RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Description:

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections in children. At highest risk are those younger than 2 years of age with prematurity, chronic lung disease (CLD) of prematurity (formerly known as bronchopulmonary dysplasia), congenital heart disease or multiple congenital anomalies. Immune prophylaxis against RSV is a prevention strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants. Based on the weight of the clinical evidence from randomized clinical trials, systematic reviews and strong clinical consensus, immune prophylaxis for RSV has demonstrated reductions in RSV-related hospitalizations in select populations of susceptible infants and children.

Criteria:

See Resources section for FDA-approved dosage.

- Palivizumab monthly administration for respiratory syncytial virus (RSV) immune prophylaxis during the RSV season is considered medically necessary with documentation of no previous significant hypersensitivity reaction to palivizumab and ANY of the following:
  
  1. In the first year of life, i.e., younger than 12 months at the start of the RSV season or born during the RSV season, and documentation of ANY of the following:

     - Infants born before 29 weeks, 0 days’ gestation
     - Preterm infants with chronic lung disease (CLD) of prematurity, defined as birth at less than 32 weeks, 0 days’ gestation and a requirement for more than 21% oxygen for at least the first 28 days after birth
     - Certain infants with hemodynamically significant heart disease (e.g., infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures; infants with moderate to severe pulmonary hypertension; infants with lesions adequately corrected by surgery who continue to require medication for heart failure)
     - Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways (e.g., ineffective cough, recurrent gastroesophageal tract reflex, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy)
     - Children with cystic fibrosis who have ANY of the following:

         - Clinical evidence of CLD
         - Nutritional compromise


RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Criteria: (cont.)

- Palivizumab monthly administration for respiratory syncytial virus (RSV) immune prophylaxis during the RSV season is considered medically necessary with documentation of no previous significant hypersensitivity reaction to palivizumab and ANY of the following: (cont.)

2. In the second year of life, i.e., younger than 24 months at the start of the RSV season, and ANY of the following:
   - Children who were born at less than 32 weeks, 0 days’ gestation and required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) during the 6-month period before the start of the second RSV season
   - Children with cystic fibrosis and ANY of the following:
     - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable)
     - Weight for length less than the 10th percentile

3. In the first or second year of life, children who will be profoundly immunocompromised (e.g., will undergo solid organ or hematopoietic stem cell transplantation or receive chemotherapy) during the RSV season
4. Postoperative dose of palivizumab after cardiopulmonary bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months who still require prophylaxis

- Immunoprophylaxis for respiratory syncytial virus is considered not medically necessary with documentation of ANY of the following:
  1. 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)
  2. Infants with lesions adequately corrected by surgery, unless they continue to require medication for heart failure
  3. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
  4. Children with congenital heart disease in the second year of life
RESPIRATORY SYNCTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Criteria: (cont.)

- Immune prophylaxis for respiratory syncytial virus for all other indications not previously listed or if above criteria not met are considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting

These indications include, but are not limited to:

- Children greater than 24 months of age
- Controlling outbreaks of health care-associated disease
- Use in immunocompromised children (unless criteria for medical necessity outline above are satisfied)
- Children with cystic fibrosis (unless criteria for medical necessity outline above are satisfied)
- Children with Down syndrome (unless criteria for medical necessity outline above are satisfied)

Resources:

Literature reviewed 05/01/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 09/18/14 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Resources: (cont.)

FDA Product Approval Information for Synagis®:

- FDA-approved dosage:

<table>
<thead>
<tr>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mg per kg of body weight, administered intramuscularly prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season. Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.</td>
</tr>
</tbody>
</table>

Initial Approval Duration:
Maximum of 5 months (5 doses) during RSV season for the region where they live

Renewal Approval Duration:
Will not be authorized, each new RSV season is considered initiation
Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator 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, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un interprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah níilíngíí Blue Cross Blue Shield of Arizona haada yit’éego bina’ídilkidgo éí doodago Háida bíjá aniyeedígíí t’áadoo le’é yina’ídilkidgo bee hahaz’áaníi hóló díí t’àá hazaadk’e’íí háká a’doowolgo bee haz’a doo báah ilííngóó. Atá’ halne’ígíí kojí bich’íí hodiíínihí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, cố cầu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viễn, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدك أسئلة بخصوص Blue Cross Blue Shield of Arizona غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، للاستفسار على المساعدة والمعلومات غير، Lلاحتمال من دون اية تكلفة. للتحدث مع مرشد الصحب أصل، 877-475-4799. 

RESPIRATORY SYNCTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)
RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLACTIC TREATMENT (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuihanan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuhang tulungan at impormasyon sa iyong wika ng walang gastos. Upang makaukapsa ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 무담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 매기하기 위해서는 877-475-4799로 전화하시십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

اگر شما، یا کسی که شما به آن کمک می‌کنید، سوالی دارید که به زبان خود را به طور رایگان درخواست نمایید 877-475-4799.

Assyrian:

Blue Cross Blue Shield of Arizona نین کوکتیرا، سوولو مایا، زنکنین. 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือถามคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizonaคุณมีสิทธิ์ที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่ค่าใช้จ่าย ติดต่อที่หมายเลขโทรศัพท์ 877-475-4799