IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Community Plan reimbursement policies uses Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS) or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement. This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy. This information is intended to serve only as a general reference resource regarding UnitedHealthcare Community Plan’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Community Plan may use reasonable discretion in interpreting and applying this policy to health care services provided to UnitedHealthcare Community Plan enrollees.

Other factors affecting reimbursement supplement, modify or, in some cases, supersede this policy. These factors include, but are not limited to: federal &/or state regulatory requirements, the physician or other provider contracts, the enrollee’s benefit coverage documents, and/or other reimbursement, medical or drug policies.

Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Community Plan due to programming or other constraints; however, UnitedHealthcare Community Plan strives to minimize these variations.

UnitedHealthcare Community Plan may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication. (*CPT® is a registered trademark of the American Medical Association)

Application

This drug policy applies to UnitedHealthcare Community Plan Medicaid Product.

This reimbursement policy applies to services reported using the 1500 Health Insurance Claim Form (a/k/a CMS-1500) or its electronic equivalent or its successor form. This policy applies to all products and all network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals.

Employer & Individual please use this link.
Medicare & Retirement and UnitedHealthcare Community Plan Medicare Policies are listed under Medicare Advantage Reimbursement Policies.
Employer & Individual are listed under Reimbursement Policies-Commercial.
**Overview**

This policy provides information about Synagis (palivizumab) and its recommended use. Synagis is a monoclonal antibody used for the prevention of complications of respiratory syncytial virus (RSV) infection in children at high-risk for serious disease. RSV is a common viral agent affecting young children and poses a serious threat for selected high-risk children. It is appropriately used in carefully selected high-risk children to prevent complications from RSV, which can require hospitalization.

**Reimbursement Guidelines**

Palivizumab is proven for the prevention of complications of respiratory syncytial virus (RSV) disease in infants and young children at defined high risk, up to 24 months of age. In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Children who qualify for the entire RSV season should receive palivizumab monthly injections only during the 5 months following the onset of RSV season in their region (maximum of 5 doses), which should provide coverage during the peak of the season, when prophylaxis is most effective.

Palivizumab (Synagis™) is proven to prevent serious respiratory syncytial virus disease (RSV) in high risk infants and young children under the following circumstances:

1. Administered during RSV season as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departments to confirm the start of the respiratory syncytial virus (RSV) season.

2. Monthly doses of palivizumab does not exceed 15 mg/kg per dose.

3. Monthly dose of palivizumab does not exceed 5 doses per single RSV season
   - Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV season, fewer than 5 monthly doses may be needed.

4. **One** of the following clinical situations:
   - **Prematurity**
     - Infants born before 29 weeks, 0 day’s gestations who are < 12 months of age at the start of RSV season.
   - **Chronic Lung Disease (CLD)**
     - **Age 0 to < 12 months:** Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth.
     - **Age ≥ 12 to < 24 months:** Palivizumab is proven for use in pre-term infants born at < 32 weeks, 0 day’s gestation who are ≥ 12 to < 24 months of age who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV season.
   - **Congenital Heart Disease (CHD)**
     - **Age 0 to < 12 months:** Infants and children with hemodynamically significant CHD who are born within 12 months of onset of RSV season and who will most likely benefit from immunoprophylaxis include:
- Infants and children with acyanotic heart disease that are receiving medication to control congestive heart failure and will require cardiac surgical procedures.
- Infants and children with moderate to severe pulmonary hypertension
- Documentation that decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life were made in consultation with a pediatric cardiologist.
  - **Age < 24 months**: A postoperative dose for children who still require prophylaxis and who have undergone surgical procedures should be administered palivizumab prophylaxis after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation.
  - Children who undergo cardiac transplantation during the RSV season may be considered for palivizumab prophylaxis.

**Congenital abnormalities of the airway or neuromuscular disease**
- **Age 0 to < 12 months**: Infants and children with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough may be considered for prophylaxis during the first year of life.

- **Immunocompromised children < 24 months of age**
  - Palivizumab may be administered when used for prophylaxis in children who are receiving cancer chemotherapy or are severely immunocompromised although the efficacy of prophylaxis in this population is unknown (e.g., children who are receiving chemotherapy or undergo hematopoietic stem cell transplantation or solid organ transplantation).

**Cystic fibrosis (CF) with other qualifying indications**
- **Age 0 to < 12 months**: Infants and children with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis.
- **Age ≥ 12 to < 24 months**: Continued use of palivizumab prophylaxis in the second year may be considered for infants and children with manifestations of severe lung disease including:
  - Previous hospitalization for pulmonary exacerbation in the first year of life.
  - Abnormalities on chest radiography or chest computed tomography that persists when stable.
  - Weight for length less than the 10th percentile on a pediatric growth chart.

