administration, not for the Synagis® itself. The Synagis® will be billed through the pharmacy.

These visits cannot exceed five (5) standard registered nurse (RN) visits, if approved. The provider's order for or approval of the Synagis® injections must be included with the PAR request.

Contact ColoradoPAR.com for Prior Authorization Questions or Alexandra Koloskus at Alexandra.Koloskus@state.co.us for Home Health policy questions.

Seasonal Influenza Vaccine

Seasonal Influenza Vaccine is a Benefit for Children and Adults

Place of Service

Health First Colorado does not reimburse any seasonal influenza vaccinations provided at pharmacies.

For Children/Adolescents (Age 18 and Under)

A free seasonal influenza vaccine is available through the Vaccines for Children (VFC) Program for all Health First Colorado enrolled children/adolescents (age 18 and under).

Who Should Get Seasonal Influenza Vaccine (All Ages)?

The seasonal influenza vaccine is recommended for individuals who are six (6) months of age or older. Additionally, a seasonal influenza vaccine is strongly recommended for those who, because of age or underlying medical conditions, are at increased risk for complications from influenza.

The following groups are considered high risk and are strongly recommended to get a yearly flu vaccine:

- Children ages six (6) months through 23 months;
- People with chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic, hematologic or metabolic disorders (including diabetes mellitus);
- People who are immunosuppressed (including immunosuppression caused by medications or by Human Immunodeficiency Virus (HIV);
- Women who are or will be pregnant during influenza season;
- Children ages two (2) through 18 years who receiving long-term aspirin therapy and who might therefore be at risk for experiencing Reye Syndrome after influenza virus infection;
- Residents of nursing homes and other chronic-care facilities that have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration;
- People who are household contacts and/or caregivers of children younger than five (5) years and adults age 50 years and older, with particular emphasis on vaccinating contacts of children aged younger than six (6) months; and
- Health care workers, household contacts or caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

Dosages

At-risk children should receive seasonal influenza vaccines in an age-appropriate dosage (0.25 ml if age 6-35 months or 0.5 ml if age is greater or equal to three (3) years). Two (2) doses of the vaccine are recommended for children age six (6) months through eight (8) years if they have not been previously vaccinated for seasonal influenza. For new information on the two (2) approaches for determining the number of doses required for children ages six (6) months through eight (8) years, refer to the Centers for Disease Control (CDC) Update: Influenza Activity — United States and Worldwide, May 19-September 28, 2019, and Composition of the 2020 Southern Hemisphere Influenza Vaccine.

Children/Adolescents and Adults

Children/Adolescents

For new information on the two (2) approaches for determining the number of doses required for children age six (6) months through eight (8) years, refer to the Update: Influenza Activity — United States and Worldwide, May 19-September 28, 2019, and Composition of the 2020 Southern Hemisphere Influenza Vaccine.

- Information on Febrile Seizures in young children associated with influenza Vaccinations can be found at the Center for Disease Control: Febrile Seizures Following Childhood Vaccinations, Including Influenza Vaccination. The US Food and Drug Administration (FDA) approved a seasonal quadrivalent LAIV (live

attenuated influenza vaccine), FluMist Quadrivalent (MedImmune). View a full list of approved vaccines on the Center for Disease Control website.

- For more information on the Influenza Vaccines for 2018-2019, please see the Centers for Disease Control (CDC) Update: Influenza Activity — United States and Worldwide, May 19-September 28, 2019, and Composition of the 2020 Southern Hemisphere Influenza Vaccine
- The Advisory Committee on Immunization Practices (ACIP) voted for two seasons, (2016-2017 and 2017-2018), that live attenuated influenza vaccine (LAIV), also known as the "nasal spray" flu vaccine, not be used. However, ACIP voted in February 2018 to recommend that for the 2018-2019 season, vaccination providers may choose to administer any licensed, age-appropriate influenza vaccine (IIV, RIV4, or LAIV4). LAIV4 is an option for those for whom it is appropriate in the 2019-20 season.
- The ACIP reviewed the use of the influenza vaccine on those who have an egg allergy or have a history of having an egg allergy. The ACIP's recommendations for the 2018-2019 influenza season for this population can be found at the Centers for Disease Control (CDC) Update: Influenza Activity — United States and Worldwide, May 19-September 28, 2019, and Composition of the 2020 Southern Hemisphere Influenza Vaccine.

Billing Information for Seasonal Influenza Vaccine

Current Procedural Terminology (CPT) codes **90460**, **90461**, and **90471-90474** for vaccine administration are a benefit and can be billed in conjunction with the vaccine code. Vaccine administration codes **90460** and **90471-90474** will be reimbursed. The immunization administration add-on code for each vaccine component in a given Vaccines for Children (VFC) vaccine, **90461**, will be reimbursed at zero. For members 18 and under, seasonal influenza vaccine reimbursement is limited to an administration fee. Since the vaccines are available at no cost through the VFC Program, providers will only be reimbursed for the vaccine administration fee for members 18 and under.

Refer to the Immunization Rates Schedule located on the Provider Rates & Fee Schedule web page for current immunization rates, including flu shots.

Pharmacies are not an eligible provider and will not be reimbursed for any rendered services.

Additionally, providers who choose to obtain VFC Program eligible vaccines from other suppliers may not request nor receive reimbursement for the vaccine in addition to the administration payment.

Contact Alexandra Koloskus at Alexandra.Koloskus@state.co.us with questions regarding Synagis® policy. Contact the Provider Services Call Center at 1-844-235-2387 with general billing questions and for general provider assistance.

Remember to check the Provider Services web page for new and updated content.

The Pharmacy Prior Authorization Request (PAR) form is available on the Pharmacy Resources web page.

Synagis® Pharmacy Benefit Prior Authorization Request Form

DXC Contacts

DXC Office
Civic Center Plaza
1560 Broadway St, Suite 600
Denver, CO 80202

Provider Services Call Center
1-844-235-2387

DXC 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

eQHealth Contacts

Mailing Address
eQHealth Solutions
Attn: ColoradoPAR program
5802 Benjamin Center Dr, Suite 105
Tampa, FL 33634

Call Center
1-888-801-9355