Children's Health Ireland at Crumlin

GUIDELINES FOR THE ADMINISTRATION OF PALIVIZUMAB (SYNAGIS®)	
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1.0 Purpose of the Guideline

To guide the medical and nursing staff of OLCHC on the correct use and administration of palivizumab (synagis®).

2.0 Definition of Guidelines

Palivizumab (synagis®) is a humanised monoclonal antibody preparation given over the winter season as prophylaxis against the respiratory syncytial virus (RSV). Palivizumab is administered by intramuscular injections monthly throughout the winter months when RSV is most prevalent.

3.0 What is RSV?

RSV is a respiratory pathogen which can infect people of all ages. It is the most common cause of bronchiolitis / pneumonia in infants and children < 2 years (Nair et al., 2010). RSV occurs as an annual epidemic from October to April in temperate climates. RSV is a highly contagious virus spread by direct or close contact with contaminated secretions, which may involve droplets or fomites (American Academy of Paediatrics Redbook 2018). Infants with certain underlying health issues are at higher risk of developing serious respiratory illness with RSV with significant associated morbidity including the need for ventilation and prolonged hospitalisation. These babies may be eligible for RSV prophylaxis with the monoclonal antibody Palivizumab. Palivizumab provides passive immunisation against RSV, it does not elicit an immune response and has a half-life of 20 days, consequently a monthly dosing schedule throughout the winter is recommended to maintain protective serum levels (Resch 2017).

4.0 Patients considered for Palivizumab prophylaxis in CHI at Crumlin

Patients considered for Palivizumab prophylaxis in CHI at Crumlin	
Preterm	Born at < 29/40 gestation and are < I year at the start of the RSV season
Chronic lung of prematurity	In their first year of life infants born < 32 /40 gestation with chronic lung disease of prematurity (required >21% for > 28 days post birth) Patients 1-2 years with more severe CLD who continue to require cardiac / respiratory medication
Congenital Heart Disease	Infants < 1 year with haemodynamically significant cyanotic or acyanotic heart disease
Immunocompromised	Infants with profound immunocompromised and children who are anticipated to need a bone marrow transplant in the first 2 years of life
Neuromuscular	Infants with pulmonary abnormalities or neuromuscular impairment that interferes with their ability to clear secretions

Action	Rationale and References
Patients must be assessed by consultant and deemed suitable for RSV prophylaxis according to AAP guidance 2014. American Academy of Paediatrics guidance 2014 Pediatrics. 2014;134(2):415–420. Available at: https://pediatrics.aappublications.org/content/134/2/415	Palivizumab is associated with significant cost. Prophylaxis with Palivizumab necessitates monthly intramuscular injections for the child. Careful selection of patients is therefore essential. AAP guidance 2014
RSV prophylaxis referral form must be completed by the patient's primary consultant and sent to the infectious diseases department. (Referral forms are available on all the infant wards in CHI at Crumlin and also in the specialised units CHC, PICU and TCU). On completion of the referral form the **top copy (white sheet)** is sent to the RSV clinical nurse specialist in the infectious diseases dept., **The yellow copy** must be forwarded to pharmacy. Note: always attach patient addressograph label. **The blue copy** is filed in the patient's medical records. **The pink copy** is retained for ward records. The RSV nurse specialist can be contacted: ext: 2680 Bleep:8268 rsvnurse@olchc.ie	E4 Completion of the referral form allows processing of all patients for RSV prophylaxis. Patient details must be clear. A written record of the referral in both the patient and ward files is useful in avoiding unnecessary repeated referrals.
Once the referral form is received by the RSV Nurse Specialist the patients' parents will be contacted and a schedule of injections planned for the winter season. Palivizumab is given by monthly intramuscular injection at 28- 32 day intervals for the duration of the RSV season. Depending on the prevalence of RSV the first injection	The majority of patients are suitable for the home administration service. Referral to the community agency TCP Home Care (temperature controlled pharmaceuticals) is coordinated by the RSV Nurse Specialist For high risk patients who may not tolerate intramuscular injections in the home they may attend a specialist outpatient clinic monthly or will be referred to their local hospital for Palivizumab injections. Inpatients receive Palivizumab during their inpatient stay Palivizumab does not elicit an immune response, it has a half-life of 20 days necessitating a monthly dosing schedule to maintain protective serum levels Prevalence of the virus varies from year to year.

