PRODUCT APPLICATION:

- PreferredOne Administrative Services, Inc. (PAS) ERISA
- PreferredOne Administrative Services, Inc. (PAS) Non-ERISA
- PreferredOne Community Health Plan (PCHP)
- PreferredOne Insurance Company (PIC) Individual
- PreferredOne Insurance Company (PIC) Large Group
- PreferredOne Insurance Company (PIC) Small Group

Coverage is subject to the terms of the member’s pharmacy benefit plan and formulary. To the extent there is any inconsistency between this criteria set/policy and the terms of the member’s pharmacy benefit plan and/or formulary, the member’s pharmacy benefit plan and formulary govern.

Approval of a drug under this criteria document does not ensure full coverage of the drug. Other pharmacy programs may be in place affecting supply and payment of the medication such as but not limited to formulary and quantity limits.

This criteria document applies only to PAS members when the employer group has adopted the applicable drug trend management program(s).

PURPOSE:
The intent of the Synagis Prior Authorization criteria document is to ensure that the intended use is medically necessary for prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus (RSV).

GUIDELINES:
Medical Necessity Criteria – must satisfy both of the following: I and II

I. Indications – must satisfy one of the following: A-F

   A. Member born before 29 weeks, 0 days’ gestation who is less than 12 months of age at the beginning of the RSV season; or

   B. Member diagnosed with chronic lung disease (CLD) of prematurity – must satisfy: 1, and either 2 or 3
      1. Born before 32 weeks, 0 days’ gestation; and
      2. Less than 12 months of age during the RSV season and requires greater than 21% oxygen for at least the first 28 days after birth; or
      3. Between 12 to less than 24 months of age – must meet both of the following: a and b
         a. The member required greater than 21% oxygen for at least the first 28 days after birth; and
         b. The member still requires medical support (eg, chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.
C. Member diagnosed with hemodynamically significant congenital heart disease (CHD) – must satisfy any of the following: 1 or 2
   1. Initial request - less than 12 months of age, born within 12 months of onset of the RSV season – must have any of the following: a-c
      a. *Acyanotic heart disease* – must meet both of the following: 1) and 2)
         1) The member is receiving medication to control congestive heart failure; and
         2) The member will require cardiac surgical procedures.
      b. Moderate to severe *pulmonary hypertension*; or
      c. *Cyanotic heart defects* in the first year of life with documentation of decision for prophylaxis made in consultation with a pediatric cardiologist.
   2. Additional dose request - less than 24 months of age and the prescriber is requesting one additional postoperative dose of Synagis for prophylaxis – must meet any of the following: a or b
      a. The member has undergone cardiac transplantation during the RSV season; or
      b. The member has undergone cardiac bypass or after extracorporeal membrane oxygenation during the RSV season.

   [Note: One additional dose will be approved if medically necessary.]

D. Member diagnosed with anatomic pulmonary abnormalities or neuromuscular disorders – must satisfy both of the following: 1 and 2
   1. Less than 12 months of age; and
   2. The member’s anatomic pulmonary abnormalities (eg, pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disorders (eg, cerebral palsy) impair the member’s ability to clear secretions from the upper airway because of ineffective cough.

E. Member is profoundly immunocompromised (eg, solid organ transplantation, hematopoietic stem cell transplantation, severe combined immunodeficiency syndrome) and is less than 24 months of age during the RSV season.

F. Member diagnosed with cystic fibrosis – must satisfy either of the following: 1 or 2
   1. Less than 12 months of age with evidence of CLD and/or nutritional compromise; or
   2. Between 12 to 24 months of age – must meet either of the following: a or b
      a. Manifestations of severe lung disease (ie, previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable); or
      b. Weight for length is less than the 10th percentile on the pediatric growth chart.

II. Dosing – Allowed dose must follow the Dosing Allowance policy (see Attachment A).
DEFINITIONS:
Acyanotic heart disease:
An acyanotic heart defect, also known as non-cyanotic heart defect, is a class of congenital heart defects. In these, blood is shunted (flows) from the left side of the heart to the right side of the heart due to a structural defect (hole) in the septum. People often retain normal levels of oxyhemoglobin saturation in systemic circulation. Examples include atrial septal defect (ASD), patent ductus arteriosus (PDA), and ventricular septal defect (VSD).

