

Provider Bulletin

Reference: B1200329 October 2012

Synagis® & Seasonal Influenza Vaccines

Synagis® (Palivizumab) Vaccine

The 2012-2013 Synagis® season will begin November 15, 2012 and end March 31, 2013. The Colorado Medical Assistance Program will approve requests for a maximum of 5 doses, at a dosing interval of no fewer than 28 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 National Respiratory and Enteric Virus Surveillance System (NREVSS) page of the Centers for Disease Control and Prevention (CDC) Web site.

Reimbursement and Prior Authorization of Synagis®

Reimbursement for Synagis® administered in a physician's office is \$1271.42 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 clients.



The Department of Health Care Policy and Financing (the Department) is continuing use of coverage criteria based on the American Academy of Pediatrics (AAP) 2009 and the Colorado Chapter of the AAP recommendations for 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 (PAR) in the Pharmacy PAR Requests section below. Clients must appeal this decision through the normal client appeal process.

Effective November 1, 2012, 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 1, 2012 will be denied and will need to be resubmitted beginning November 1, 2012.

Pharmacy PAR Requests

All pharmacy PAR requests (Synagis® administered in the home) should be faxed to 1-800-772-9696 or call the Pharmacy Prior Authorization (PA) Helpdesk at 1-800-365-4944. 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 Web site at colorado.gov/hcpf. No other forms will be accepted.

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

Contacts

Billing and Bulletin Questions 1-800-237-0757 or 1-800-237-0044

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 Web site. For any questions regarding the status of a pharmacy Synagis® PAR or the PAR form, please contact the Pharmacy PA Helpdesk at 1-800-365-4944.

If additional clinical consideration is requested, please visit <u>coloradopar.com</u> or <u>CareWebQI</u> (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 <u>Pharmacy Prior Authorization Policies</u> section of the <u>Department's Web site</u>. In addition, pharmacy claims will be limited to one 50mg vial per 28 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) in order for a secondary review of medical necessity.

Medical PAR Requests

All medical PAR requests must be submitted through <u>CWQI</u>. Any medical PAR submitted as a pharmacy PAR will be denied and will need to be re-submitted through <u>CWQI</u> 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).

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

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

The client is under age two (2) at the start of the current RSV season or at the time of the first injection for the current RSV season, who meets one of the following:

- Diagnosis of Chronic Lung Disease (CLD) AND having one or more of the following clinical needs during the previous six (6) months:
 - a. Supplemental oxygen;
 - b. Regular use of inhaled or oral bronchodilators;
 - c. Recent use of corticosteroid therapy; or
 - d. Regular or intermittent use of diuretics to treat pulmonary disease.
 - *A maximum of five monthly doses is recommended.
- Diagnosis of Interstitial Lung Disease and/or Neuromuscular disease which impacts pulmonary function
 - * A maximum of five monthly doses is recommended.
- Any infant or child under the age of 2 who has a diagnosis of congenital heart disease and meets any of the following criteria:
 - a. Receiving medication to control congestive heart failure (diuretics, antihypertensives);
 - b. Suffering from moderate to severe pulmonary hypertension; or
 - c. Suffering from Cyanotic Heart Disease.
 - *A maximum of five monthly doses is recommended.
- Any infant up to 6 months of age, born 29 to less than 32 weeks gestation
 - *A maximum of five monthly doses is recommended.
- Any infant up to 12 months of age, born at 28 weeks or less gestation
 - *A maximum of five monthly doses is recommended.
- Infants up to 2 years of age with hemodynamically significant heart disease defined as having one or more of the following:
 - a. Infants receiving medication to control congestive heart failure;
 - b. Infants with moderate to severe pulmonary hypertension; or
 - c. Infants with cyanotic heart disease.
 - *A maximum of five monthly doses is recommended.

 Any infant younger than three (3) months of age at the start of the RSV season, born at 32 to less than 35 weeks gestation and meets one of the following risk factors:

- a. Currently attends day care;
- b. Has a sibling younger than five (5) years of age;
- c. Has congenital abnormalities of the airway; or
- d. Has a neuromuscular condition that compromises handling of respiratory secretions.

*A maximum of three monthly doses is recommended for clients in this category, or until the child reaches 3 months of age.

Additional PAR instructions:

Please note that the first 6 boxes on the PAR form for qualifying diagnoses are for 5 monthly injections. The last qualifying diagnosis box is only for 3 monthly injections. Do not check criteria underneath both the 5 monthly and 3 monthly injections as the request will be denied. 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 a 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.

For additional questions, please contact Amanda Belles at <u>Amanda.Belles@state.co.us</u> or 303-866-2830; Richard Delaney at <u>Richard.Delaney@state.co.us</u> 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 use the Long Term Home Health (LTHH) PAR form for the visits related to the Synagis® injections. The form is located under Prior Authorization Request Forms in the Provider Services Forms section. 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.