is usually given in October and monthly thereafter until March / April. The infectious diseases consultants and clinical microbiologists determine the duration of the prophylaxis programme.	The optimum time to start and end the monthly injections is based on the circulating levels of RSV.
The Administration of Palivizumab **<u>Dosage</u>** Palivizumab dosage is calculated according to the patients' weight. The recommended dose of Palivizumab is 15mg per kg of body weight. This dose is calculated on the most recent weight of the child. Inpatients are weighed on the day before the Palivizumab is due. Parents of outpatients are asked to get their child weighed by their public health nurse the day before the injection is due. If this is not possible, the patient is weighed on arrival at CHI at Crumlin	An accurate patient weight ensures that the appropriate dosage of Palivizumab is prescribed
Prescription A dose rounding chart is used to calculate the recommended dosage of Palivizumab. The Palivizumab dosage must prescribed clearly in the patient's drug kardex by the relevant medical team.	Palivizumab is an expensive product, to maximise efficient vial usage and avoid wastage, all doses of Palivizumab in CHI at Crumlin are prepared in the pharmacy ACU (aseptic compounding unit) according to a drug rounding scale.
Reconstitution Palivizumab is drawn up by the pharmacy staff in the ACU (Aseptic compounding unit) The palivizumab is ordered the day before by the CNSp and details of the patient weight included. If a recent weight is unavailable, a provisional weight (based on the patients' last weight) is given and confirmation of the patients' present weight conveyed to ACU once the patients has been weighed in CHI at Crumlin. Once the dosage of Palivizumab is accurately drawn up by the pharmacy staff, it is labelled with • Patient's Name • Hospital Identification Number • Dosage of Palivizumab	Aseptic preparation allows vial sharing of this expensive product. Patients are grouped together to minimise Palivizumab wastage. To ensure correct preparation is given to the patient. Medication policy OLCHC 2017

• Time of Reconstitution • Expiry Time **Storage and Shelf Life** Palivizumab has a shelf life of three years. It must be stored in a refrigerator (2° - 8°). Not to be frozen. Palivizumab contains no preservatives and must be administered within 3 hours following reconstitution. (Once reconstituted in ACU under sterile conditions palivizumab must be administered within 6 hours) **Palivizumab should not be mixed with any medications or diluents other than water for injection.**	To ensure the safe preparation and handling of Palivizumab according to the manufacturers recommendations. OLCHC Medication Policy 2017
Information for Parents The role of Palivizumab in helping to lower the risk of hospitalisation with RSV is explained to parents. The schedule of injections is discussed along with the necessary steps to guard against RSV infection with regard to hand washing, avoiding ill contacts and crowded areas etc. A copy of the information booklet for parents "Synacare", provided by Abbvie laboratories Ireland ltd is given to each family.	To inform parents. To gain co-operation and encourage compliance with the prophylaxis regime. To help reduce the risk of cross infection in the home. Information pack for parents Abbvie June 2020
Consent Form Consent for the administration of a course of Palivizumab injections must be obtained from parents of inpatients prior to the first injection. This consent form must be completed and signed by the clinical nurse specialist or medical team with the child's parent or legal guardian. A copy of this consent is filed in the patient's medical records. For patients receiving Palivizumab in the community or in their local hospital, consent is required to share patient details with the appropriate agency. Assurance is given that all data is handled in accordance with GDPR (2018) guidance.	To ensure that consent for this intervention is obtained and written documentation recorded in the patient case notes. The sharing of a patient's personal data with an outside agency requires explicit consent.

Referral to TCP Using an online referral portal, patients are referred to TCP for monthly Palivizumab injections. Parents are given a high tech prescription to take to their local pharmacy. They are advised of a need to update their pharmacist monthly regarding their child's weight A copy of the high tech prescription is sent by encrypted email to TCP home care. A further copy is emailed to the high tech co-ordination unit of the HSE.	TCP arrange for a paediatric nurse to visit the child's home each month to administer Palivizumab.
Administering Palivizumab in the hospital environment The presence of working suction equipment and oxygen must be established at the bedside. An emergency trolley should be close by containing the necessary drugs to combat extreme hypersensitive reactions including anaphylaxis.	To ensure patient safety during Palivizumab administration. To facilitate appropriate patient care in a case of a rare adverse reaction to this Antibody preparation.
Patient assessment Prior to administration of Palivizumab the patients' condition needs to be assessed. The assessment is done by checking the patients' vital signs and asking the parents about the child's recent health. Baseline vital signs are recorded in the patients' records. If there is any indication that the child is unwell he/she must be assessed by the relevant medical team before the dose of Palivizumab is given.	To ascertain that the patient is well enough to receive palivizumab. To allow for accurate monitoring of the effects of the injection. **Contraindications** Palivizumab is contraindicated in patients with a known hypersensitivity to Palivizumab or any other humanised monoclonal antibodies. A moderate to severe acute or febrile illness may warrant delaying the dose of Palivizumab unless in the opinion of the physician withholding the dose entails a greater risk. <u>Note:</u> *A mild febrile illness is not usually reason to defer administration of palivizumab.* *Palivizumab administration does not interfere with routine vaccination schedule.* (Redbook 2018)
Patients due Palivizumab within the week prior to cardiac surgery necessitating the use of cardiopulmonary bypass may have their dose postponed until after the surgery. For patients who still require prophylaxis post	There is a 58% decrease in serum Palivizumab levels post cardiopulmonary bypass (AAP 2014).

