وزارة الصحة
Ministry of Health

High risk infants & Children Respiratory Syncytial Virus (RSV) Prophylaxis Policy

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High risk infants & Children RSV Prophylaxis	N/A	General directorate of hospital affairs	NA
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☐ Corporate Policy (General) ☐ Inter-department Policy ■ Department Policy	01-10-2024	15-10-2024	01-09-2025

1. Statement of Purpose

1.1. 1.1. To establish the procedural guidelines for administration of RSV prophylaxis for the high risk group infants and children

2. Defintions

2.1. **Respiratory Syncytial Virus (RSV)** is a virus that causes severe lower respiratory tract infection among infants and young children.

2.2. **Palivizumab (Synagis)** is a drug used in prophylaxis of RSV.

2.3. **RSV Season** is the period during which the prevalence of the virus is suspected to be more and this varies among the regions and the nations according to the seasonality. In Saudi Arabia, generally the onset ranged from the middle to late of October and offset ranged from early to middle of March.

2.4. **Bronchopulmonary dysplasia (BPD)** is defined as oxygen dependency for babies < 32 weeks GA at 36 weeks corrected gestational age.

3. Equpiment/Material/Form(s)

3.1. Palivizumab (Synagis)

3.2. Water for injection

3.3. Syringe 1 ml

3.4. RSV Card

4. Policy Statment

4.1. RSV clinics in MOH hospitals shall start Middle of October until middle of March.

4.2. Palivizumab prophylaxis should be administered to all infants born before 28, 6 days weeks' gestation, who are younger than 12 months at the start of the RSV season.

4.3. Palivizumab prophylaxis should be administered to all infants born as Mid preterm (29 weeks GA, 0 days to 32 weeks, 6 days GA) who are ≤6 months of age at the start of the RSV season.

4.4. Palivizumab prophylaxis should be administered to all infants born as preterm infants and diagnosed with BPD who are <12 months for all, (considered) <24 months if still receiving medication for BPD within 6 months from the beginning of the RSV season

4.5. Palivizumab prophylaxis can be (considered) to all infants diagnosed with certain hemodynamically significant heart diseases (acyanotic heart disease under medical support and moderate to severe pulmonary hypertension) who are <12 months for all; <24 months if still receiving medications for the cardiac condition<6 months from the beginning of the RSV season .

4.6. Palivizumab prophylaxis can be (considered) to all infants diagnosed with anatomic pulmonary abnormalities or neuromuscular disorder or immunocompromised children with impaired ability to handle respiratory secretions or

Down syndrome with accompanying qualifying heart disease, CLD, airway clearance issues, or prematurity who are <24 months old from the beginning of the RSV season.

4.7. Palivizumab prophylaxis can be (considered) to all infants diagnosed cystic fibrosis who are <12 months with clinical evidence of CLD and/or nutritional compromise <24 months with manifestations of severe lung disease OR weight for length <10th percentile at the beginning of the RSV season.

4.8. Palivizumab should be administered up to a maximum of 5 monthly doses (15 mg/kg per dose during the RSV season to infants who qualify for prophylaxis in the first year of life.

4.9. Qualifying infants born during the RSV season must receive doses according to their month of birth. For example, infants born in January would receive their last dose in March.

4.10. Monthly Prophylaxis can be considered to be continued in any child who experiences a breakthrough RSV hospitalization as planned until a maximum of 5 doses have been administered during the season.

4.11. Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease.

4.12. Injection. Palivizumab should be stored in refrigerator at 2' c to 8'c.

4.13. To reduce the risk for RSV and other vital infections, all infants, especially preterm infants, should be offered breast milk and parents should be instructed to avoid smoke exposure, attendance in the large group childcare during the first winter season, and contract with ill people.

4.14. It is recommended that household members should be immunized against influenza, practice good hand hygiene, and cough hygiene.

5. Procedures

5.1. Preparation of Palivizumab (synagis):

5.1.1. Obtain the injection. Palivizumab from the refrigerator and dilute the powder using water for injection.

5.1.2. Use 1 ml of water for injection, for 100mg vial of palivizumab and 0.6 ml for 50 mg vial, thus the final concentration is 100 mg/ml.

5.1.3. Slowly add the water among the inside wall of the vial to minimize foaming and tilt the vial slightly and gently rotate the vial for 30 seconds. DO NOT SHAKE VIAL.

5.1.4. Leave the palivizumab solution at room temperature for a minimum of 20 minutes until the solution clarifies.

5.1.5. Since the palivizumab does not contain any preservative, it must be administered within 3 hours of preparation.

5.2. Administration of palivizumab:

5.2.1. Verify the patient identity and data.

5.2.2. Calculate the dose to be administered according to the weight. The dose should be 15 mg/ kg.

For Example:

$$\text{Weight x } \frac{15\text{ mg}}{100\text{mg}} = \text{--- ml to be administered.}$$

5.2.3. Obtain required amount of injection and administer intramuscularly in the anterolateral aspect of thigh using standard aspect technique. Gluteal muscle is not preferred as an injection site because of the risk of sciatic nerve damage.

5.2.4. Administer injection volumes over 1 ml as a divided dose.

5.2.5. Palivizumab is contraindicated in the patients with hypersensitivity to the active substance or other humanized monoclonal antibodies.

5.2.6. Keep all equipments needed for treatment id sever hypersensitivity reaction ready before administration of prophylaxis.

5.2.7. Do not reconstitute palivizumab with any other diluents or medical components.

5.2.8. Health provider educates the mother regarding the adverse effects like fever, nervousness and diarrhea which are common post administration of Prophylaxis.

5.2.9. Document the patient details and the date of administration in the RSV area in seha portal and/or card.

6. Responsiblity

6.1. It is the responsibility of the Head of the Department and head nurse of neonatology department to monitor the implementation of this policy for effective compliance by all medical and nursing staff

7. References

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7.2. Synagis Package Insert. Gaithersburg, MD: MedImmune; April 2013. Available at: www.medimmune.com/docs/defaultsource/pdf/prescribing-informationfor-synagis.pdfzzz Accessed April 24.2014

7.3. ABIM Foundation. American Board of Internal Medicine; ACP-ASIM Foundation. Federation College of Physicians-American Society of Internal Medicine. Medical professionalism in the new millennium; a physician charter. Ann Intern Med. 2012; (3);243-246

7.4. **Saudi Initiative of Bronchiolitis Diagnosis, Management, and Prevention 2024 updated consensus on the prevention of respiratory syncytial virus, https://journals.lww.com/aotm,**

8. Appendix

N/A