

## Immune Prophylaxis for Respiratory Syncytial Virus

**Policy # 00177**

Original Effective Date: 08/24/2005

Current Effective Date: 01/13/2025

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider administration of immune prophylaxis for respiratory syncytial virus (RSV) with palivizumab (Synagis<sup>®</sup>)<sup>‡</sup> during RSV season in infants and children who meet guidelines from the American Academy of Pediatrics (AAP) to be **eligible for coverage**.\*\*

#### Patient Selection Criteria

Administration of immune prophylaxis for respiratory syncytial virus (RSV) with palivizumab (Synagis) will be considered when the following criteria are met:

- Monthly dose does not exceed 15 mg per kg of body weight given by intramuscular injection (maximum of 5 doses per RSV season); AND  
*(Note: Maximum of 5 doses per RSV season is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Patient has not received nirsevimab-alip (Beyfortus<sup>™</sup>)<sup>‡</sup> for the prevention of RSV during the current RSV season; AND
- Patient meets criteria for one of the following respective categories of “high risk”:
  - **Infants born prematurely [WITHOUT chronic lung disease (CLD) OR WITHOUT hemodynamically significant cyanotic or acyanotic heart disease OR WITHOUT other listed “high risk” factors]:**
    - The infant is ≤ 1 year of age at the start of the RSV season and was born before 29 weeks, 0 days’ gestation (≤ 28 weeks, 6 days’ gestation); OR
  - **Children WITH chronic lung disease (CLD) (one of the below sets of criteria must be met):**
    - Infants ≤ 1 year of age at the start of the RSV season:
      - ❖ The infant was born at < 32 weeks, 0 days’ gestation; AND
      - ❖ The infant required > 21% oxygen for at least 28 days after birth; OR

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- Children  $\leq 2$  years of age at the start of the RSV season (second season dosing):
  - ❖ The child was born at  $< 32$  weeks, 0 days' gestation; AND
  - ❖ The child required  $> 21\%$  oxygen for at least 28 days after birth; AND
  - ❖ The child has required medical therapy (i.e., supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy) during the 6 months before the start of the second RSV season; OR
- **Infants with congenital heart disease (CHD):**
  - The infant is  $\leq 1$  year of age at the start of the RSV season; AND
  - The infant meets one of the following conditions:
    - ❖ The infant has hemodynamically significant cyanotic congenital heart disease (CHD); OR
    - ❖ The infant has acyanotic heart disease AND is receiving medication to control congestive heart failure AND will require a cardiac surgical procedure; OR
    - ❖ The infant has moderate to severe pulmonary hypertension; OR
    - ❖ The infant has lesions that have been adequately corrected by surgery, but continues to require medication for congestive heart failure; OR
- **Children with cardiac transplant:**
  - The child is  $< 2$  years of age at the start of the RSV season; AND
  - The child has undergone or will undergo cardiac transplantation during the current RSV season; OR
- **Infants with a congenital anatomic pulmonary abnormality or neuromuscular disease:**
  - The infant is  $\leq 1$  year of age at the start of the RSV season; AND
  - The infant's congenital anatomic pulmonary abnormality or neuromuscular disease impairs the ability to clear secretions from the upper airways; OR
- **Immunocompromised children:**
  - The child is younger than 24 months of age at the start of the RSV season; AND
  - The child is/will be profoundly immunocompromised during the RSV season (e.g., chemotherapy or transplant).

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*

*Note: Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization*



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### **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers immune prophylaxis for RSV with more than 5 doses per season of palivizumab (Synagis) to be **not medically necessary.\*\***

Based on review of available data, the Company considers immune prophylaxis for RSV in children outside of RSV season (defined as beginning when the first 2 consecutive weeks when the percentage of positive tests for RSV is > 3% by PCR [real-time polymerase chain reaction] or > 10% by antigen testing and ending 6 months after) to be **not medically necessary.\*\***

Based on review of available data, the Company considers immune prophylaxis for RSV in children that do NOT meet the requirements of the most current American Academy of Pediatrics (AAP) RSV Prophylaxis Guidelines to be **not medically necessary.\*\***

Based on review of available data, the Company considers immune prophylaxis for RSV for any of the following (UNLESS OTHER "HIGH RISK" FACTORS ARE PRESENT and subsequent criteria in the patient selection criteria listed above are met) to be **not medically necessary\*\***:

- Prevention of RSV in infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Prevention of RSV in infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Prevention of RSV in patients with Cystic Fibrosis
- Prevention of RSV in patients with Down Syndrome.

