MEDICAL POLICY – 5.01.10

Immune Prophylaxis for Respiratory Syncytial Virus

BCBSA Ref. Policy: 5.01.10

Effective Date: Nov. 1, 2019
Last Revised: Oct. 4, 2019
Replaces: 5.01.504

RELATED MEDICAL POLICIES:
None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Respiratory syncytial virus (RSV) is the most common cause of infection in the small airways of the lungs (bronchiolitis) and pneumonia in children. Very young children who were born too early (prematurity) or have chronic lung disease (CLD) of prematurity, congenital heart disease, or immune problems are at highest risk to get pneumonia. Providing a regular infusion of antibodies against the RSV virus during RSV season may decrease lung infections and hospital stays. This policy outlines when the Plan covers these infusions, based on guidelines of the American Academy of Pediatrics.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Synagis® (palivizumab) | Monthly administration of immune prophylaxis for respiratory syncytial virus (RSV) with Synagis® (palivizumab) during the RSV season may be considered medically necessary in the following infants and children in accordance with guidelines-based recommendations (American Academy of Pediatrics [2014]):  
  1. **In the first year of life**, ie, younger than 12 months at the start of the RSV season or born during the RSV season, for the following:  
     a. Infants born before 29 weeks, 0 days of gestation  
     b. Preterm infants with chronic lung disease (CLD) of prematurity, defined as birth at less than 32 weeks, 0 days of gestation and a requirement for more than 21% oxygen for at least the first 28 days after birth  
     c. Certain infants with hemodynamically significant heart disease (eg, 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)  
        i. Decisions regarding Synagis® (palivizumab) prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist  
     d. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways (eg, ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy)  
     e. Children with cystic fibrosis who have at least one of the following conditions:  
        i. Clinical evidence of CLD  
        **AND / OR**  
        ii. Nutritional compromise |
Drug | Medical Necessity
--- | ---
2. **In the second year of life**, ie, younger than 24 months at the start of the RSV season:
   a. Children who were born at less than 32 weeks, 0 days of 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
   b. Children with cystic fibrosis who have either:
      i. 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 (CT) that persists when stable)
      OR
      ii. Weight for length less than the 10th percentile
3. **In the first or second year of life**:
   a. Children who will be profoundly immunocompromised (eg, will undergo solid organ or hematopoietic cell transplantation or receive chemotherapy) during the RSV season
4. After surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of Synagis® (palivizumab) may be considered medically necessary after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation (ECMO) for infants and children younger than 24 months.

**Immune prophylaxis for RSV with Synagis® (palivizumab) is considered not medically necessary in:**

1. Infants and children with hemodynamically insignificant heart disease (eg, 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
### Drug | Medical Necessity
---|---
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

### Drug | Investigational
---|---
**Synagis® (palivizumab)**  
Other indications for immune prophylaxis for RSV are considered investigational (unless criteria for medical necessity outlined above are satisfied), including but not limited to:
- Controlling outbreaks of health care-associated disease (nosocomial infection)  
- Use in children with Cystic Fibrosis (CF)  
- Use in children with Down syndrome without other risk factors  
- Use in children over 2 years of age

### Documentation Requirements
The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:
- Diagnosis/condition  
- History and physical examination documenting the severity of the condition  
- Gestational age at birth (when the baby was born during the pregnancy, counted in weeks)

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 90378</td>
<td>Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
**Consideration of Age**

Immune prophylaxis for respiratory syncytial virus (RSV) with palivizumab (Synagis®) is considered medically necessary in infants and children during the RSV season in accordance with current (2014) guidelines from the American Academy of Pediatrics and medical literature. The evidence for the use of immune prophylaxis for RSV in infants with Down syndrome or children over the age of 2 is insufficient without other risk factors.

**Dosing and Administration**

Synagis® (palivizumab) is administered by intramuscular injection at a dose of 15 mg/kg of body weight per month. The anterolateral aspect of the thigh is the preferred injection site. Routine use of the gluteal muscle for the injection site can cause sciatic nerve damage.

Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the respiratory syncytial virus (RSV) season to infants who qualify for prophylaxis. Qualifying infants born during the RSV season will require fewer doses. For example, infants born in January would receive their last dose in March (see *Initiation and Termination of Immunoprophylaxis* subsection below) (American Academy of Pediatrics [2014]).

Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge.

**Breakthrough RSV**

Guidelines make the following recommendation on breakthrough RSV: “If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood (<0.5%) of a second RSV hospitalization in the same season” (AAP [2014]).

