

Affected Programs: BadgerCare Plus, Medicaid

To: Federally Qualified Health Centers, Nurse Midwives, Nurse Practitioners, Nurses in Independent Practice, Pharmacies, Physician Assistants, Physician Clinics, Physicians, Rural Health Clinics, HMOs and Other Managed Care Programs

Revised Prior Authorization Guidelines for Synagis®

This *ForwardHealth Update* provides revised clinical criteria to obtain prior authorization (PA) for Synagis® based on the updated American Academy of Pediatrics (AAP) guidelines. Clinical criteria described in this *Update* apply to PA requests received by ForwardHealth on and after October 1, 2014.

The American Academy of Pediatrics (AAP) recently released revised clinical guidance for the use of Synagis® (palivizumab). This *ForwardHealth Update* provides revised clinical criteria to obtain prior authorization (PA) for Synagis® based on the updated AAP guidelines. Clinical criteria described in this *Update* apply to PA requests received by ForwardHealth on and after October 1, 2014.

Prior authorization requests for Synagis® must be submitted using the Prior Authorization Drug Attachment for Synagis® form, F-00142 (10/14), which has been revised. Providers may refer to Attachments 1 and 2 of this *Update* for a copy of the revised completion instructions and form. Prior authorization requests received for the 2014-2015 Synagis® season must be submitted on the revised form or they will be returned.

Background

Synagis® (palivizumab), a monoclonal antibody, is used as a prophylaxis to reduce lower respiratory tract disease caused by respiratory syncytial virus (RSV) in high-risk children.

Synagis® is not part of the provider-administered drugs carve-out policy; therefore, a member's BadgerCare Plus HMO program should reimburse providers for Synagis®. For more information about the provider-administered drugs carve-out policy, providers may refer to the ForwardHealth Online Handbook on the Portal. The information in this *Update* applies to members in fee-for-service. For more information about PA criteria and reimbursement for members enrolled in an HMO, contact the member's HMO.

Requesting Prior Authorization for Synagis®

Prior authorization is required for Synagis®. Prior authorization for Synagis® must be requested by prescribers or their designees, *not* pharmacy providers. Synagis® administered in a hospital does not require PA.

For the 2014-2015 treatment season, PA requests for Synagis® may be submitted beginning October 1, 2014, with PA grant dates as early as November 1, 2014, and PA expiration dates as late as April 30, 2015.

For additional information about PA requests and amendments for Synagis®, providers may refer to the Prior Authorization Requests and Amendments for Synagis® topic (topic #7877) in the Services Requiring Prior Authorization chapter of the Prior Authorization section of the Pharmacy or Physician service areas of the Online Handbook.

Submitting Prior Authorization Requests on the Portal, by Fax, or by Mail

Prescribers or their designees are required to request PA for Synagis® using one of the following options:

- Drug Authorization and Policy Override (DAPO) Center.
- ForwardHealth Portal.
- Fax.
- Mail.

A prescriber, or their designees, should have all PA information completed before calling the DAPO Center to obtain PA.

Prescribers are required to retain a copy of the PA form and any supporting documentation.

If a prescriber or his or her designee chooses to submit a paper PA request for Synagis® by fax or mail, the following must be completed and submitted to ForwardHealth:

- Prior Authorization Request Form (PA/RF), F-11018 (05/13), for physician services.
- Prior Authorization Drug Attachment for Synagis®.
- Supporting documentation, as appropriate.

The Prior Authorization Fax Cover Sheet, F-01176 (12/11), is available on the Forms page of the Portal for providers submitting the forms and documentation by fax.

Prescribers are reminded that they are required to sign and date each PA request form when submitting the request on paper.

Clinical Criteria

The following conditions will be considered for approval of a PA request:

- Chronic lung disease (CLD) of prematurity.
- Congenital heart disease (CHD).
- Heart transplant.
- Pre-term infants.
- Pulmonary Abnormalities and Neuromuscular Disease.
- Immunocompromised.