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of palivizumab (Synagis) for non-U.S. Food and Drug Administration (FDA) approved indications such as use in adults or treatment of RSV to be **investigational.\***

Based on review of available data, the Company considers the use of palivizumab (Synagis) when the monthly dose exceeds 15 mg per kg of body weight given by intramuscular injection to be **investigational.\***

Based on review of available data, the Company considers the use of palivizumab (Synagis) when the patient has received nirsevimab-alip (Beyfortus) for the prevention of RSV during the current RSV season to be **investigational.\***



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## **Background/Overview**

RSV is the most common cause of lower respiratory infections in children. Immune prophylaxis against RSV is a prevention strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants. Synagis is a humanized monoclonal antibody that has neutralizing and fusion-inhibitory activity against RSV. Synagis is approved by the FDA for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease. Synagis is dosed at 15mg/kg per dose on a monthly basis. In the absence of a specific definition of “high risk” by the FDA, the AAP has been providing pediatricians and other health care providers with more precise guidance for determining who is at increased risk since Synagis was first licensed.

### **RSV Seasonality**

Prior to the COVID-19 pandemic, RSV infections in the United States followed seasonal patterns and typically occurred in the winter months. The Centers for Disease Control and Prevention (CDC) National Respiratory and Enteric Virus Surveillance System (NREVSS) monitors viral activity in the United States and provides reports determining RSV seasonality, both nationally and by region. Laboratory data from all 50 states is reported to NREVSS, and regional data is categorized according to the 10 geographical regions established by the U.S. Department of Health and Human Service (HHS). From 2017 to 2020, pre-pandemic seasons nationally began in October, peaked in December, and ended in April. However, the seasonality of RSV was disrupted by the COVID-19 pandemic from 2020 to 2022. According to the CDC’s Morbidity and Mortality Weekly Report, RSV circulation was historically low during 2020–21 and began earlier and continued longer during 2021–22 than during pre-pandemic seasons. The 2022–23 season started later than the 2021–22 season but earlier than pre-pandemic seasons, suggesting a return toward pre-pandemic seasonality. In both pre-pandemic and pandemic periods, RSV epidemics began earlier in Florida and the Southeast and later in regions further north and west. Although an eventual return to pre-pandemic RSV seasonality is expected, monitoring of RSV seasonality can guide the timing of immunoprophylaxis, as the off-season RSV circulation may continue.

The CDC has traditionally described national RSV circulation by defining the seasonality of RSV on the basis of weeks during which antigen-based tests detect RSV in > 10% of specimens. However, molecular testing has become more widely used by many clinical laboratories, and a 3% threshold for PCR (real-time polymerase chain reaction) tests has been found to be a simple method to assess the onset and offset of the RSV season (defining the RSV season onset as the first of 2 consecutive weeks when the weekly percentage of positive tests for RSV is > 3% by PCR and season offset as the last week that the percentage of positive tests is > 3% by PCR). The traditional 10% threshold remains reasonable for antigen testing. For analysis of NREVSS reports in the CDC Morbidity and Mortality Weekly Report, the epidemic onset and offset weeks were defined, respectively, as the first and last of 2 consecutive weeks when the percentage of positive PCR tests for RSV was  $\geq$  3%.



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For the sake of this policy, the RSV season start date will be determined as the first 2 consecutive weeks when the percentage of positive tests for RSV is > 3% by PCR or >10% by antigen testing, whichever occurs first and subject to laboratory data availability from NREVSS. The CDC NREVSS will be consulted to determine RSV activity for the appropriate region. The season will be considered to last six months, and five doses of Synagis will be allowed per season. Per the American Academy of Pediatrics, 5 monthly doses of Synagis at the recommended dose will provide more than 6 months of adequate serum drug concentrations for most infants. At the end of 6 months, the season will be re-evaluated.

### **Guidelines**

Nirsevimab-alip intramuscular injection (Beyfortus) launched in July of 2023, and in the same month, the American Academy of Pediatrics (AAP) released their Policy Statement on the Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for RSV Infection. The AAP Red Book was updated in 2024 citing that Synagis may be administered if Beyfortus is not available. If Beyfortus becomes available during the RSV season and before the 5th dose of Synagis, a single Beyfortus dose should be given and no additional Synagis doses should be administered.

In August of 2023, CDC's Advisory Committee on Immunization Practices (ACIP) approved recommending one dose of nirsevimab-alip intramuscular injection (Beyfortus) for all infants < 8 months of age born during or entering their first RSV season and for children 8 to 19 months of age who are at increased risk for severe RSV disease and entering their second RSV season.

ACIP and AAP both recommend that if Beyfortus is administered to an infant, Synagis should not be administered later in the season. If Synagis was initially administered for the season and < 5 doses were administered, the infant should receive one dose of Beyfortus, and no further Synagis should be administered. If Synagis was administered in the first RSV season, and the child is eligible for RSV prophylaxis in the second RSV season, the child should receive Beyfortus in the second RSV season, if available.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

In June 1998, the biologic drug palivizumab (Synagis; MedImmune, Gaithersburg, MA) was approved for marketing by FDA through a biologics license application (BLA) for use in the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease. In 2004, FDA approved a liquid formulation of Synagis, supplied as a sterile solution ready for injection, thus providing improved convenience for administration. This formulation is used in the physician office or home setting.



