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Charlotte Keel MEDICAL PRACTICE

Diagnosing and Managing Vitamin B12 Deficiency

Version:	Owner:	Created:
1.0	Safeeya Mohamed: Clinical Pharmacist Dr Heather Saxby: GP Registrar Dr Shaba Nabi: Practice Medicine Lead	17/07/2025
Published:	**Approving Director:**	**Next Review**
01/08/2025	Kathy Ryan (Medical Director)	01/08/206

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Introduction

Vitamin B12 deficiency affects 5% of patients aged 65-75 and more than 10% of patients aged 75 and over. Currently, there is an inconsistent approach in treating Vitamin B12 deficiency in the practice. The aim of this Standard Operating Procedure (SOP) is to standardise the management of Vitamin B12 deficiency in patients in the practice following NICE Guidance: NG239, 2024, as well as local guidance shared within Remedy.

Vitamin B12 (cobalamin) deficiency can be a serious condition and a potentially reversible cause of bone marrow failure and demyelination. Early identification and treatment can avoid permanent neurological disability.

Vitamin B12 is a co-factor for two enzymes in the body required for:

- Normal bone marrow function and red blood cell production
- Development and myelination of the nervous system and its maintenance

When to Test

Only offer an initial diagnostic test for Vitamin B12 deficiency in patients who have at least one common symptom/ sign and one common risk factor from the boxes below.

Pregnancy: see additional information for B12 testing in pregnancy which is rare.

Common Signs and Symptoms	Common Risk Factors
• Blood: anaemia or macrocytosis • Cognitive difficulties: - poor concentration - short-term memory loss/ brain fog • Neurological problems: - balance issues, impaired gait or falls - pins & needles or numbness (paraesthesia) • Unexplained fatigue • Glossitis • Optic Nerve Dysfunction: - Blurred vision or optic atrophy - Visual field loss (scotoma)	• Restricted diet - vegan/eating disorder/neglect • Autoimmune conditions: - coeliac, thyroid disease, Type 1 Diabetes • Gastrointestinal issues: - GI surgery: gastrectomy, terminal ileum resection, bariatric surgery - Atrophic gastritis • Drugs: - Metformin, Colchicine, PPIs, H2-receptor antagonists, Pregabalin, Topiramate. - Recreational Nitrous Oxide use (measure homocysteine as well as B12) • Family history: - of B12 deficiency. - of any autoimmune condition.

Further Tests

If Vitamin B12 level LOW (< 145 ng/L) or INDETERMINATE (145 – 180 ng/L), consider these additional tests.

1. Intrinsic Factor (IF) antibodies - > to diagnose pernicious anaemia (unless obvious surgical cause)
2. TTG - > to diagnose Coeliac's disease
3. Parietal cell antibodies - > *only* if IF antibody negative and strong suspicion of autoimmune gastritis

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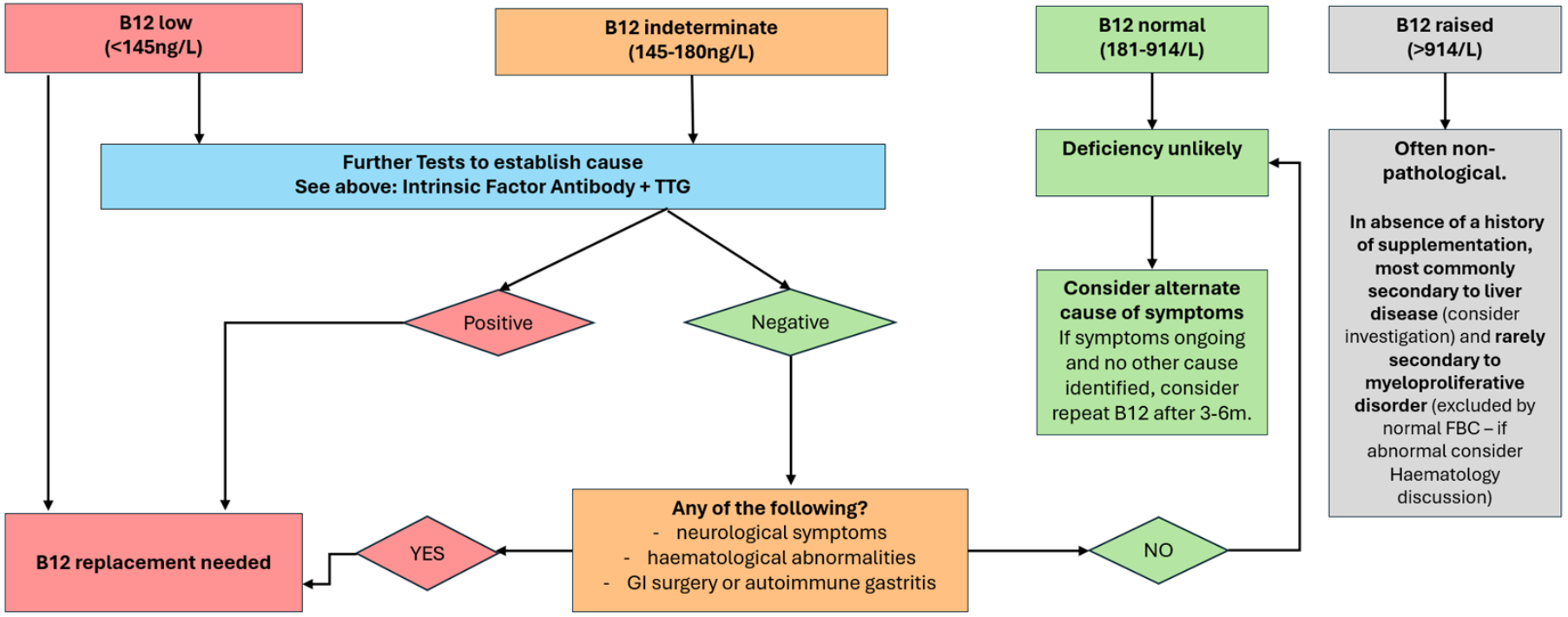
Interpreting B12 Test Results