Chronic Lung Disease of Prematurity

For children younger than 12 months of age at the start of the RSV season, PA requests must document that the child meets *all* of the following criteria:

- Gestational age **at delivery** is younger than 32 weeks (i.e., zero days through 31 weeks, six days).
- Required oxygen greater than 21 percent for at least the first 28 days after birth.

For children between 12 and 24 months of age at the start of the RSV season, PA requests must document that the child meets *all* of the following criteria:

- Gestational age **at delivery** is younger than 32 weeks (i.e., zero days through 31 weeks, six days).
- Required oxygen greater than 21 percent for at least the first 28 days after birth.
- The child required medical support (corticosteroid, diuretic, or supplemental oxygen) during the six-month period before the start of the RSV season.

Congenital Heart Disease

Prior authorization requests must document that the child is younger than 12 months of age at the start of the RSV season and has hemodynamically significant CHD.

Heart Transplant

Prior authorization requests must document that the child is younger than 24 months of age at the start of the RSV season and will undergo cardiac transplantation during the RSV season.

Pre-term Infants

Prior authorization requests must document that the child is born before 29 weeks gestation (i.e., zero days through 28 weeks, six days) and is younger than 12 months of age at the start of the RSV season.

Pulmonary Abnormalities and Neuromuscular Disease

Prior authorization requests must document that the child meets all of the following criteria:

- The child is younger than 12 months of age at the start of the RSV season.
- The child has a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of an ineffective cough.

Immunocompromised

Prior authorization requests must document that the child meets all of the following criteria:

- The child is younger than 24 months of age at the start of the RSV season.
- The child is profoundly immunocompromised. Immunodeficiency may be a result of, but not limited to, any of the following conditions:
 - ✓ Acquired Immune Deficiency Syndrome (AIDS).
 - ✓ Solid organ transplant.
 - ✓ Stem cell transplant.
 - ✓ Receiving chemotherapy.

Prior Authorization Approval

A maximum of five doses of Synagis® will be approved. For children born during the RSV season, fewer than five monthly doses will be needed. The following table includes the weight range, the rounded calculated Synagis® dose, the number of 50 mg units of Synagis®, and is used for the adjudication of PA requests to determine the allowed billing units per dose.

Weight Range (in kg)	Synagis® Calculated Dose	Number of Units*
Up to 3.6 kg	0 - 54 mg	1
3.7 to 6.9 kg	55 mg - 104 mg	2
7.0 to 10.2 kg	105 mg - 154 mg	3
10.3 to 13.6 kg	155 mg - 204 mg	4
13.7 to 16.9 kg	205 mg - 254 mg	5
17.0 to 20.3 kg	255 mg - 304 mg	6

* Units are a 50 mg dose.

Professional Claim Submission

Claims for Synagis® must be submitted on a professional claim. To comply with the requirements of the Deficit Reduction Act of 2005, the National Drug Code (NDC) of the drug dispensed, the quantity, qualifier, and unit dispensed must also be indicated on claims for Synagis®.

For example, if a provider administers 150 mg of Synagis®, and a 100 mg vial and a 50 mg vial were used, then the NDC from each vial would be submitted on the claim. Although the vials have different NDCs, the drug has one procedure code, 90378 (Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each). In this example, the same procedure code would be reported on two details of the claim and paired with different NDCs.

Procedure Code	NDC	NDC Description
90378	60574-4111-01	Synagis® — 100 mg
90378	60574-4112-01	Synagis® — 50 mg

For additional information regarding submission of a professional claim, providers may refer to the Synagis® topic (topic #1951) in the Submission chapter of the Claims section of the Pharmacy or Physician service areas of the Online Handbook.

Information Regarding Managed Care Organizations

This *Update* contains fee-for-service policy and applies to services members receive on a fee-for-service basis only. For managed care policy, contact the appropriate managed care organization. Managed care organizations are required to provide at least the same benefits as those provided under fee-for-service arrangements.

The *ForwardHealth Update* is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Health Care Access and Accountability, Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, Wisconsin DHS.

For questions, call Provider Services at (800) 947-9627 or visit our Web site at www.forwardhealth.wi.gov/.

P-1250

This *Update* was issued on 09/15/2014 and information contained in this *Update* was incorporated into the Online Handbook on 10/01/2014.

