



colorado.gov/hcpf

Provider Bulletin

Reference:

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Synagis® & Seasonal Influenza Vaccines

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Synagis® (Palivizumab) Vaccine

The 2014-2015 Synagis® season will begin December 1, 2014 and end April 30, 2015. 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 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 of Synagis®

Reimbursement for Synagis® administered in a physician's office is \$1,372.73 and is calculated at 50mg per unit. Providers should bill less than the reimbursement maximum per unit if the 50mg vial is split between two (2) clients.



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 clients 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. Clients must appeal this decision through the normal client appeal process.

Effective November 17, 2014, 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 17, 2014 will be denied and will need to be resubmitted beginning November 17, 2014.

Pharmacy PAR Requests

All pharmacy PAR requests (Synagis® administered in the home) should be called into the Pharmacy Prior Authorization (PA) Helpdesk at 1-800-365-4944 or faxed to 1-800-772-9696. An example of the Pharmacy PAR form and an example of how to complete the Pharmacy PAR form are attached to this bulletin. The Pharmacy PAR form can be found in the Provider Services [Forms](#) section of the Department's website (colorado.gov/pacific/hcpf). No other forms will be accepted.

Xerox State Healthcare
Denver Club Building
518 17th Street, 4th floor
Denver, CO 80202

Contacts

Billing and Bulletin Questions
1-800-237-0757

Claims and PARs Submission
P.O. Box 30
Denver, CO 80201

Correspondence, Inquiries, and Adjustments
P.O. Box 90
Denver, CO 80201

Enrollment, Changes, Signature Authorization and Claim Requisitions
P.O. Box 1100 Denver, CO 80201

ColoradoPAR Program PARs
www.coloradopar.com

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 1-800-365-4944 with any questions regarding the status of a pharmacy Synagis® PAR or the PAR form.

If additional clinical consideration is requested, please visit coloradopar.com or CareWebQI ([CWQI](#)) to submit for Medical Synagis® prior authorization consideration.

Note: For pharmacy Synagis® claims (claims to be billed through a pharmacy for home health administration), prior authorization will only be approved for clients 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 one 50mg vial (NDC 60574-4114-01) and two 100mg vials (NDC 60574-4113-01). If a client 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 must be submitted through CareWebQI ([CWQI](#)). Any medical PAR submitted as a pharmacy PAR will be denied and will need to be re-submitted through [CWQI](#) to be processed. "Medical Benefit" is defined as being administered in the practitioner's office or hospital outpatient setting (not given in the client's home).

Please contact the ColoradoPAR Program at 1-888-454-7686, with questions regarding the status of a medical Synagis® PAR or for help submitting a PAR through CWQI.

Prior authorization for pharmacy and medical requests is required and will be approved:

For infants in the 1st year of life when one of the criteria below is present

- An infant up to 12 months of age, born before 29 weeks 0 days gestation.
- An infant 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
- An infant with cystic fibrosis with clinical evidence of CLD **AND/OR** nutritional compromise
- An infant with neuromuscular disease or pulmonary abnormality **AND** is unable to clear secretions from the upper airways
- 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:
 - 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
 - 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)

For infants in the 2nd year of life when one of the criteria below is present

- 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)
- An infant who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)
- Infants with manifestation of severe lung disease and one of the following:
 - 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.

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 [Colorado 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 clients to obtain Synagis® from a pharmacy and take it to the practitioner's office for administration.
- 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 client's home or long-term care facility.**

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 1-800-511-5010, or US Bioservices at 303-706-0053.

Please contact Meredith Henry at Meredith.Henry@state.co.us or 303-866-4538; Richard Delaney at Richard.Delaney@state.co.us or 303-866-3436.

Synagis® and Home Health Agencies

If a client has been approved for Synagis® injections to be delivered in the client's home by a Home Health Agency (HHA), the HHA must enter the Long Term Home Health (LTHH) PAR into CareWebQI ([CWQI](#)) for the visits related to the Synagis® injections. If the client 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 client has been approved. These visits cannot exceed 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 with questions or additional information regarding HHA injections.

Seasonal Influenza Vaccine

Seasonal influenza vaccine is a benefit for children and adults.

For Children/Adolescents (aged 18 and under):

Free seasonal influenza vaccine is available through the Vaccines for Children Program (VFC Program) for all Colorado Medicaid enrolled children/adolescents (aged 18 and under).

For Adults (ages 18 and up):

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

Who Should Get Seasonal Influenza Vaccine?

Seasonal influenza vaccine is recommended for individuals who are 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 of influenza.

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

- are aged 6 months through 23 months;
- have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic,

- neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
- are immunosuppressed (including immunosuppression caused by medications or by Human Immunodeficiency Virus (HIV));
- are or will be pregnant during influenza season;
- are aged 2 through 18 years and receiving long-term aspirin therapy and who might therefore be at risk for experiencing Reye Syndrome after influenza virus infection;
- are residents of nursing homes and other chronic-care facilities; 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;
- are household contacts and caregivers of children aged younger than 5 years and adults aged 50 years and older, with particular emphasis on vaccinating contacts of children aged younger than 6 months; and
- are health care workers, household contacts, and 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 vaccine in an age appropriate dosage (0.25 ml if age 6-35 months or 0.5 ml if age is greater or equal to 3 years). Two doses of vaccine are recommended for children aged 6 months through eight (8) years of age if they have not been previously vaccinated for seasonal influenza. For new information on the two approaches for determining the number of doses required for children aged 6 months through 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, 2014-15 Influenza Season](#)

Children/Adolescents and Adults

Children/Adolescents

For new information on the two approaches for determining the number of doses required for children aged 6 months through 8 years, please see [Prevention and Control Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunizations Practices \(ACIP\) – United States, 2014-15 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), Fluvirin (Novartis).