For questions or additional information regarding HHA injections, please contact Guinevere Blodgett at Guinevere.Blodgett@state.co.us or 303-866-5927.

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, 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 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 pages 613 through 614 of the Centers for Disease Control and Prevention (CDC) August 17, 2012 Morbidity and Mortality Weekly Report (MMWR).

NEW for 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 pages 613 through 614 of the <u>Centers for</u> <u>Disease Control and Prevention (CDC) August 17, 2012 Morbidity and Mortality Weekly Report</u> (MMWR).
- New information on Febrile Seizures in young children associated with Trivalent Inactivated Influenza vaccine (TIV) and PCV13 can be found on page 616 of the <u>Centers for Disease</u> Control and Prevention (CDC) August 17, 2012 Morbidity and Mortality Weekly Report (MMWR).
- The Federal Drug Administration (FDA) approved a new seasonal quadrivalent LAIV (Live attenuated influenza vaccine), FluMist® Quadrivalent (MedImmune) in February 2012. This vaccine is expected to replace the current seasonal trivalent FluMist® (90660) formulation, but is not projected to be available until the 2013-14 flu season. For more information, please see page 617 of the Centers for Disease Control and Prevention (CDC) August 17, 2012 Morbidity and Mortality Weekly Report (MMWR).

Please note that CPT code 90660, Influenza virus vaccine, live, for intranasal use (brand name FluMist) is not a benefit for adults aged 21 or older. For more information on FluMist, please visit the <u>Centers for Disease Control Vaccine Information Statements</u> page. Then click on **Live, Intranasal FLU** under Influenza Vaccine - Live, Intranasal.

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 2012-13 influenza season for this population can be found on pages 616 through 617 of the CDC) August 17, 2012 Morbidity and Mortality Weekly Report (MMWR).

Billing Information:

Now Until December 31, 2012:

CPT Code	Valid Ages	Reimbursement for children (under age 21)	Reimbursement for adults (age 21 and older)
90655	2 and under	\$0	Not a benefit
90656	3 years and above	\$0	\$17.44
90657	2 and under	\$0	Not a benefit
90658	3 years and above	\$0	\$13.74
90660	2-20 years	\$0	Not a benefit

As of January 1, 2013**:

CPT Code	Valid Ages	Reimbursement for children (under age 19)	Reimbursement for adults (age 19 and older)
90655	2 and under	\$0	Not a benefit
90656	3 years and above	\$0	\$17.44
90657	2 and under	\$0	Not a benefit
90658	3 years and above	\$0	\$13.74
90660	2-20 years	\$0	Pending (for 19 and 20 year-olds)

** NOTE: Beginning January 1, 2013, immunizations for Colorado Medicaid clients ages 19 and 20 will no longer be provided through the Colorado Immunization Program. Immunizations for adults ages 19 and older (instead of ages 21 and older) will be a Colorado Medicaid benefit when recommended by the ACIP. More information will be forthcoming towards the end of 2012.

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 90474-90474 are reimbursed at \$6.33. 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 of \$6.33. 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 <u>Provider Services</u> home page on the Department's Web site 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 Xerox State Healthcare at 1-800-237-0757 or 1-800-237-0044.

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

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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® 2012-2013 Provider Bulletin** (<u>B1200329</u>) for more information.

The 2012-2013 Synagis® season will begin November 15, 2012 and end March 31, 2013. Colorado Medicaid will approve requests for a maximum of 5 doses, at a dosing interval of no fewer than 28 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 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 <u>Centers for Disease Control and Prevention (CDC) Web site</u>.

Effective November 1, 2012, Colorado Medicaid will begin accepting PARs for Synagis®. All requests for Synagis® (Palivizumab) require prior authorization and when submitted for pharmacy, 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 Web site. No other forms will be accepted. All pharmacy requests intended to be administered in the home must use the form located on the Department's Web site. It can be faxed to 1-888-772-9696 or completed by calling the Pharmacy Prior Authorization Helpdesk at 1-800-365-4944. NOTE: All requests for administration in the provider's office or facility should be submitted through CareWebOI (CWQI) which can be accessed at coloradopar.com.

- Please note that the first 6 boxes on the Pharmacy Benefit PAR form are for qualifying diagnoses for 5 monthly injections. The last qualifying diagnosis box is only for 3 monthly injections. DO NOT check criteria underneath both the 5 monthly and 3 monthly injections as your request will be DENIED.
- All Synagis® Pharmacy PARs must be signed by the prescribing physician, even if submitted by an agent of the prescriber.