**Prevention of Health Care-Associated RSV Disease**

RSV is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. Among hospitalized infants, the best way to reduce RSV transmission is to strictly observe common infection control practices; this includes the restriction of visitors to the
neonatal intensive care unit during peak respiratory virus season, and to promptly initiate all standard precautions when coming into contact with RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (eg, pediatric or neonatal intensive care unit or stem cell transplantation unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose.

Interactions

Synagis® (palivizumab) does not interfere with response to other scheduled childhood vaccines. However, palivizumab may interfere with RSV diagnostic tests that are immunologically based (eg, some antigen detection-based assays).

Risk Minimization Techniques

For all infants, particularly those who are preterm, the environment should be optimized to prevent RSV and other viral respiratory infections by doing the following: offering breast milk feeds, immunizing household contacts with influenza vaccine, practicing hand and cough hygiene, avoiding tobacco or other smoke exposure, and by not attending large group child care during the first winter season, whenever possible (Technical Report: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. Aug 2014;134(2):e620-e638. PMID 25070304).

Initiation and Termination of Immunoprophylaxis

Initiation of immunoprophylaxis in November and continuation for a total of 5 monthly doses will provide protection into April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February.

In the temperate climates of North America, peak RSV activity typically occurs between November and March, whereas in equatorial countries, RSV seasonality patterns vary and may occur throughout the year. The annual occurrence of the RSV season is predictable, but the severity, time of onset, peak activity, and end of the season cannot be predicted precisely. Substantial variation in timing of community outbreaks of RSV disease from year to year exists in the same community and between communities in the same year, even in the same region.
These variations occur within the overall pattern of RSV outbreaks, usually beginning in November or December, peaking in January or February, and ending by late March or sometime in April. Communities in the southern United States, particularly in Florida, tend to experience the earliest onset of RSV activity. In recent years, the national duration of the RSV season has been 21 weeks (MMWR [2013]).

Clinical trial results have indicated that Synagis® (palivizumab) trough serum concentrations more than 30 days after the fifth dose will be well above the protective concentration for most infants. Five monthly doses of palivizumab will provide more than 20 weeks of protective serum antibody concentration. In the continental United States, a total of 5 monthly doses for infants and young children with congenital heart disease, chronic lung disease of prematurity, or preterm birth before 32 weeks of gestation (31 weeks, 6 days) will provide an optimal balance of benefit and cost, even with variation in season onset and end.

Data from the Centers for Disease Control and Prevention have identified variations in the onset and offset of the RSV season in Florida that affect the timing of palivizumab administration. Northwest Florida has an onset in mid-November, which is consistent with other areas of the United States. In North Central and Southwest Florida, the onset of RSV season typically is late September to early October. The RSV season in Southeast Florida (Miami-Dade County) typically has its onset in July. Despite varied onsets, the RSV season is of equal duration in the different regions of Florida. Children who receive palivizumab prophylaxis for the entire RSV season should receive palivizumab only during the 5 months after the onset of RSV season in their region (maximum of 5 doses).

**Evidence Review**

**Description**

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections in children. Several factors that put certain children at a higher risk for contracting RSV have been identified: they are (age <2 years old), prematurity, chronic lung disease of prematurity (formerly known as bronchopulmonary dysplasia), congenital heart disease, immunodeficiencies, and multiple congenital anomalies. Immune prophylaxis against RSV is a preventive strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants.
Background

Respiratory Syncytial Virus Infections

Respiratory syncytial virus (RSV) infections typically occur in the winter months, starting from late October to mid-January and ending anywhere from March to May. Considerable variation in the timing of community outbreaks is observed year to year. According to U.S. Centers for Disease Control and Prevention, the onset of the RSV season occurs when the median percentage of specimens testing positive for RSV is 10% higher over a 2-week period. Annually in the United States, RSV infection has been associated with an estimated 57,527 hospitalizations and 2.1 million outpatient visits among children less than 5 years of age. While RSV is a near-ubiquitous infection, infants with underlying medical issues, especially a history of prematurity with associated lung problems, are at risk of developing serious complications from bronchiolitis secondary to RSV.

Treatment

Synagis® (palivizumab) is a humanized monoclonal antibody, made using recombinant DNA technology, directed against a site on the antigenic site of the F protein of RSV.

Other RSV preventive agents, including vaccines, have been under development. A recombinant RSV fusion protein nanoparticle vaccine has been shown to induce an immune response in a phase 2 trial.

This policy does not address therapies to treat RSV infection.