ATTACHMENT 1

Prior Authorization Drug Attachment for Synagis® Completion Instructions

(A copy of the “Prior Authorization Drug Attachment for Synagis® Completion Instructions” is located on the following pages.)

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FORWARDHEALTH PRIOR AUTHORIZATION DRUG ATTACHMENT FOR SYNAGIS® COMPLETION INSTRUCTIONS

ForwardHealth requires certain information to enable the programs to authorize and pay for medical services provided to eligible members.

Members of ForwardHealth are required to give providers full, correct, and truthful information for the submission of correct and complete claims for reimbursement. This information should include, but is not limited to, information concerning enrollment status, accurate name, address, and member identification number (DHS 104.02[4], Wis. Admin. Code).

Under s. 49.45(4), Wis. Stats., personally identifiable information about program applicants and members is confidential and is used for purposes directly related to ForwardHealth administration such as determining eligibility of the applicant, processing prior authorization (PA) requests, or processing provider claims for reimbursement. Failure to supply the information requested by the form may result in denial of PA or payment for the services.

Prior authorization requests for Synagis® submitted on paper require the use of this form. If necessary, attach additional pages if more space is needed. Refer to the applicable service-specific publications for service restrictions and additional documentation requirements. Provide enough information for ForwardHealth to make a determination about the request.

INSTRUCTIONS

Prescribers are required to complete and sign the Prior Authorization Drug Attachment for Synagis® form, F-00142, to request PA for Synagis®. Prescribers are required to retain a completed copy of the form.

Prescribers may submit PA requests in one of the following ways:

- 1) For requests submitted through the Drug Authorization and Policy Override (DAPO) Center, prescribers may call (800) 947-9627. A prescriber, or their designees, should have all PA information completed before calling the DAPO Center to obtain PA.
- 2) For requests submitted on the ForwardHealth Portal, prescribers can access www.forwardhealth.wi.gov/.
- 3) For PA requests submitted by fax, prescribers should submit a Prior Authorization Request Form (PA/RF), F-11018, and the appropriate PA drug attachment form to ForwardHealth at (608) 221-8616.
- 4) For PA requests submitted by mail, prescribers should submit a PA/RF and the appropriate PA drug attachment form to the following address:

ForwardHealth
Prior Authorization
Ste 88
313 Blettner Blvd
Madison WI 53784

Providers should make duplicate copies of all paper documents mailed to ForwardHealth. The provision of services that are greater than or significantly different from those authorized may result in nonpayment of the billing claim(s).

SECTION I — MEMBER AND PROVIDER INFORMATION

Element 1 — Name — Member

Enter the member's last name, first name, and middle initial. Use Wisconsin's Enrollment Verification System (EVS) to obtain the correct spelling of the member's name. If the name or spelling of the name on the ForwardHealth identification card and the EVS do not match, use the spelling from the EVS.

Element 2 — Member Identification Number

Enter the member ID. Do not enter any other numbers or letters. Use the ForwardHealth card or the EVS to obtain the correct member ID.

Element 3 — Date of Birth — Member

Enter the member's date of birth in MM/DD/CCYY format.

Element 4 — Name — Prescriber

Enter the name of the medical practitioner prescribing the medication for PA.

Element 5 — National Provider Identifier (NPI) — Prescriber

Enter the prescribing provider's 10-digit National Provider Identifier (NPI).

Element 6 — Address — Prescriber

Enter the address (street, city, state, and ZIP+4 code) of the prescriber.

Element 7 — Telephone Number — Prescriber

Enter the telephone number, including area code, of the prescriber.

Element 8 — Name — Billing Provider

Enter the name of the billing provider. If a prescriber or a prescriber's clinic or group intends to submit the claim, enter the prescriber or prescriber's clinic or group name. If a pharmacy intends to submit the claim, enter the pharmacy's name.

Element 9 — NPI — Billing Provider

Enter the NPI of the billing provider. If a prescriber or a prescriber's clinic or group intends to submit the claim, enter the prescriber or prescriber's clinic or group NPI. If a pharmacy intends to submit the claim, enter the pharmacy's NPI.

