



## ECG Clinical PGD FAQs – Vitamin B12 injection v2.0

### What does our PGD Cover?

Our vitamin B12 PGD covers administration of hydroxocobalamin injection to those with a diagnosed deficiency, and who are being treated according to the licenced information and NICE guidelines. The PGD will not cover administration of vitamin B12 for use as a diet or health supplement.

### Why does our PGD not cover administration of vitamin B12 injection as a diet or health supplement?

This can be explained as follows:

**PGD legislation** does not allow for unlicensed medicines to be supplied and/or administered. PGDs are written to cover administration or supply of a Prescription Only Medicine under its licenced indications. They will cover treatment of conditions that require diagnosis and management from a registered clinician. National Institute for Health and Care Excellence guidance (NICE) states that PGDs are not appropriate where there is diagnostic uncertainty, or where the condition is not well defined.

A PGD must apply to a defined clinical condition which is supported by evidence and national/local guidance. Vague wellness goals do not meet this threshold.

**Licencing of vitamin B12 injection.** Vitamin B12 injection is classified as a Prescription Only Medicine. It is licenced for treatment of vitamin B12 deficiency which has been diagnosed by a clinician to follow NICE guidelines. Treatment for "well-being" and "low energy" are not approved indications in any B12 product licence. Using a PGD for these reasons would therefore constitute off-label use, and this is not permissible within a PGD framework without exceptional, evidence-backed justification.

**Use of PGDs as a framework to keep healthcare professionals and patients safe.** A PGD is written as a framework for safe supply of medication to treat disease. Our PGDs are written with this in mind. We appreciate the importance of keeping our patients, and those healthcare professionals using our service, safe.

Patients may seek vitamin B12 injections if they have low energy or fatigue, however this is potentially unsafe if a diagnosis for these symptoms has not been sought. Low energy and fatigue can be a symptom of many diseases such as thyroid disorders, autoimmune disorders, and cancer. Treatment with vitamin B12 may only lead to delayed specialist referral or treatment for disease.

Note that an independent prescriber (IP) would be able to issue the product for this purpose. An IP takes full accountability for what they prescribe.

## **How is vitamin B12 deficiency diagnosed?**

Diagnosis of vitamin B12 deficiency will include taking a patient history, and investigations such as a full blood count, serum concentrations of vitamin B12 and folate, and intrinsic factor antibody test. The clinician will need to determine whether the symptoms of anaemia are related to vitamin B12 or folate, in order that treatment can be prescribed appropriately. Other tests may be needed when considering a differential diagnosis, and these may include liver function tests or thyroid tests.

## **Further information on vitamin B12 deficiency.**

For adults, the daily requirement of vitamin B12 is about 1-2microgram which is present in most normal diets.

On oral intake, vitamin B12 substances bind to an intrinsic factor which enables absorption from the gastrointestinal tract. Pernicious anaemia develops in patients who have an absence of intrinsic factor. Absorption is also impaired in patients with disease or abnormality of the gastrointestinal tract. Treatment usually results in rapid haematological improvement and a striking clinical response. However neurological symptoms respond more slowly.

Deficiency is more likely in patients with malabsorption disorders, following gastric surgery, in those who use nitrous-oxide or with some medications. As vitamin B12 only occurs in animal products, those with a vegetarian or vegan diet may not absorb adequate amounts and may also develop a deficiency. Symptoms of vitamin B12 deficiency may take several years to become apparent.

Symptoms of vitamin B12 deficiency include extreme tiredness, a lack of energy, pins and needles, a sore and red tongue, mouth ulcers, muscle weakness, visual disturbance, and psychological problems (includes depression, anxiety, confusion, memory, understanding).

## **For those who ask about vitamin B12 supplementation.**

Generally for those who need supplements because of their diet, oral vitamin B12 supplements should be recommended. If malabsorption issues are suspected, or the patient is showing symptoms of vitamin B12 deficiency, they should be referred to their GP for further investigation.