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### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

#### **Respiratory Syncytial Virus (Package Insert Data)**

In the 1998 Impact-RSV Study Group, prophylaxis with palivizumab for preterm infants without CLD or children with CLD resulted in a 55% reduction in RSV hospital admission; 4.8% (48/1,002) in the palivizumab group and 10.6% (53/500) in the no prophylaxis group. Similar reductions in other measures of RSV severity in breakthrough infections were also reported. In a 2003 double-blind, placebo-controlled randomized trial of 1287 children with hemodynamically significant CHD, Feltes et al reported prophylaxis with palivizumab was associated with a 45% reduction in hospitalization rate for RSV among children with CHD. Hospitalization rates for RSV were 5.3% (34/639) in the palivizumab group and 9.7% (63/648) in the no prophylaxis group. The authors concluded that prophylaxis with palivizumab is clinically effective for reducing the risk of serious lower respiratory tract infection caused by RSV infection and requiring hospitalization in high-risk children.

#### **American Academy of Pediatrics Guidelines**

The AAP released updated guidelines regarding the prophylaxis of RSV in 2014 (reaffirmed in 2019), targeting infants considered to be at “high risk” for severe disease and most likely to benefit from prophylaxis with Synagis based on available clinical literature. The AAP Red Book was updated in 2021, providing eligibility criteria for prophylaxis of high-risk infants and children.

#### **Preterm Infants without Chronic Lung Disease**

Data regarding the risk of RSV hospitalization for most preterm infants do not support a benefit from prophylaxis. In recent large cohort studies of moderately preterm infants, the majority of whom did not receive palivizumab, 2.5% to 4.9% required hospitalization for RSV infection during the RSV season indicating that more than 95% did not require hospitalization. The rate of hospitalization among infants  $\geq 35$  weeks' gestation (5.1/1000) was no different than the rate for term infants (5.3/1000). The hospitalization rate of infants  $\geq 30$  weeks to 35 weeks' gestation indicate only a slight increase in risk (less than twofold). Data concerning host or environmental risk factors for hospitalization in preterm infants without CLD or CHD are inconsistent, with the exception of age younger than 3 months at the start of the RSV season, which has been associated with an increased risk of hospitalization. The environment should be optimized for all infants, but especially preterm infants, to prevent RSV. Environmental optimization includes breast milk feeds, immunization of household contacts for influenza, practicing hand and cough hygiene, and avoiding tobacco exposure and large group childcare during the first winter season, wherever possible.



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### **Preterm Infants with Chronic Lung Disease**

Studies have documented that infants and young children with CLD have increased rates of RSV hospitalization. Results from the IMPact-RSV trial evaluating all preterm infants with CLD (n = 762 randomized preterm infants) demonstrated that the RSV hospitalization rate among placebo recipients was 12.8% and 7.9% among palivizumab recipients (P = .038).

### **Infants with Hemodynamically Significant Congenital Heart Disease**

As mentioned above, the study looking at patients with CHD showed that hospitalization rates for RSV were 5.3% (34/639) in the palivizumab group and 9.7% (63/648) in the no prophylaxis group (p=0.003). There were 29 fewer RSV hospitalizations over the 4 year study in those that received palivizumab versus those that didn't receive prophylaxis. There appeared to be less benefit in cyanotic children than acyanotic children (23 fewer RSV hospitalizations/1000 palivizumab recipients vs. 68 fewer RSV hospitalizations/1000 palivizumab recipients). Other investigators describe the RSV hospitalization rate in those with hemodynamically significant CHD to be lower than the 9.7% reported in the earlier described study. A retrospective analysis of children younger than 3 years in the Tennessee Medicaid program revealed that the RSV hospitalization rate for children with CHD in the second year of life (18.2/1000) was less than half the hospitalization rate for low-risk infants in the first 5 months after birth (44.1/1000), a group for whom palivizumab prophylaxis is not recommended. Therefore, prophylaxis in the second year of life is not recommended for this population.

### **Children with Pulmonary Abnormalities or Neuromuscular Disorders**

The risk of RSV hospitalization is not well defined in children with neuromuscular disorders that impair the ability to clear secretions from the upper airway. Studies have shown that those with neuromuscular disease that are hospitalized with RSV are likely older than other groups that are hospitalized and are more likely to have a pre-existing immunity to RSV.

### **Immunocompromised Children**

The most current AAP guidelines (2014 update) state that, "Population-based data are not available on the incidence or severity of RSV disease among children who receive solid organ transplants (SOTs) or hematopoietic cell transplants (HCTs), children who receive chemotherapy, or children who are immunocompromised because of other conditions." The guidelines also mention, "No data are available to suggest benefit from immunoprophylaxis among immunocompromised patients, and practices vary nationwide. Further research is required before definitive recommendations can be made for the use of palivizumab in this heterogeneous group of children. The AAP recommends that children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.