SECTION II — CLINICAL INFORMATION FOR ALL PA REQUESTS

Element 10

Indicate whether or not Synagis® was administered when the child was hospitalized. If yes, indicate the date(s) of administration in the space(s) provided. (No more than five doses will be authorized, inclusive of any hospital-administered doses.)

Element 11 — Current Weight — Child

Enter the child's current weight in kilograms.

Element 12 — Date Child Weighed

Enter the date the child was weighed for the amount listed in Element 11.

Element 13 — Calculated Dosage of Synagis®

Enter the calculated dosage of Synagis® (15 milligrams per kilogram of body weight). The following table includes the weight range, the rounded calculated Synagis® dose, and the number of 50 mg units of Synagis® used for the adjudication of PA requests to determine the allowed billing units.

Weight Range (in kg)	Synagis® Calculated Dose	Number of Units*
Up to 3.6 kg	0 – 54 mg	1
3.7 to 6.9 kg	55 mg – 104 mg	2
7.0 to 10.2 kg	105 mg – 154 mg	3
10.3 to 13.6 kg	155 mg – 204 mg	4
13.7 to 16.9 kg	205 mg – 254 mg	5
17.0 to 20.3 kg	255 mg – 304 mg	6

* Units are a 50 mg dose.

SECTIONS III A, III B, III C, III D, III E, or III F

Providers are required to complete *one* of either Section III A, III B, III C, III D, III E, or III F (depending on the child's medical condition) for a PA request to be considered for approval. Providers should indicate the reason for administration of Synagis®. Under the appropriate condition, check the boxes and/or indicate the information that apply to the member's medical condition.

SECTION III A — CLINICAL INFORMATION FOR CHRONIC LUNG DISEASE

Element 14

Indicate whether or not the child has chronic lung disease of prematurity.

Element 15

Indicate whether or not the child required oxygen at greater than 21 percent for at least the first 28 days after birth.

Element 16

Indicate the child's gestational age at delivery (in weeks and days).

Element 17

Check the boxes to indicate the therapies that the child has continuously used over the past six months.

SECTION III B — CLINICAL INFORMATION FOR CONGENITAL HEART DISEASE

Element 18

Indicate whether or not the child is younger than 12 months of age at the start of the respiratory syncytial virus (RSV) season and has hemodynamically significant congenital heart disease.

SECTION III C — CLINICAL INFORMATION FOR CARDIAC TRANSPLANT

Element 19

Indicate whether or not the child is younger than 24 months of age at the start of the RSV season and is scheduled to undergo a cardiac transplantation during the RSV season.

SECTION III D — CLINICAL INFORMATION FOR PRE-TERM INFANTS

Element 20

Indicate whether or not the child is younger than 12 months of age at the start of the RSV season and was born before 29 weeks gestation (i.e., zero days through 28 weeks, six days). In the space provided, indicate the child's gestational age at delivery (in weeks and days).

SECTION III E — CLINICAL INFORMATION FOR PULMONARY ABNORMALITIES AND NEUROMUSCULAR DISEASE

Element 21

Indicate whether or not the child is younger than 12 months of age at the start of the RSV season and has a neuromuscular disease or congenital abnormality that impairs the ability to clear secretions from the upper airway because of an ineffective cough. If yes, indicate the disease or anomaly in the space provided.

SECTION III F — CLINICAL INFORMATION FOR IMMUNOCOMPROMISED CHILDREN

Element 22

Indicate whether or not the child, who is younger than 24 months of age at the start of the RSV season, is profoundly immunocompromised due to a solid organ transplant, stem cell transplant, receiving chemotherapy, Acquired Immune Deficiency Syndrome (AIDS), or another cause. If Other, enter the cause of the child's immunodeficiency in the space provided.

SECTION IV — AUTHORIZED SIGNATURE

Element 23 — Signature — Prescriber

The prescriber is required to complete and sign this form.

Element 24 — Date Signed — Prescriber

Enter the month, day, and year the form was signed by the prescriber in MM/DD/CCYY format.

SECTION V — ADDITIONAL INFORMATION

Element 25

Indicate any additional information in the space provided. Additional diagnostic and clinical information explaining the need for the product requested may be included here.