Summary of Evidence

For individuals with high-risk indications for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes several RCTs and systematic reviews. The relevant outcomes are overall survival, symptoms, morbid events, and hospitalizations. Evidence from systematic reviews of RCTs has demonstrated that RSV prophylaxis with Synagis® (palivizumab) is associated with reductions in RSV-related hospitalizations and intensive care unit stays. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with cystic fibrosis without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes an RCT, several prospective and
retrospective cohort studies, and multiple systematic reviews. The relevant outcomes are overall survival, symptoms, morbid events, and hospitalizations. Although some studies have demonstrated reductions in hospitalizations in palivizumab-treated patients, studies that used contemporaneous controls did not. In the available RCT, rates of adverse events were high in both the palivizumab and the placebo groups, making it difficult to draw conclusions about the net benefit of palivizumab. A more recent nonrandomized study using noncontemporaneous controls found fewer RSV infections in palivizumab-treated patients with CF. Additional studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with immunodeficiencies without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes case series. The relevant outcomes are overall survival, symptoms, morbid events, and hospitalizations. Descriptive findings from a consensus panel and case reports of 2 infants with primary immunodeficiencies and 2 infants with acquired immunodeficiencies in whom palivizumab was used with good compliance and efficacy have been reported in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Down syndrome without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes a prospective cohort study. The relevant outcomes are overall survival, symptoms, morbid events, and hospitalizations. The available cohort study reported reduced rates of RSV-related hospitalization in treated patients but had methodologic limitations, including the use of a noncontemporaneous comparative cohort from a different country; such limitations introduce uncertainty into any conclusions that can be made. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in July 2019 did not identify any ongoing or unpublished trials that would likely influence this review.
Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 3 physician specialty societies (7 responders) while this policy was under review in 2009. Most providing input agreed with the policy statements; these statements concurred with the 2009 American Academy of Pediatrics guidelines.

Practice Guidelines and Position Statements

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2014) updated its guidelines on the use of Synagis® (palivizumab) in high-risk infants. In 2017, the guidelines were reviewed by AAP, the American Academy of Family Physicians, American College of Chest Physicians, American College of Emergency Physicians, and the Committee on Infectious Diseases. Following that review, the AAP concluded that its recommendations should remain unchanged (see Table 1).

Table 1. Guidelines on Use of Palivizumab Prophylaxis for Infants

<table>
<thead>
<tr>
<th>Recommendations for Using Palivizumab Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prophylaxis recommended</strong></td>
</tr>
<tr>
<td>• Infants born before 29 weeks, 0 days of gestation, during first year of life</td>
</tr>
<tr>
<td>• Infants born before 32 weeks, 0 days of gestation with chronic lung disease of prematurity, during first year of life</td>
</tr>
<tr>
<td>• Children in the second year of life who require 28 or more days of supplemental oxygen and continue to require medical intervention during respiratory syncytial virus season</td>
</tr>
<tr>
<td><strong>Prophylaxis may be considered</strong></td>
</tr>
<tr>
<td>• Infants with hemodynamically significant heart failure, during first year of life</td>
</tr>
</tbody>
</table>
Recommendations for Using Palivizumab Prophylaxis

- Infants with a pulmonary abnormality or neuromuscular disease that impairs ability to clear secretions from lower airways, during first year of life
- Children younger than 24 months who are profoundly immunocompromised during respiratory syncytial virus season

Prophylaxis not recommended

- Healthy infants born at or after 29 weeks, 0 days of gestation
- There is insufficient evidence for children with cystic fibrosis or Down syndrome without other risk factors

AAP (2014) also published guidelines on the diagnosis, management, and prevention of bronchiolitis (updating 2006 guidelines), and made the following recommendations about the use of palivizumab for RSV prevention (see Table 2)\(^{28}\).

Table 2. Guideline on the Diagnosis, Management, and Prevention of Bronchiolitis

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>QOE</th>
<th>SOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of 29 weeks, 0 days or greater.&quot;</td>
<td>B</td>
<td>Strong</td>
</tr>
<tr>
<td>&quot;Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants &lt;32 weeks 0 days' gestation who require &gt;21% oxygen for at least the first 28 days of life.&quot;</td>
<td>B</td>
<td>Moderate</td>
</tr>
<tr>
<td>&quot;Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the respiratory syncytial virus season to infants who qualify for palivizumab in the first year of life.&quot;</td>
<td>B</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

