



This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Hydroxocobalamin injection 1000 micrograms

By registered health care professionals for

Vitamin B12 deficiency

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 96

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	<ul style="list-style-type: none"> Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	<ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Vitamin B12 deficiency
Inclusion criteria	<ul style="list-style-type: none"> • Patients over the age of 16 years • Addisonian pernicious anaemia • Tobacco amblyopia (poor sight caused by toxins such as tobacco) • Leber's atrophy (Degeneration of the optic nerve resulting in loss of central vision) • Treatment/prevention of other macrocytic anaemias due to deficiency in vitamin B12 • Vitamin B12 should be given prophylactically after total gastrectomy or total ileal resection (or after partial gastrectomy if vitamin B12 absorption test shows vitamin B12 malabsorption)
Exclusion criteria	<ul style="list-style-type: none"> • Patients under the age of 16 years • Diagnosis not fully established • Previous history of sensitivity to vitamin B12 or are allergic to any of the ingredients • Should not be used to treat certain types of anaemia during pregnancy
Cautions (including any relevant action to be taken)	Should not be given before diagnosis fully established
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

8. Details of the medicine

Name, form and strength of medicine	Hydroxocobalamin injection 1000 micrograms
Legal category	Prescription only medicine (POM)
Indicate any <u>off-label use</u> (if relevant)	None
Route/method of administration	Intramuscularly

Dose and frequency	Initial dose: 1000mcg given on alternate days (5 doses) over a two week period Maintenance dose: 1000mcg every three months if vitamin B12 levels are insufficient/Intrinsic factor level is unacceptable
Quantity to be administered and/or supplied	As per dose
Maximum or minimum treatment period	One episode of care based on blood levels
Storage	Room temperature
Adverse effects	<ul style="list-style-type: none"> • Diarrhoea • Dizziness • Headache • Hot flush • Nausea • Skin reactions • Urine discolouration • Arrhythmia • Chills • Drug fever • Hypokalaemia • Malaise • Pain • Thrombocytosis • Tremor • Vomiting
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. Patient information

Verbal/Written information to be given to patient or carer	<ul style="list-style-type: none"> • Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

10. Appendix A

References
<ol style="list-style-type: none"> 1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. The General Optical Council 6. Electronic medicines compendium available online: https://www.medicines.org.uk

11. Appendix B

Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves