RSV (Respiratory Syncytial Virus) is an infection that affects the lungs and can cause serious breathing problems for children and babies. There is one medication, palivizumab, that has been successful at protecting children from contracting RSV, but you and your doctor must apply for it and be accepted by the pharmaceutical manufacturer to use the medication.

Here are some steps you can take to help your pulmonologist, pediatrician, or other clinician make a strong case for treating your infant with this medication.

- Ask your pediatrician or pulmonologist to contact the medical director associated with your health plan to plead the case for palivizumab.
- Develop and provide your doctor with a list of the illnesses (major and minor) that occurred in the NICU and post-NICU to show a timeline of immunity challenges your infant is facing.
- Document any and all appointments related to those illnesses (pediatrician, specialists, ER, pediatrics, admissions, PICU admissions) as well as any post-illness therapy that was needed.
- Describe the home regimen for all medicine the infant takes daily, as well as any precautions the family applies to prevent illness, such as taking vitamins; family changing clothes before entering the house; no visitors; wearing protective gloves; using hand sanitizer; and any other precautions your family incorporates into your daily routine.
- If your child had RSV already, describe the details of the illness and its impact on both your infant and family.
- Communicate if there are other young children that live in the house and/or if the baby is in daycare. More children means more germs so it becomes even more important to protect at-risk infants.
- Be the squeaky wheel - help your doctor make your application a priority by calling in and being pushy. Be sure to keep a log of all calls for later reference.

If you are denied palivizumab for your infant, here are some additional steps you can take:

- Your provider will receive the denial, after which your doctor/provider or you can submit an appeal.
- Contact the case manager at the hospital and/or for your infant's health plan to discuss the denial and see what steps the case manager suggests would be helpful to challenge your denial.
- Contact a human resources representative at your workplace responsible for managing your health insurance and let them know there are issues with denial of treatment options. They may or may not be able to help with your denial, but should be informed for future reference.
- If your appeal is denied, consider contacting your state's Bureau of Insurance to file a complaint around a denial.

There are also some legal actions you can pursue if your appeal is denied:

- If you are on Medicaid and if your child has been denied palivizumab and meets American Academy of Pediatrics RSV prophylaxis guidelines consider partnering with a local legal-aid group to get a response from your Medicaid plan. Talk to your provider to confirm your infant meets the American Academy of Pediatrics guidelines for RSV prophylaxis.
- Contact an attorney for help. There have been lawsuits filed in the past that have been won over this issue.

For more information about RSV, go to chestnet.org/patient-education-resources/rsv

Many factors beyond what are listed in this infographic can affect your infant's health, and should be discussed thoroughly with your clinician(s) regarding your specific case.

These materials were supported in part by a grant from AstraZeneca Pharmaceuticals.
What Is RSV?

PARENT FACT SHEET

RSV (Respiratory Syncytial Virus) is an infection that affects the lungs and can cause serious breathing problems for children and babies that usually occurs in the fall and winter months.

Who’s At Risk?

Preemies and infants with chronic health conditions are most at risk for RSV. Specifically:

- Preterm infants born at less than 30 weeks gestation
- Current age of 6 months or less
- Infants/babies who are being treated for chronic lung disease and congenital heart disease
- Other issues that affect lung development or respiratory muscle strength

What Are the Symptoms of RSV?

For most babies, RSV looks a lot like a common cold to begin with, including a runny nose, sniffles and a fever. Signs to watch for as RSV progresses are:

- Rapid breathing or difficulty breathing
- Blue tint of mouth, fingernails or skin
  - Under 3 months old – a temperature of 100.4° or more
  - Between 3-6 months old – a temperature of over 101°
  - Over 6 months old – a temperature of over 103°
- Thick discharge from nose
- Persistent coughing
- Wheezing (high-pitch whistling while breathing)
- Dehydration
- Chest retractions

Many factors beyond what are listed in this infographic can affect your infant’s health, and should be discussed thoroughly with your clinician(s) regarding your specific case.

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What Can You Do to Help Prevent RSV?

There are a number of steps you can take to help prevent your infant from exposure to RSV:

- Everyone who cares for your baby & visitors should wash hands with soap and water or use an alcohol based hand sanitizer
- Limit visitors. Avoid crowds
- Stay away from sick people & keep sick people away from your baby
- Have siblings change clothes after school or group activities
- Wipe down commonly used surfaces with a bleach wipe
- No smoking around or in the same room as the baby
- Wash baby’s bedding & toys often
- Don’t share baby’s items, like pacifiers, spoons, etc with other children

Is There Medication That Can Help Prevent RSV?

There is an injectible drug called palivizumab that is highly recommended for premature infants. The injection needs to take place once a month for five months, throughout the fall and winter months when RSV occurs. Here are the steps to follow to determine if palivizumab treatment is right for your infant:

Step 1: Talk to your pediatrician or pulmonologist and discuss your baby’s level of risk

Step 2: Work with your doctor to talk to your insurance company and determine how you can get coverage for palivizumab. This therapy is often covered by insurance carriers

Step 3: Complete the Patient Authorization Form the doctor gives you

Step 4: Ensure your baby receives their dose of palivizumab monthly

Step 5: Watch your baby for signs of distress

How Can I Learn More?

