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Department of Health Care Policy & Financing

Provider Bulletin

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Synagis® & Seasonal Influenza Vaccines

In this issue:

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Synagis® (Palivizumab) Vaccine

The 2016-2017 Synagis® season will begin November 30, 2016, and end April 30, 2017. The Colorado Medical Assistance 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 National Respiratory and Enteric Virus Surveillance System (NREVSS) page of the Centers for Disease Control and Prevention (CDC) website.

Reimbursement and Prior Authorization (PAR) of Synagis®

Reimbursement for Synagis® administered in a physician's office is **$1,386.88 for each 50mg/0.5mL unit**. When billing, providers should calculate how much of a unit is used per member per dose.

Note: The units billed for each dose will be different from the units indicated in the prior authorization request (PAR) approval. The PAR must include all units that will be used over the course of the dosing.

The Department of Health Care Policy and Financing (the Department) is using coverage criteria based on the American Academy of Pediatrics (AAP) 2014 for Respiratory Syncytial Virus (RSV) prophylactic therapy. 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 will be denied. Please see additional information regarding Secondary Reviews of denied pharmacy prior authorization requests (PARs) in the Pharmacy PAR Requests section below. Members may appeal this decision and must follow the normal member appeal process.

Effective November 16, 2016, the Colorado Medical Assistance Program will begin accepting PARs for Synagis®. All requests for Synagis® (Palivizumab) require a PAR. Any PARs received prior to November 16, 2016, will be denied and will need to be resubmitted beginning November 16, 2016.

Pharmacy PAR Requests

All pharmacy PAR requests (Synagis® administered in the home) should be called into the Pharmacy Call Center at 800-365-4944 or faxed to 888-424-9696. An example of the Pharmacy PAR form and an example of how to complete it are attached to this bulletin. The Pharmacy PAR form can be found in the Provider Forms section of the Department's website. No other forms will be accepted.

All requests intended to be administered in the home must use the form located on the Department's website. Please contact the Pharmacy PA Helpdesk at 800-424-5725 with any questions regarding the status of a pharmacy Synagis® PAR or the PAR form.

If additional clinical consideration is requested after denial from the Pharmacy PA Helpdesk for a home administration (pharmacy benefit), please escalate to the state pharmacist at fax number 303-866-3590. For office/outpatient administration (medical benefit), please visit ColoradoPAR.com for information about how to submit a medical prior authorization for Synagis®. Members or providers may appeal Synagis® prior authorization denials through the normal appeals process.

Note: 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 of the Pharmacy Prior Authorization Policies section of the Department's website. In addition, 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). If a member requires therapy outside of the approved age and diagnosis criteria, a PAR must be submitted for approval as a medical benefit (for office administration) for a secondary review of medical necessity.

Medical PAR Requests

All medical PAR requests (office/outpatient administration) must be submitted through the ColoradoPAR Program. Please visit ColoradoPAR.com for information about how to submit a medical PAR for Synagis®. Any medical PAR submitted as a pharmacy PAR will be denied and will need to be re-submitted as a medical PAR through the ColoradoPAR Program. "Medical Benefit" is defined as being administered in the practitioner's office or hospital outpatient setting (not given in the member's home).

Please visit ColoradoPAR for additional information, or you may contact the ColoradoPAR Provider Helpline at 888-801-9355 for any questions or assistance submitting a PAR.

Prior authorization for pharmacy and medical requests is required 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 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 for 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 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:

- All pharmacy Synagis® PARs must be signed by the prescribing physician, even if submitted by an infusion or long-term care facility.

Billing Instructions:

- Providers administering Synagis® in the office must use Current Procedural Terminology (CPT) code 90378 on the CMS 1500 paper claim form or when submitting an 837 Professional (837P) electronic transaction. Electronically submitted claims must include the National Drug Code (NDC) 6057441141.
- 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 50 mg 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.**

Please contact Elizabeth Freudenthal at Elizabeth.Freudenthal@state.co.us or 303-866-6814 with questions.

Note: A separate Synagis® PAR process exists for CHP+ State Managed Care Network members. Any questions regarding this process should be directed to Colorado Access at 303-751-9005 or 800-511-5010 or US Bioservices at 303-706-0053.

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) 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.

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.

Please contact Alexandra Koloskus at Alexandra.Koloskus@state.co.us or 303-866-5578 for questions or additional information regarding HHA injections.

Seasonal Influenza Vaccine

Seasonal Influenza Vaccine is a Benefit for Children and Adults

Place of Service:

Health First Colorado (Colorado's Medicaid Program) does not reimburse any vaccinations provided at pharmacies.

For Children/Adolescents (aged 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).

For Adults (ages 18 and up):

Note: The valid CPT billing codes (**90656, 90658**) are listed in the Billing Information table below for adult seasonal influenza vaccine.

Who Should Get Seasonal Influenza Vaccine?

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, please see the Centers for Disease Control (CDC) Prevention and Control Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunizations Practices (ACIP) – United States, 2015-16 Influenza Season.

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, please see Prevention and Control Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunizations Practices (ACIP) – United States, 2015-16 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 Federal 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 2016-17, please see the Center for Disease Control, Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practices—United States, 2016-17 Influenza Season.

