From the Chief Medical Officer
Professor Sir Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

HSS(MD) 46/2021

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: Michael.McBride@health-ni.gov.uk

Our Ref: HSS(MD) 46/2021
Date: 16 July 2021

FOR ACTION
Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/ NIAS
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleagues

PALIVIZUMAB PASSIVE IMMUNISATION AGAINST RESPIRATORY SYNCYTIAL VIRUS (RSV) IN AT-RISK PRE-TERM INFANTS

ACTION REQUIRED

Chief Executives must ensure arrangements are put in place immediately to commence the administration of palivizumab to eligible preterm infants at risk of serious Respiratory Syncytial Virus (RSV) infection.

The HSCB should take the necessary steps to make palivizumab (Synagis®) available with immediate effect during the 2021/2022 RSV season as a preventative measure for infants who meet the access criteria outlined in this letter.

My letter of 31 March 2021 (HSS(MD) 27/2021) advised that due to no detection of RSV in Northern Ireland at that time, no further doses of palivizumab should be given until further notice.

My March letter also advised that, in anticipation of an early surge in RSV cases as social distancing measures are relaxed, the numbers of cases of RSV would be monitored. Trusts were asked to put in place plans to be able to restart vaccination clinics if an increase in cases is detected and when advised to do so.

RSV has now been detected in Northern Ireland and Trusts should immediately stand up arrangements to commence immunisation of eligible infants in line with the policy set out below.

Since publication of the letter in March 2021, the COVID-19 Rapid Policy Statement (RPS), which extended eligibility for palivizumab beyond the guidance issued by the Joint Committee on Vaccination and Immunisation (JCVI) in the context of the COVID-19 pandemic, has now been updated to take the expected early and prolonged RSV season into account. The revised statement increases the maximum number of monthly doses a baby can receive from five to seven.

The additional doses are to take account of the early and prolonged season expected, thereby protecting vulnerable babies to prevent serious illness and decrease hospital and intensive care admission rates.

To this effect, and without prejudice to extant Managed Entry arrangements, the HSC Board should now take the necessary steps to make palivizumab (Synagis®) available with immediate effect during the 2021/21 RSV season as a prevenative measure for infants who meet the access criteria set out in the interim clinical commissioning policy. The HSC Board should monitor uptake of treatment through extant HSC Board processes.

Eligibility criteria

Infants who meet the current JCVI recommendations will continue to be eligible for palivizumab. *In addition*, during the COVID-19 pandemic, the following additional access criteria are permitted:

- Infants born at ≤34^{+0} weeks gestation; **AND**
- Diagnosed with CLD[1]; **AND**
- Discharged from hospital on home oxygen in the 9 months prior to the start of the RSV season (for the start of the 2021/2022 RSV season this is for patients discharged on or after 1 October 2020).

Dose

The recommended dose of palivizumab is 15mg/kg of body weight, given once a month. Where possible the first dose should be administered at the start of the RSV season. **Subsequent doses should be administered monthly throughout the RSV season for up to a maximum of seven doses.** Where the course of treatment begins later in the RSV season then up to seven doses should be given one month apart until the end of the RSV season.

Contraindications and precautions

Palivizumab should **not** be given to infants or children who have had:

[1] Defined for the purpose of this policy as "preterm infants with compatible x-ray changes who continue to receive supplemental oxygen or respiratory support at 36 weeks post-menstrual age" (Department of Health, 2015). Please note that the JCVI define CLD as "oxygen dependency for at least 28 days from birth" (JCVI, 2010).

- A confirmed anaphylactic reaction to a previous dose of palivizumab
- A confirmed anaphylactic reaction to any components of palivizumab
- A confirmed anaphylactic reaction to another humanised monoclonal antibody.

Palivizumab should be given with caution to patients with thrombocytopenia or any coagulation disorder.

Please note that the Northern Ireland Regional Group for Specialist Medicines has classified Synagis® as a red list drug. This is defined below:

Red List Drug: It is recommended that the prescribing responsibility should remain with the consultant or specialist clinician and that the supply of these medicines should be organised via the hospital pharmacy.

Yours sincerely

PROF SIR MICHAEL McBRIDE
Chief Medical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)
Assistant Director Public Health (Health Protection), Public Health Agency
Director of Nursing, Public Health Agency
Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board *(for onward distribution to Community Pharmacies)*
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, HSCB
Family Practitioner Service Leads, Health and Social Care Board *(for cascade to GP Out of Hours services)*
Medical Directors, HSC Trusts *(for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads)*
Nursing Directors, HSC Trusts *(for onward distribution to all Community Nurses, and Midwives)*
Directors of Children's Services, HSC Trusts
RQIA (*for onward transmission to all independent providers including independent hospitals*)
Medicines Management Pharmacists, HSC Board *(for cascade to prescribing advisers)*
Regional Medicines Information Service, Belfast HSC Trust
Regional Pharmaceutical Procurement Service, Northern HSC Trust
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB
Professor Sonja McIlfatrick, Head of School of Nursing, University of Ulster
Siobhan Murphy, CEC

Donna Gallagher, Open University
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU
Professor Colin McCoy, Head of School, School of Pharmacy, QUB
Professor Colin Adair, Postgraduate Pharmacy Dean, NI Centre for Pharmacy Learning and Development, QUB
Joe Brogan, Assistant Director of Integrated Care, HSCB
Donncha O'Carolan, HSCB *(for distribution to all General Dental Practitioners)*
Raymond Curran, Head of Ophthalmic Services, HSCB *(for distribution to Community Optometrists)*
Trade Union Side
Clinical Advisory Team
Louise McMahon, Director of Integrated Care, HSCB

This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications