COLORADO
Department of Health Care Policy & Financing

Special Provider Bulletin – Synagis® & Seasonal Influenza Vaccines Reference: B2000454

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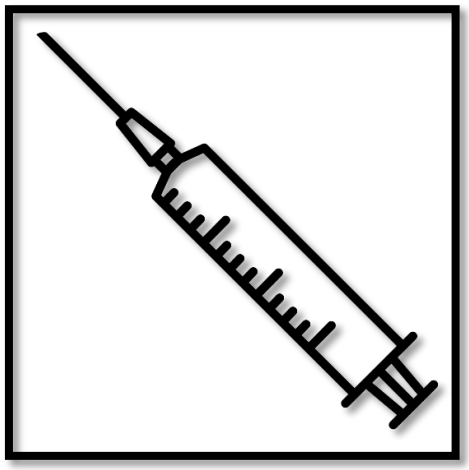
Synagis® (Palivizumab) Vaccine Benefit

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 2020-2021 Synagis® season will begin November 16, 2020, and end April 16, 2021.

Effective November 2, 2020, 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). 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

Home Administration (Limited to Members Receiving Home Health Services)

For 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, first 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 the Synagis® Pharmacy Prior Authorization Request Form drop-down section.

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 2020-2021 season, medical PARs for Synagis® will only need the Current Procedural Terminology (CPT) code submitted on the PAR with eQHealth Solutions.

Visit the Synagis® web page of the ColoradoPAR 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. Providers may also submit an online helpline ticket through eQSuite® with 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. 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 provider, 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 Health First Colorado provider forms web page.

Guidelines

The Department is continuing use of coverage criteria based on the recommendations of the 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 or long-term care facility.

Contact John Lentz at John.Lentz@state.co.us 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® 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, then 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 the Synagis® itself. The Synagis® will be billed through the pharmacy.

These visits cannot exceed five (5) standard registered nurse (RN) visits.

Contact the Department's benefits team at hcpf_benefitsupport@state.co.us with Home Health policy questions.

Seasonal Influenza Vaccine

Seasonal Influenza Vaccine is a Benefit for Children and Adults

Place of Service

Health First Colorado now reimburses select vaccinations provided at pharmacies. Adults may receive their seasonal influenza vaccine at the pharmacy.

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
- 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 Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020-21 Influenza Season.

Children/Adolescents and Adults

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 Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020-21 Influenza Season.

- 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). The FDA has also approved the following quadrivalent injectable vaccines: Fluarix Quadrivalent (GlaxoSmith Kline), Fluzone Quadrivalent (Sanofi Pasteur), and Fluvirin (Novatris).
- For more information on the Influenza Vaccines for 2020-2021, review the Centers for Disease Control (CDC) Prevention and Control of Seasonal Influenza with Vaccines, 2020-21.
- 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.
- 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 2020-2021 influenza season for this population can be found at the Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020-21 Influenza Season.

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. 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 may be an eligible provider and will be reimbursed for eligible 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 Christina Winship at Christina.Winship@state.co.us with questions regarding Synagis® policy. Contact the Provider Services Call Center billing questions and for general provider assistance.

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

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

eQHealth Solutions Contacts

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

Call Center
1-888-801-9355