Palivizumab is **unproven** for the following situations:

1. Infants with chronic lung disease (CLD) who do not continue to require medical support in the second year of life.

2. Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).

3. Infants with cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure.

4. Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy.

5. Children in the second year of life unless otherwise indicated as proven above.

6. Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the in the ability to clear secretions from the upper airway]
because of ineffective cough, or prematurity (<29 weeks, 0 day’s gestation) is present].

7. Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present).

8. Administration of monthly palivizumab prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab.

9. Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children.


11. When palivizumab prophylaxis is administered in any of the following scenarios:
   a. Outside of the RSV season
   b. In doses greater than needed to provide protection in the RSV season c. In excess of 5 doses per single RSV season
d. To persons other than those at defined high risk, as specified above

12. Treatment of symptomatic RSV disease.

Additional Information:
In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV season in the state of Florida that could affect the timing of palivizumab administration.

• Despite varied onsets, the RSV season is of the same duration (5 months) in the different regions of Florida.

• On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.

• Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV season offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10%. Use of specimens to determine the start of the RSV season requires that the number of specimens tested be statistically significant.

Synagis administration relies on weight-based dosing to guide treatment, and it is dosed at 15 mg/kg. Typical doses administered do not exceed 200mg. This is consistent with the expected weight of a child 2 years of age or less. One unit of Synagis (palivizumab) is equal to 50 mg, therefore, the number of units on a claim will typically range from one to three, but should not exceed four.

All services incurred without authorization for use:

a) outside of this approved time frame, and/or
b) in excess of 1 treatment/dose per month, and/or

c) for a diagnosis not included in the Allowed Diagnosis List, and/or

d) in a child greater than or equal to 3 years of age, will be denied.

## State Exceptions

<table>
<thead>
<tr>
<th>State</th>
<th>Policy Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>California</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>Iowa</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>Maryland</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>Nebraska</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>Mississippi</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>New Jersey</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>New York</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>New Mexico</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>Ohio</td>
<td>This policy does not apply.</td>
</tr>
<tr>
<td>Washington</td>
<td>This policy does not apply.</td>
</tr>
</tbody>
</table>

## Questions and Answers

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How was this reimbursement methodology derived?</td>
<td>The coding edits are based upon recommendations for Synagis use as outlined by the American Academy of Pediatrics.</td>
</tr>
<tr>
<td>2. What is the approved time frame?</td>
<td>Synagis is to be given from November 1st through March 31st.</td>
</tr>
</tbody>
</table>

## Codes

<table>
<thead>
<tr>
<th>CPT code section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90378</td>
<td>Synagis (palivizumab) - Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each.</td>
</tr>
</tbody>
</table>

## Attachments: Please right-click on the icon to open the file

- **UnitedHealthcare Community Plan Synagis Allowable ICD-10 Diagnosis Codes List**: A list of ICD-10 codes for which CPT code 90378 will be reimbursed
Resources

Individual state Medicaid regulations, manuals & fee schedules


Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/1/2017</td>
<td>Policy Retired</td>
</tr>
<tr>
<td>7/18/2017</td>
<td>Application Section: Removed UnitedHealthcare Community Plan Medicare products as applying to this policy. Added location for UnitedHealthcare Community Plan Medicare reimbursement policies</td>
</tr>
<tr>
<td>3/5/2017</td>
<td>State Exceptions Section: Exception added for California</td>
</tr>
<tr>
<td>1/1/2017</td>
<td>Annual Version Change</td>
</tr>
<tr>
<td>10/2/2016</td>
<td>Attachment Section: UnitedHealthcare Community Plan Synagis Allowable ICD-10 Diagnosis Codes List updated.</td>
</tr>
<tr>
<td>3/16/2016</td>
<td>Annual Approval Date: Revised</td>
</tr>
<tr>
<td>3/13/2016</td>
<td>State Exceptions Section: Exception added for Mississippi, New Mexico and Pennsylvania</td>
</tr>
<tr>
<td>1/1/2016</td>
<td>Annual Policy Version Change</td>
</tr>
<tr>
<td>3/1/2015</td>
<td>Revised verbiage to state this policy applied to UnitedHealthcare Community Plan Medicaid and Medicare products</td>
</tr>
<tr>
<td>1/1/2015</td>
<td>Annual Version Change</td>
</tr>
<tr>
<td>11/22/2005</td>
<td>Policy implemented for the following plans: AZ, MD, NE, NJ, NY, PA, TX and WI</td>
</tr>
</tbody>
</table>