For more information about RSV, go to chestnet.org/patient-education-resources/rsv
Palivizumab is a recommended injectible medication for premature infants at a higher risk for contracting RSV (respiratory syncytial virus). Here are the steps you can follow to refer patients for palivizumab therapy:

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<tbody>
<tr>
<td><strong>1</strong></td>
<td>Identify whether the patient is at increased risk for severe RSV infection and determine the patients’ eligibility for palivizumab</td>
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<tr>
<td><strong>2</strong></td>
<td>Educate parents and caregivers about severe RSV disease and about palivizumab</td>
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<td>Explain the approval process and set parent and specialty expectations</td>
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<td></td>
<td>Have the parent/caregiver review and sign the Patient Authorization Form</td>
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<tr>
<td><strong>3</strong></td>
<td>Determine the patients’ medical and pharmacy benefits and confirm where the patient will need to go to receive treatment</td>
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<tr>
<td><strong>4</strong></td>
<td>Submit referral to the appropriate party with supportive documentation; follow up with drug provider pharmacy and payer</td>
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<tr>
<td><strong>5</strong></td>
<td>Communicate approval or denial to the parent/caregiver</td>
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<tr>
<td></td>
<td>If approved, parent/caregiver will receive consent-to-ship call</td>
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<tr>
<td><strong>6</strong></td>
<td>Coordinate delivery and confirm scheduled injection</td>
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<tr>
<td></td>
<td>Ensure adherence with monthly injection</td>
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The Facts About RSV in Premature Infants

**CLINICIAN FACT SHEET**

The fact is that RSV can pose a significant risk to premature infants.

There are two factors that put premature infants ≤30 wGA at high risk for severe RSV disease:

1. **Interrupted lung development compromises lung capacity**
   - 34% of lung volume for preterm infants born at 30 weeks GA compared to full term infants
   - 42% of lung volume for preterm infants born at 32 weeks GA compared to full term infants
   - 52% of lung volume for preterm infants born at >37 weeks GA compared to full term infants

2. **Reduced maternally transmitted antibodies**
   - 32% of the serum antibody levels at birth in preterm vs. full term infants born at 28 – 31 weeks GA
   - 57% of the serum antibody levels at birth in preterm vs. full term infants born at 33 – 35 weeks GA
   - 100% of the serum antibody levels at birth in preterm vs. full term infants born at >37 weeks GA

Preterm infants ≤30 wGA had 2 times higher rate of RSV-related hospitalizations vs. full term infants within the first 6 months of life.

Preterm infants exposed to environmental risk factors, such as daycare attendance, non-multiple births and preschool-aged siblings have a 3 times higher rate of RSV-related hospitalizations vs. full term infants.

Learn more about RSV at chestfoundation.org/patient-education-resources/rsv
Efficacy of Palivizumab

- **55%** reduction in hospitalizations associated with severe RSV for preterm infants $\leq 30$ wGA treated with palivizumab
- **42%** fewer total days or RSV-related hospitalization for preterm infants $\leq 30$ wGA treated with palivizumab
- **57%** fewer RSV-related ICU admissions for preterm infants $\leq 30$ wGA treated with palivizumab
- **40%** fewer total days with increased supplemental oxygen for preterm infants $\leq 30$ wGA treated with palivizumab

6 Steps to Successful Palivizumab Treatment

1. Identify at-risk patients for severe RSV and determine patients’ eligibility
2. Educate parents/caregivers about risk factors and the disease
3. Determine medical and pharmacy benefits, identify a drug provider and fill out the referral forms
4. Submit and track the referral to make sure the dose is received in time for the scheduled injection
5. Obtain approval or denial and convey the outcome to the parents/caregivers; if approved, coordinate delivery with the drug provider and parents/caregivers
6. Administer the injections on a monthly basis throughout the RSV season, reviewing and updating forms each month

Increase Your Success Advocating For Your Patients

Here are some tips to help you navigate the Peer to Peer (P2P) discussion when advocating for your patients to receive palivizumab:

- Take time to thoroughly complete the P2P request if you are serious about getting the infant palivizumab.
- It is completely normal for the prior authorization request to be questioned.
- In your interactions with authorizers/peers, do NOT play the “expert” or “specialist” card.
- Bring your patient chart with you when you meet for the P2P discussion; specific details are important.
- Explain the specific circumstances surrounding the individual patient’s need and how potential development of RSV would put the patient at a higher risk for hospitalization than the current inclusion criteria suggest, given the patient’s variables.
- Review and highlight historical information about your patient, particularly any recent hospitalizations (e.g., length of stay, loss of consciousness, unique complications, etc.), which can help bolster your case.

Many factors beyond what are listed in this infographic can affect your infant’s health, and should be discussed thoroughly with your clinician(s) regarding your specific case.

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