ATTACHMENT 2

(A copy of the "Prior Authorization Drug Attachment for Synagis®" form is located on the following pages.)

**FORWARDHEALTH
PRIOR AUTHORIZATION DRUG ATTACHMENT FOR SYNAGIS®**

Instructions: Type or print clearly. Refer to the Prior Authorization Drug Attachment for Synagis® Completion Instructions, F-00142A, for more information.

Providers may call the Drug Authorization and Policy Override Center at (800) 947-9627 with questions.

SECTION I — MEMBER AND PROVIDER INFORMATION

1. Name — Member (Last, First, Middle Initial)

2. Member Identification Number

3. Date of Birth — Member

4. Name — Prescriber

5. National Provider Identifier (NPI) — Prescriber

6. Address — Prescriber (Street, City, State, ZIP+4 Code)

7. Telephone Number — Prescriber

8. Name — Billing Provider

9. NPI — Billing Provider

SECTION II — CLINICAL INFORMATION FOR ALL PA REQUESTS

10. Was Synagis® administered when the child was hospitalized? Yes No

If yes, indicate the date(s) of administration in the space(s) provided. (No more than five doses will be authorized, inclusive of any hospital-administered doses.)

1. _____ 2. _____ 3. _____

11. Current Weight — Child (In kilograms)

12. Date Child Weighed

13. Calculated Dosage of Synagis® (15 milligrams per kilogram of body weight)

Providers are required to complete *one* of either Section III A, III B, III C, III D, III E, or III F (depending on the child's medical condition) for a prior authorization (PA) request to be considered for approval.

SECTION III A — CLINICAL INFORMATION FOR CHRONIC LUNG DISEASE

14. The child has chronic lung disease of prematurity. Yes No

15. Did the child require oxygen at greater than 21 percent for at least the first 28 days after birth? Yes No

16. Indicate the child's gestational age at delivery (in weeks and days).

_____ Weeks _____ Days

17. Check all therapies below that the child has continuously used over the past six months.

Corticosteroid Diuretic Supplemental Oxygen

Continued

SECTION III B — CLINICAL INFORMATION FOR CONGENITAL HEART DISEASE

18. The child is younger than 12 months of age at the start of the respiratory syncytial virus (RSV) season and has hemodynamically significant congenital heart disease. Yes No

SECTION III C — CLINICAL INFORMATION FOR CARDIAC TRANSPLANT

19. The child is younger than 24 months of age at the start of the RSV season and is scheduled to undergo a cardiac transplantation during the RSV season. Yes No

SECTION III D — CLINICAL INFORMATION FOR PRE-TERM INFANTS

20. The child is younger than 12 months of age at the start of the RSV season and was born before 29 weeks gestation (i.e., zero days through 28 weeks, six days). Yes No

Indicate the child's gestational age at delivery (in weeks and days).

_____ Weeks _____ Days

SECTION III E — CLINICAL INFORMATION FOR PULMONARY ABNORMALITIES AND NEUROMUSCULAR DISEASE

21. The child is younger than 12 months of age at the start of the RSV season and has a neuromuscular disease or congenital abnormality that impairs the ability to clear secretions from the upper airway because of an ineffective cough. Yes No

If yes, indicate the disease or anomaly. _____

SECTION III F — CLINICAL INFORMATION FOR IMMUNOCOMPROMISED CHILDREN

22. The child is younger than 24 months of age at the start of the RSV season and is profoundly immunocompromised due to the following:

- | | | |
|---|------------------------------|-----------------------------|
| a. Solid Organ Transplant | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Stem Cell Transplant | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Receiving Chemotherapy | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Acquired Immune Deficiency Syndrome (AIDS) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Other | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If other, indicate the cause of the child's immunodeficiency.

SECTION IV — AUTHORIZED SIGNATURE

23. SIGNATURE — Prescriber

24. Date Signed — Prescriber

SECTION V — ADDITIONAL INFORMATION

25. Indicate any additional information in the space provided. Additional diagnostic and clinical information explaining the need for the product requested may be included here.