Dubai Standards of Care – 2019

Respiratory Syncytial Virus (RSV) Immunoprophylaxis
Acknowledgment

“Dubai standards of care – RSV immunoprophylaxis”

These guidelines were established in order to increase awareness on RSV immunoprophylaxis. In addition to that, these guidelines aim to improve evidence based approaches especially appropriate medication prescribing. These guidelines were prepared and approved by the Dubai Standard of Care Taskforce.

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Definitions / Key Terms:

- **Respiratory Syncytial Virus (RSV):** is a common cause of respiratory infection in infants and children that can result in bronchiolitis or pneumonia.
- **Palivizumab (Synagis):** is the only drug approved by the U.S. Food and Drug Administration (FDA) for
  - prevention of RSV lower respiratory tract disease in preterm infants and in children with CHD or
  - chronic lung disease of prematurity.
- **Chronic lung disease (CLD):** is defined as Broncho pulmonary dysplasia (BPD) or chronic respiratory distress in a preterm infant who has had an oxygen requirement lasting more than 28 days and who exhibits parenchymal changes on x-ray necessitating medical therapy as outlined in this Standard.
- **Onset month (week) of outbreak was defined as the first of two consecutive months (weeks) with at least 5(2) positive RSV cases. Offset month was defined as the last of the final two consecutive months (weeks) with at least 5(2) positive RSV findings. Duration was defined as the number of months (weeks) between the calculated onset and offset months (weeks) inclusive of those months (weeks).**
- **RSV Season Start and End:** on yearly basis RSV season will be decided based on statistics of RSV Bronchiolitis and/or Pneumonia patients hospitalized in the Pediatric wards. The onset of immunoprophylaxis may be preponed or postponed.
  - **Start:** Inj. Palivizumab should only be administered during the active RSV season, which for Dubai generally occurs from Sep/Oct to Feb/March.
  - **End:** The Immune-prophylaxis season will finish by Feb/March.
Clinical Criteria:
These guidelines provide a framework for the Immuno-prophylaxis with Inj. Palivizumab (Inj. Synagis) to reduce the risk of severe respiratory syncytial virus (RSV) infection in high-risk infants and to prevent RSV infection hospitalization among high-risk infants.

Protocol:

This clinical guideline will be implemented for all high-risk infants (refer 3.2 for the list of high risk infant) born and/or admitted in NICU, infants attending Pediatric clinics and/or PHC or admitted in Pediatrics wards.

1. Preterm Infants:

- Infants born at less than 28 weeks of gestation and are less than 12 months old at the start of the RSV season; or
- Infants born between 28-32 weeks of gestation (31 weeks and 6 days or less) and are less than 6 months old at the start of the RSV season; or
- Infants born between 32+ - 35 weeks of gestation (34 weeks and 6 days or less), and are less than 6 months old at the start of the RSV season and have a Risk Assessment Tool Score of 49 to 100. In such cases, infants must be offered prophylaxis dose until they reach 3 months chronological age (a maximum of 3 doses).

2. Preterm Infants with Chronic lungs disease:

- In preterm infants with chronic lung disease of prematurity (those born before 32 weeks’ gestation who require greater than 21% oxygen for at least the first 28 days after birth) during RSV season during the first year of life.
- If the infant continues to require medical support (maintenance corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six months before the start of his or her second RSV season.
3. **Infants with Hemodynamically Significant Congenital Heart Defect:**

- These recommendations apply to infants in the first year of life who are born within 12 months of the beginning of RSV season.

4. **Those most likely to benefit include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and/or require cardiac surgery in the 1st year of life.**

5. **Infants/Children are NOT considered at increased risk for RSV Infection and are not eligible for RSV Prophylaxis if they have any of the following conditions and do not satisfy any other eligibility criteria:**

   - Hemodynamically insignificant heart disease i.e. Secondum atrial septal defects (ASD), small ventricular septal defects (VSD), Pulmonic stenosis, Aortic stenosis, Mild coarcatation of the aorta and Patent Ductus arteriosus (PDA)
   - Infants with corrected surgical lesions unless they continue to require medication for Congestive heart failure (CHF)
   - Infants with mild cardiomyopathy who are not receiving medical therapy

6. **Multiple Birth Sets:**

   - If a high-risk infant of a multiple birth set is approved for the season, the siblings in the same set are also eligible for prophylaxis.

7. **Infants less than 24 months of age at the start of the RSV season with congenital abnormalities of the airway or neuromuscular diseases that compromise handling of respiratory secretions.**
8. Neonatologist to decide on the eligibility for prophylaxis for Repaired congenital diaphragmatic hernia & Esophageal atresia and/or TOF needing surgery on a case by case basis.

9. Immunocompromised infants with severe immunodeficiency will be considered in accordance with medical necessity on a case by case basis by the responsible treating Pediatrician; which must be supported by evidence based medical practice.

10. Infants with cystic fibrosis and who are less than 24 months of age at the start of the RSV season will be considered in accordance with medical necessity on a case by case basis by the responsible treating Pediatric Pulmonologist which must be supported by evidence based medical practice, who will decide on the eligibility.
Algorithm

Premature, no CLD, no CHD

- ≤ 28 wks GA
  Palivizumab if ≤ 12 months at start of RSV season

- 28-32 wks GA
  Palivizumab if ≤ 6 months at start of RSV season

- 32-35 wks GA
  Palivizumab if ≤ 6 months at start of RSV season with High risk tool score of ≥ 49

Hemodynamically Significant CHD

- Palivizumab if ≤ 1 years old at start of RSV season

Chronic Lung Disease* (CLD) who still require medical therapy (diuretics, steroid or oxygen)

- Palivizumab if ≤ 2 years old at start of RSV season

*Receiving medical therapy for CLD within 6 months
**Tools/Attachments Forms:**

Risk Assessment Tool for RSV Prophylaxis in infants ≥ 32 to 35 weeks of GA

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Yes</th>
<th>Yes Value</th>
<th>No</th>
<th>No Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Birth months is October, November of December</td>
<td>25</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2- Infant to attend daycare OR siblings attend daycare</td>
<td>17</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3- More than five individuals in the home including the infant (i.e. six or more)</td>
<td>13</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4- Small for gestational age (birth weight less than the 10th percentile for gestational age)</td>
<td>12</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>5- Immediate family (mother, father, sibling) history without eczema (without eczema=Yes)</td>
<td>12</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6- Sex is male</td>
<td>11</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7- Two or more smokers and/or use of bakhoor and/or shisha in the household</td>
<td>10</td>
<td></td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**Total score :**