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### Other Indications

#### Cystic Fibrosis

A Cochrane review was published in 2010 and updated in 2013, assessing the use of palivizumab in children with cystic fibrosis. Based on a literature search through October 2012, 1 randomized comparative trial met the inclusion criteria of both reviews. In the study, 186 infants younger than 2 years with cystic fibrosis were randomly assigned to receive 5 monthly doses of palivizumab (n = 92) or placebo (n = 94). One member of each group was hospitalized for RSV within the 6-month follow-up period. The rate of adverse event noted in each group was relatively high, with serious adverse events not significantly different between the palivizumab and placebo groups (20.2% and 17.3%, respectively). The authors noted that it was not possible to draw conclusions on the tolerability and safety of RSV immune prophylaxis in cystic fibrosis. The single study reported similar adverse events but did not specify how adverse events were classified. No clinically meaningful outcome differences were noted at 6-month follow-up. The authors of the review called for additional randomized studies to establish both efficacy and safety of immune prophylaxis in children with cystic fibrosis.

#### Down Syndrome

Studies have shown that RSV prophylaxis would have a limited effect on RSV hospitalization for children with Down Syndrome without other risk factors for RSV.

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| 08/03/2005 | Medical Director review  |
| 08/16/2005 | Medical Policy Committee review  |
| 08/24/2005 | Managed Care Advisory Council approval   |
| 12/20/2005 | Medical Policy Committee review. Clarification of post-operative dose following procedures requiring cardiopulmonary bypass to reflect the intent of policy to provide eligibility for children that would otherwise qualify for administration of immune prophylaxis for RSV. |
| 07/07/2006 | Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.   |
| 09/05/2007 | Medical Director review  |
| 09/19/2007 | Medical Policy Committee approval. Coverage eligibility unchanged.   |
| 09/03/2009 | Medical Policy Committee approval.   |
| 09/16/2009 | Medical Policy Implementation Committee approval. Policy updated to adopt the American Academy of Pediatrics (AAP) 2009 Red Book Guidelines.   |



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09/09/2010 Medical Policy Committee review

09/15/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/01/2011 Medical Policy Committee review

09/14/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/12/2012 Medical Policy Committee review

04/25/2012 Medical Policy Implementation Committee approval. Deleted the maximum of five doses from all of the criteria statements for immune prophylaxis for respiratory syncytial virus. Changed the criteria bullet to liberalize coverage regarding infants born at 28 weeks of gestation or earlier. These infants used to be eligible for coverage during their first respiratory syncytial virus season, but are now candidates for prophylaxis during the respiratory syncytial virus season, whenever that occurs during the first 12 months of life.

04/04/2013 Medical Policy Committee review

04/24/2013 Medical Policy Implementation Committee approval. Removed Respigam from the wording in the “When Services May Be Eligible for Coverage” section. On 1.b., clarified that it is referring to 1.a. On 1.g., deleted the wording regarding the max number of doses. Formatting to “When Services Are Considered Not Medically Necessary” and “When Services are Considered Investigational” sections.

04/03/2014 Medical Policy Committee review

04/23/2014 Medical Policy Implementation Committee approval. Added statements to clarify the administration of the policy. Clarified that multiple births do fulfill the requirement of another sibling in the household. Also added verbiage clarifying the dates of the BCBSLA RSV season and continuation of the season. Also clarified that patients receive the entire season for dosing unless specified in the patient selection criteria.

08/07/2014 Medical Policy Committee review

08/20/2014 Medical Policy Implementation Committee approval. Updated the policy to reflect changes in the 2014 American Academy of Pediatrics (AAP) Respiratory Syncytial Virus (RSV) Prophylaxis Guidelines.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

12/03/2015 Medical Policy Committee review

12/16/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/01/2016 Coding update

12/01/2016 Medical Policy Committee review

12/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

10/01/2017 Coding update



## Immune Prophylaxis for Respiratory Syncytial Virus

Policy # 00177

Original Effective Date: 08/24/2005

Current Effective Date: 01/13/2025

12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2020	Medical Policy Committee review
03/11/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021	Coding update
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Updated seasonality information due to a fluctuation in timing of RSV season. Added AAP information about 5 doses.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Added criteria requiring that Beyfortus not be received within the same RSV season and that the monthly dose not exceed 15 mg/kg (maximum 5 doses). Updated background section regarding RSV seasonality, defining RSV based on regional data from NREVSS. Added Guidelines section.

Next Scheduled Review Date: 12/2025

### **Coding**

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*



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*The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	90378
HCPCS	S9562
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.



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**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