operatively a post-operative dose of Palivizumab should be given as soon as the patient is medically stable.	
As with any intramuscular injection, Palivizumab should be given with caution to patients with thrombocytopenia or any coagulation disorders.	To minimise the risk of bleeding / haematoma formation.
Administration of Palivizumab The palivizumab injections are collected from ACU. Each syringe is clearly labelled with the patient details, name and identification number. The dosage of Palivizumab, and expiry time and date.	According to the manufacturers recommendations for safe storage and reconstitution of Palivizumab. (Abbvie Ireland laboratories ltd 2016)
Two nurses check the patient drug kardex. The patient name, hospital ID number, date of birth, weight and history of allergies must be checked.	*Palivizumab must be administered according to OLCHC administration of medication policy 2017*
Both health professionals are required to check the prescribed dose of Palivizumab and individually calculate the dose according to the patients' weight and with reference to the dose rounding chart produced by CHI at Crumlin Pharmacy. The prepared syringe of Palivizumab is checked against the drug kardex, the patients name, hospital number, dose of Palivizumab, and expiry date and time is checked.	To ensure the patient receives the correct dosage.
Both nurses go to the patient and check the patients name band with the prescription chart for correct name, date of birth and hospital number.	To confirm the correct identity of the patient. OLCHC Medication Policy 2017
The site of the injection is identified; the anterolateral aspect of the thigh into the vastus lateralis is the preferred site. The selected site is recorded so that alternating the site for the next dose can be achieved. If the dose is greater than 1ml in volume the dose is divided into 2 doses and given in separate sites.	This site allows for ease of access and also there is an absence of major blood vessels or significant nerve structures associated with this site. (Rodger and King 2000).
The parent and patient are prepared by ensuring safe and secure positioning of the child.	To ensure that the antibody is injected safely.
A needle size 25g 0.5 x 16mm is used. Following thorough hand washing, the needle is injected directly into the chosen site using an aseptic technique.	Intramuscular injection performed according to CHI at Crumlin Nurse Practice Development Unit Guidelines (2017)
The needle is then withdrawn and the needle and syringe are disposed according to hospital policy on	OLCHC Policy on the Disposal of Clinical Waste (2017).

the disposal of sharps. The site is covered with cotton wool which can be replaced by a band aid after 2-3 minutes.	
Recording Drug Administration The patients drug kardex is signed by both nurses recording the date and time of administration. A record of the dose of Palivizumab and the date and time of administration is also recorded in the patients' medical records.	To ensure that an accurate record of the administration of Palivizumab is maintained. As per "Recording clinical practice" guidelines for nurses and midwives, NMBI (2015)
Patient Observation Following the administration of the injection the patient is observed closely. Any adverse effects of the injection must be reported to the relevant medical team and monitoring / treatment of the patient's condition continued as appropriate. The patients' condition post procedure is clearly recorded in the patients' medical records.	To monitor for any signs of adverse reaction to Palivizumab. Adverse drug reactions reported in the drug trials were similar in the Palivizumab and the placebo studies. Adverse drug reactions were generally transient and mild to moderate in severity. The most common effects included fever / injection site reactions. Very rare adverse drug reaction Include: anaphylaxis, Urticaria, apnoea (Abbvie laboratories Ireland ltd., 2016)
Scheduling of next injection Parents are given the date when the next dose is due. This is confirmed in writing with an appointment sent by post. For patients seen in the community or in their local hospital a record of doses administered in CHI at Crumlin is sent to TCP or the relevant hospital.	To ensure that the appropriate interval of not more than 32 days between doses is maintained.

5.0 References

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