Cyanotic heart disease:
A group-type of congenital heart defect (CHD) that occurs due to deoxygenated blood bypassing the lungs and entering the systemic circulation or a mixture of oxygenated and unoxygenated blood entering the systemic circulation. It is caused by structural defects of the heart (i.e.: right-to-left, bidirectional shunting, malposition of the great arteries), or any condition which increases pulmonary vascular resistance with the result being the development of collateral circulation. Examples include coarctation of the aorta, hypoplastic left heart, pulmonary atresia, Tetralogy of Fallot, transposition of the great arteries, tricuspid valve abnormalities, truncus arteriosus, and total anomalous pulmonary venous connection.

Pulmonary hypertension:
It is an increase in pulmonary artery pressure. In congenital heart disease it is caused by pulmonary over circulation, pulmonary vasoconstriction, and pulmonary vascular disease, either alone in combination. Grading is based on pulmonary artery pressures (PAP) and functional limitations. Moderate to severe pulmonary hypertension is a PA systolic pressure greater than or equal to 70 mm/Hg; diastolic pressure greater than or equal to 26 mm/Hg; and/or a mean pressure of greater than 40 mm/Hg.

BACKGROUND:
Synagis (palivizumab) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. The American Academy of Pediatrics (AAP) has issued an updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for RSV.

This criteria set is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.
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COVERAGE:
Prior Authorization: Yes - Approve up to 5 monthly injections during the RSV season: For members residing in Minnesota, November - March, and the appropriate weight based units (vials), per Attachment A).

Can allow one additional postoperative dose (April for members residing in Minnesota), when Guidelines I.C.2. above are met

[Note: Initiation of Synagis prophylaxis after the start of RSV season will not require all 5 doses.]

Coverage is subject to the member’s contract benefits.

CODING:
CPT/HCPCS
90378 Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

S9562 Home injectable therapy, palivizumab, including administration services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

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RELATED CRITERIA/POLICIES/FORM:
Form: Synagis (palivizumab) Authorization Form
Medical Management Process Manual UR015 Use of Medical Policy and Criteria
Pharmacy Policy: PP/F001 Formulary Overrides
Pharmacy Policy: PP/Q003 Quantity Limits

REFERENCES:

DOCUMENT HISTORY:
Created Date: 06/07/16
Reviewed Date: 06/07/17
Revised Date:
Attachment A

Dosing Allowance

The calculated dose of Synagis is 15 mg/kg. Because this drug is available only in 50 mg and 100 mg vials, and costs approximately $1,000 per 50 mg, there is the potential for significant waste. Follow the table below, which shows a 10% difference in allowed dose from the calculated dose.

<table>
<thead>
<tr>
<th>Weight</th>
<th>Calculated dose (max wt.) (15 mg/kg)</th>
<th>Allowed Dose</th>
<th>Dispense</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 3.6 kg</td>
<td>54 mg</td>
<td>50 mg</td>
<td>One 50 mg vial</td>
</tr>
<tr>
<td>3.7 to 7.3 kg</td>
<td>110 mg</td>
<td>100 mg</td>
<td>One 100 mg vial</td>
</tr>
<tr>
<td>7.4 to 11.1 kg</td>
<td>166.5 mg</td>
<td>150 mg</td>
<td>One 100 mg and one 50 mg vials</td>
</tr>
<tr>
<td>11.2 to 14.6 kg</td>
<td>220 mg</td>
<td>200 mg</td>
<td>Two 100 mg vials</td>
</tr>
<tr>
<td>14.7 to 18.1 kg</td>
<td>271.5 mg</td>
<td>250 mg</td>
<td>Two 100 mg and one 50 mg vials</td>
</tr>
</tbody>
</table>

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:
- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:
- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)


Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).


注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

小心：如果您说德语，您可以免费获取语言援助服务。请致电1.800.940.5049 (TTY: 763.847.4013).


Mario: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appellez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company (“PIC”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:
• Qualified sign language interpreters
• Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:
• Qualified interpreters
• Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN  55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)


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ในประเทศไทย: ท่านสามารถติดต่อขอความช่วยเหลือทางภาษาได้โดยการโทรมาที่ 1.800.940.5049 (TTY: 763.847.4013).

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