All (Children/Adolescents and Adults)

- The Advisory Committee on Immunization Practices (ACIP) voted in June, 2016, in favor of an interim recommendation that live attenuated influenza vaccine (LAIV), also known as the "nasal spray" flu vaccine, should not be used during the 2016-17 flu season. The CDC presented data to the ACIP that no protective benefit of LAIV could be measured. ACIP continues to recommend annual flu vaccination, with either the inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) for everyone 6 months and older. The CDC has notified VFC programs that manufacturers project that IIV supply should be adequate to meet any increase in demand resulting from the ACIP recommendations. More information can be found at the CDC LAIV page.

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 2015-16 influenza season for this population can be found at the Center for Disease Control, Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practices—United States, 2016-17 Influenza Season.

Billing Information as of October 1, 2016

Code	Description	Valid Ages	Maximum Allowable Reimbursement	VFC Program Benefit
90654	Influenza virus vaccine, split virus, preservative free, for intradermal use (IIV3)	19+	$19.23	
90655	Flu vacc, 6-35 mo, preserv free, IM (IIV3)	0-2	$0	√
90656	Flu vacc, 3 yrs +, preserv free, IM (IIV3)	3-18	$0	√
		19+	$18.24	
90657	Flu vacc, 6-35 mo, IM (IIV3)	0-2	$0	√
90658	Flu vacc, 3 yrs +, IM (IIV3)	3-18	$0	√
		19+	$14.36	
90661	Flu vacc, egg free, preserv free	19+	$14.47	

90672	Influenza vaccine for nasal administration (LAIV4)	2-18	$0	√
		21+	$21.90	
90685	Influenza virus vacc, quadrivalent, split virus, preservative free (single dose syringe)	6-35 months	$0	√
90686	Influenza virus vacc, quadrivalent, split virus, preservative free, 3 yrs +, IM (single dose syringe)	3-18	$0	√
		19+	$15.84	
90687	Influenza virus vacc, quadrivalent, split virus, preservative free ages 6-35 months (Multi-dose vial)	6-35 months	$0	√
90688	Influenza virus vaccine, quadrivalent, split virus, when administered to individuals 3 years of age and older, for intramuscular use, IM (multi-dose vial)	3-18	$0	√
		19+	$15.84	

Current Procedural Terminology 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 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. Please refer to the Provider Rates & Fee Schedule web page for the current fee schedule.

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.

Please contact Elizabeth Freudenthal with questions regarding Synagis® policy or providers may contact the Department's fiscal agent, Xerox State Healthcare, at 1-800-237-0757 with general billing questions and general provider assistance.

Please remember to check the Provider Services section of the Department's website at colorado.gov/hcpf.

Health First Colorado Pharmacy 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® 2016-2017 Provider Bulletin for more information.

The 2016-2017 Synagis® season will begin November 30, 2016 and end April 30, 2017. Health First Colorado 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 November 16, 2016, 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 888-772-9696 or completed by calling the Pharmacy Prior Authorization Helpdesk at 800-365-4944. 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 ColoradoPAR Program. Please visit ColoradoPAR.com for information on how to submit a medical prior authorization 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**. If additional clinical consideration is requested after denial from Pharmacy PA Helpdesk for a home administration (pharmacy benefit), please escalate to the state pharmacist at fax number 303-866-3590. For office/outpatient administration (medical benefit), please visit coloradoPAR.com to submit a medical prior authorization for Synagis®. Members or providers may appeal Synagis® prior authorization denials through the normal appeals process.

Reimbursement and Prior Authorization of Synagis® Immune Globulin

Reimbursement for Synagis® administered in a physician's office is $1,386.88 per 50mg unit. Providers should bill less than the reimbursement maximum per unit, if the 50mg vial is split between two (2) members. 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).

Health First Colorado Synagis® Pharmacy Benefit* Prior Authorization Request

Fax Requests to: 888-772-9696 (forms need to be faxed for approval) or **call the PA Help Desk:** 800-365-4944

*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 Coloradopar.com for information on how to submit a PAR to the ColoradoPAR Program.

Provider Information	Client Information
Requesting Physician	Client ID #
Requesting Medicaid Provider #	Name (L/F/M)
NPI	Date of Birth
DEA	Gender [ ] Male [ ] Female
Phone	Current Weight____kg
Fax	Units per Month 0 or 1 x 50 mg ____x 100 mg
Address	Number of Months Requested (no more than 5)
City State ZIP	Today's Date
Billing Provider #	Dates of Service From: To:

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 for a maximum of 5 doses, at a dosing interval of no fewer than 26 days between refills.** Requests will be accepted beginning November 16, 2016, prior to the season start date of November 30, 2016. Do not submit requests prior to November 16, 2016.

For infants in the 1st 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.
- ☐ 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: _____

For infants in the 2nd year of life: (Check **at least** one of the following **AND** indicate diagnosis code)

- ☐ For infants 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: _____
- ☐ An infant who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) ICD 10-CM Code: _____
- ☐ Infants with manifestation of severe lung disease: (Choose one of the following **AND** add Diagnosis code) ICD 10-CM 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**
  - ☐ Weight for length less than the 10th percentile.
- ☐ An infant who undergoes cardiac transplantation during the RSV season.

Has the child received prior doses as an inpatient? Yes ☐ No ☐

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

Prescriber Signature_____ Date_____