For more information on the [Influenza Vaccines for 2014-15, please see the Center for Disease Control, Table on Influenza Vaccines- United States, 2014-15 Influenza Season](#)

All (Children/Adolescents and Adults)

- The Advisory Committee on Immunization Practices (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 2014-15 influenza season for this population can be found at the [Prevention and Control Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunizations Practices \(ACIP\) – United States, 2014-15 Influenza Season](#)

Billing Information

As of October 1, 2014

CPT Code	Valid Ages	Reimbursement for children (under age 18)	Reimbursement for adults (age 19 and older)
90658	3 years and above	\$0	\$14.92
90672	2 years and above	\$0	\$21.79
90685	6 months – 35 months	\$0	Not a benefit
90686	3 years and above	\$0	\$15.76
90687	3 years and above	\$0	\$13.74

As of **January 1, 2013**, immunizations for Colorado Medicaid clients aged 19 and 20 are no longer provided through CDPHE's Colorado Immunization Program (CIP). Immunizations for clients aged 19 and older (instead of aged 21 and older) are a Colorado Medicaid benefit when recommended by the CDC's Advisory Committee on Immunization. For more information on Immunizations for 19 and 20 year olds, please refer to the [Immunization Billing Manual](#) located in the Billing Manual section of Provider Services.

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 are reimbursed. The immunization administration add-on code for each vaccine component in a given vaccine, 90461, will be reimbursed at zero. For clients 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 the vaccine administration fee for clients 18 and under. Please refer to the bottom of the [Provider Services](#) home page on the Department's website 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 direct questions about Colorado Medical Assistance Program billing or the information in this bulletin to the Department's fiscal agent at 1-800-237-0757.

Please remember to check the [Provider Services](#) section of the Department's website at colorado.gov/hcpf.

Colorado Pharmacy Medicaid 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® 2014-2015 Provider Bulletin (please enter provider bulletin number here) for more information.

The 2014-2015 Synagis® season will begin December 1, 2014 and end April 30, 2015. Colorado Medicaid will approve requests for a maximum of 5 doses, at a dosing interval of no fewer than 26 days between injections. Requests for doses exceeding the 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 17, 2014, Colorado Medicaid 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 Colorado Medicaid 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 1-888-772-9696 or completed by calling the Pharmacy Prior Authorization Helpdesk at 1-800-365-4944. 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 CareWebQI (CWQI) which can be accessed at [coloradopar.com](#).**

The Department is using coverage criteria based on the recommendations of the [American Academy of Pediatrics \(AAP\) 2014](#) for Respiratory Syncytial Virus (RSV) prophylactic therapy. These recommendations are 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 clients 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 Colorado Medicaid Synagis® Pharmacy Benefit PAR Form or CWQI will be DENIED. If additional clinical consideration is requested, please visit [coloradopar.com](#) or [CWQI](#) to submit for medical Synagis® prior authorization consideration. Clients must appeal this decision through the normal client appeals process.

Reimbursement and Prior Authorization of Synagis® Immune Globulin

- Reimbursement for Synagis® administered in a physician's office is \$1,372.73 per 50mg unit. Providers should bill less than the reimbursement maximum per unit, if the 50mg vial is split between two clients.
- Reimbursement for Synagis® through a pharmacy will be based on the current pharmaceutical reimbursement method. Go to Department's website→[Provider Rates & Fee Schedules](#)→Average Acquisition Cost (AAC) for more information. Please note that no more than one 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 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 years (10 C.C.R. 2505-10, Section 8.040.2)

Colorado Medicaid Synagis® Pharmacy Benefit* Prior Authorization Request Form Example

Fax Requests to: 1-888-772-9696 (forms need to be faxed for approval) or call the **PA Help Desk:** 1-800-365-4944

*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 or submit through CareWebQI.

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 <u>0</u> or <u>1</u> 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 _____	

Colorado Medicaid 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 17, 2014, prior to the season start date of December 1, 2014.** Do not submit requests prior to November 17, 2014.

For infants in the 1st year of life: (Check **at least** one of the following **AND** indicated 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 9-CM Code: _____
- An infant with cystic fibrosis with clinical evidence of CLD **AND/OR** nutritional compromise
ICD 9-CM Code: _____
- An infant with neuromuscular disease or pulmonary abnormality **AND** is unable to clear secretions from the upper airways
ICD 9-CM Code: _____
- An infant who undergoes cardiac transplantation during the RSV season. _____
- Infants with hemodynamically significant heart disease (cyanotic heart disease) defined as having one or more of the following:
 - ICD 9-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 9-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 9-CM Code: _____

For infants in the 2nd year of life: (Check **at least** one of the following **AND** indicated 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 9-CM Code: _____
- An infant who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)
ICD 9-CM Code: _____
- Infants with manifestation of severe lung disease: (Choose one of the following **AND** add Diagnosis code) ICD 9-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 _____