QOE: Quality of Evidence  
SOR: Strength of Recommendation

Medicare National Coverage

There is no national coverage determination.
Regulatory Status

In 1998, the biologic drug palivizumab (Synagis®; MedImmune) was approved for marketing by the Food and Drug Administration through a biologics license application (103770) 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, the Food and Drug Administration 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. There are no therapeutic equivalents to this drug.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/99</td>
<td>Add to Prescription Drug Section - New Policy</td>
</tr>
<tr>
<td>11/02/99</td>
<td>Replace policy - Policy reviewed and updated.</td>
</tr>
<tr>
<td>09/21/00</td>
<td>Replace policy - Policy reviewed and updated.</td>
</tr>
<tr>
<td>07/01/02</td>
<td>Replace policy - Policy language revised pertaining to dates of RSV season, making it generic. No criteria changes for prophylactic administration.</td>
</tr>
<tr>
<td>06/17/03</td>
<td>Replace policy - Policy reviewed; no changes required.</td>
</tr>
<tr>
<td>11/16/03</td>
<td>Replace policy - Policy updated with revised recommendations for the use of palivizumab (Synagis) in infants of 32 –35 weeks gestational age</td>
</tr>
<tr>
<td>01/13/04</td>
<td>Replace policy - Policy changed from PR to BC. Policy updated; added indication for infants with hemodynamically significant heart disease and for those born between 32-35 weeks gestation with additional high-risk factors. Policy based on AAP guidelines. Policy held for notification, effective 4/15/04.</td>
</tr>
<tr>
<td>03/08/05</td>
<td>Replace policy - Policy reviewed; references added; RSV immune prophylaxis in stem cell transplantation added to the investigational policy statement.</td>
</tr>
<tr>
<td>01/10/06</td>
<td>Replace policy - Policy reviewed with literature search; no change to policy statement. Information added regarding new liquid formulation of Synagis to policy guidelines.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>11/13/07</td>
<td>Replace policy - Policy reviewed with literature search; no change to policy statement.</td>
</tr>
<tr>
<td>12/16/08</td>
<td>Minor Update - Policy statement clarified regarding definition of weeks of gestation.</td>
</tr>
<tr>
<td>10/13/09</td>
<td>Replace policy - Policy updated with literature search. The policy statement has been modified to reflect the 2009 AAP. References added.</td>
</tr>
<tr>
<td>11/10/09</td>
<td>Minor Update - Minor update was made to number 4 in the policy statement: “infants born before 35 wks of gestation” was deleted and “Infants less than one year of age” was added.</td>
</tr>
<tr>
<td>12/14/10</td>
<td>Replace policy - Policy updated with literature search. References 15 and 16 added. Policy statements unchanged. Reviewed by a practicing pediatrician.</td>
</tr>
<tr>
<td>12/29/10</td>
<td>Codes Updated - Code 90378 added; no other changes.</td>
</tr>
<tr>
<td>12/16/11</td>
<td>Replace policy – Policy updated with literature search. Policy statement number 4 modified with removal of “born before 35 weeks of gestation” to be consistent with the AAP guidelines. Other policy statements are unchanged. Codes updated: CPT codes 96365, 96366 and 963372; ICD-10 codes added.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Policy updated with literature search through June 18, 2013. References 3 and 6 added; references 1, 10 and 15 updated. Policy statements unchanged. CPT</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/08/14</td>
<td>Annual Review. Policy updated with literature review through July, 2014. References 1-2, 16-17, 20-22, 25, 27-28, 30, 32 added; reference 31 updated; others renumbered/removed. Policy statements revised to reflect the 2014 updated guidance from AAP. Coding update: ICD-9 and ICD-10 codes removed; these do not facilitate administration of the policy.</td>
</tr>
<tr>
<td>11/10/15</td>
<td>Annual Review. Immune prophylaxis in children over 2 years old was added to the Investigational policy statement. Policy updated with literature review through September 8, 2015; references 2, 7, 10, 33-34 added. Policy statement updated as noted.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>Interim Review, approved October 11, 2016. Supportive language added to address age application criteria in compliance with non-discrimination act.</td>
</tr>
<tr>
<td>03/07/17</td>
<td>Minor formatting update; separated investigational and medically necessary indications.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Interim update, approved December 20, 2017. It was clarified that the use of Synagis® (palivizumab) in children over 2 years of age is investigational.</td>
</tr>
<tr>
<td>11/01/18</td>
<td>Annual Review, approved October 26, 2018. Policy updated with literature review through June 2018; no references added. Policy statements amended to clarify RSV prophylaxis and children with Down syndrome. For children with Down syndrome without other risk factors, RSV prophylaxis is considered investigational. Therefore, the clause “without other risk factors” was added to the policy statement. Re-added Consideration of Age information, which was inadvertently removed during a previous review.</td>
</tr>
<tr>
<td>03/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
</tr>
</tbody>
</table>

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  • Information written in other languages

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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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