The Department is continuing use of coverage criteria based on the American Academy of Pediatrics (AAP) 2009 and the Colorado Chapter of the AAP recommendations for (RSV) prophylactic therapy. Synagis® is used to prevent serious lower respiratory tract disease caused by Respiratory Syncytial Virus (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 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 \$1271.42 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 Web site→Providers→Pharmacy→State Maximum Allowable Cost (State MAC) for more
 information. Please note that no more than one 50mg vial will be allowed per month through the pharmacy benefit.

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)

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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: <u>coloradopar.com</u> or submit through <u>CareWebQl</u>.

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 Weightkg		
Fax	Units per Month <u>0 or 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		
season, who meet one of the following conditions. Requests will be no fewer than 28 days between injections. Requests will be accept November 15, 2012. Do not submit requests prior to November 1, 2012. The following diagnoses qualify for up to five (5) monthly doses. Chronic Lung Disease (CLD) with one of the following clinical needs and supplemental Oxygen. Regular use of inhaled or of all bronchodilators. Recent use of conficosteroid therapy. Regular or intermittent use of diuretics to treat pulmona. Interstitial Lung Disease and/or Neuromuscular disease which im Any infant or child under the age of 2 who has a diagnosis of contict in the supplemental oxygen. Suffering from moderate to severe pulmonary hypertensing Suffering from Cyanotic Heart Disease.	oted beginning November 1, 2012, prior to the season start date of 012. Sof Synagis®: eds in last 6 months: ICD 9-CM Code: ICD 9-CM Code: Inpacts pulmonary function. ICD 9-CM Code: ICD 9-CM Code:		
Any infant up to 6 months of age, born 29 to less than 32 weeks	gestation. ICD 9-CM Code:		
☐ Any infant up to 12 months of age, born at 28 weeks or less gest.	ation. ICD 9-CM Code:		
☐ Infants up to 2 years of age with hemodynamically significant head ICD 9-CM Code: ☐ Infants receiving medication to control congestive heart ☐ Infants with moderate to severe pulmonary hypertensio ☐ Infants with cyanotic heart disease.	t failure;		
The following diagnoses qualify for up to three (3) monthly dose Any infant younger than 3 months of age at the start of the RSV salso meets one of the following risk factors. Currently attends day care; Having a sibling younger than 5 years of age; Having congenital abnormalities of the airway; or Having a neuromuscular condition that compromises have	season, born from 32 weeks to less than 35 weeks gestation who ICD 9-CM Code:		
Has the child received prior doses as an inpatient?	☐ Yes ☐ No		
If yes, how many doses did the child receive?	_		
Provider Signature	Date		

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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 client's home (ex. physician's office) please visit; coloradopar.com or submit through CareWebQI.

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er	Requesting Physician Bee Well, M.D.	Client ID# A123456			
vido n	Requesting Medicaid Provider # N/A for Pharmacy PARs	Name (L/F/M) Client, Iman			
pro	NPI 9876543210 Date of Birth 09/01/2012				
all I	DEA BW123456	Gender [X] Male [] Female		ıt in	
ude all provi information	Phone (555) 123-4567	Current Weight 2.4 kg		lien	
Include all provider information	Fax (555) 1234658	Units per Month 1x 50 mg	x 100 mg	e all client inform	
	Address 123 Any Street	Number of Months Requested (no m	ore than 5) 2	de a	
	City Denver State CO ZIP 80000	Today's Date 11/08/2012		Include all client information, including weight	
	Billing Provider # N/A for Pharmacy PARs	Dates of Service From 11/20/20:	12 To 03/2012013		
	Colorado Medicaid will approve Synagis® prior authorization request season, who meet one of the following conditions. Requests will be no fewer than 28 days between injections. Requests will be acception November 15, 2012. Do not submit requests prior to November 1, 2 The following diagnoses qualify for up to five (5) monthly doses Chronic Lung Disease (CLD) with one of the following clinical new Supplemental Oxygen Regular use of inhaled or oral branchodilators Recent use of corticosteroid therapy	approved for a maximum of 5 dos oted beginning November 1, 2012, pr 012. s of Synagis®:	ses, at a dosing interval or ior to the season start dat of the season start data of the	of te of	
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				-	
	☐ Infants up to 2 years of age with hemodynamically significant heart disease defined as having one or more of the following: ICD 9-CM Code:				
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Do not select criteria in the up to 3 – and 5 – month diagnoses 1	The following diagnoses qualify for up to three (3) monthly dose Any infant younger than 3 months of age at the start of the RSV also meets one of the following risk factors. Currently attends day care; Having a sibling younger than 5 years of age; Having congenital abnormalities of the airway; or Having a neuromuscular condition that compromises have	season, born from 32 weeks to less t ICD 9			
ot sel	Has the child received prior doses as an inpatient?	☐ Y	es No		
)0 nc	If yes, how many doses did the child receive?				
7	Provider Signature	Date			