See NICE guidelines for diagnosis and management of B12 deficiency – note these reference ranges differ from BNSSG local guidelines

TREATMENT SHOULD BE COMMENCED IMMEDIATELY WITHOUT WAITING FOR TEST RESULTS IN SUSPECTED MEGALOBLASTIC ANAEMIA AND NEUROLOGICAL SYMPTOMS (especially any symptoms of subacute combined degeneration of the spinal cord)



Management

Vitamin B12 Replacement

The table below provides information on the treatment based on cause of deficiency.

If deficient in both folate and B12, start B12 before folate		
Cause of B12 deficiency	**Route**	**Treatment**
Any cause of B12 deficiency **with** neurological involvement	IM	• Seek urgent specialist advice from neurologist and/or haematologist. • **Initially:** 1mg Hydroxocobalamin IM on alternate days until advised to stop by specialist, then swap to maintenance. • **Maintenance:** 1mg IM every 2 months lifelong.
Malabsorption from: • Total or partial gastrectomy • Complete terminal ileal resection • Bariatric surgery • Autoimmune gastritis (pernicious anaemia) • Coeliac Disease	IM	• **Initially:** 1mg Hydroxocobalamin IM three times a week for 2 weeks (6 doses), then continue with maintenance • **Maintenance:** 1mg IM every 3 months lifelong even if symptom free. • Coeliac: consider switching to oral Vitamin B12 Cyanocobalamin 1000mcg (1mg)/ day lifelong if symptoms improve
Dietary deficiency, e.g. vegan, poor feeding Lifelong supplementation for vegans, can be stopped on non-vegans once diet improved Dietary deficiency and haematological abnormality OR concerns about adherence	Oral OTC IM	• Advise on how to improve B12 intake https://www.nhs.uk/conditions/vitamins-and-minerals/vitamin-b/ • **Maintenance:** Oral Cyanocobalamin 50 – 150mcg/ day between meals (can be purchased OTC) • **Initially:** 1mg Hydroxocobalamin IM three times a week for 2 weeks (6 doses), then continue with maintenance. • **Maintenance:** 1mg IM every 3 months (if diet/symptoms improve, can be stopped)
Nitrous Oxide recreational use (see above for neurological involvement) • Advice stopping - > B12 can be stopped, 12 months after stopping nitrous oxide	IM or Oral OTC	IM or Oral B12 replacement depending on clinical judgement and patient preference: **IM:** • **Initially:** 1mg Hydroxocobalamin IM three times a week for 2 weeks (6 doses), then continue with maintenance of 1mg IM every 3 months **Oral:** Cyanocobalamin 1000mcg (1mg)/ day OTC
Unknown cause provided not likely to be malabsorption	Oral OTC	Cyanocobalamin 50 – 150mcg/ day OTC lifelong.

Medication cause: - Review if medication can be stopped but continue supplementation while using drug	IM or Oral OTC	**IM:** • **Initially:** 1mg Hydroxocobalamin IM three times a week for 2 weeks (6 doses), then continue with maintenance of 1mg IM every 3 months **Oral:** Cyanocobalamin 50-150 mcg/day

Length of B12 Treatment

For many, IM B12 treatment is lifelong as the underlying cause is irreversible.

- Rechecking B12 levels on patients receiving IM B12 is not required as not useful in practice. Treatment should be guided by the presence or resolution of symptoms.
- Where symptoms have improved or resolved with either IM or oral B12, the cause is unknown and investigations ongoing, treatment should continue to reduce the risk of a return of B12 deficiency until either B12 deficiency is confirmed with alternative testing or an alternative diagnosis has been identified.
- Treatment could be stopped if all symptoms resolve and the underlying cause is identified and resolved e.g. stopped being vegetarian, coeliac disease was the cause and is on a strict gluten-free diet, with patients' safety-netted to come back if there is a return of symptoms or new symptoms that may indicate B12 deficiency.

Documentation

On initiation of therapy, the diagnosing clinician must document:

- Indication for which Vitamin B12 replacement is required
- Vitamin B12 treatment regime:
  - whether IM or oral therapy
  - dosing regimen (e.g. whether three times a week for 6 weeks, then every 3 months; alternate days until symptoms improve then every 2 months etc)
- Length of time of treatment (e.g. long-term, for review after 6 months etc)
- Any follow up or further review i.e. anti-intrinsic factor antibody or coeliac screen, plasma homocysteine
- If administration by intramuscular injection, Hydroxocobalamin must be added as an acute medication to medication records and Patient Specific Direction completed following the B12 injection PSD. This process is detailed below in the Appendix

On review or change of therapy, the clinician must document:

- Any changes to the patient's treatment regime
- Length of time of treatment

This is to ensure that:

- patients are being treated safely and appropriately
- the non-medical prescribers processing the B12 Patient Specific Direction (PSDs) and the nursing team administering the B12 injection are following clear instruction.
- the best use is being made of our NHS resources

Administration

Check

Before administration the following requirements must be met:

- Check PSD is up-to-date and includes the initials of the administering clinical team member
    - (task NMP if a new PSD needed)
- Administered by trained nurse or HCA who has been trained and assessed as competent in the skill

Site

The Hydroxocobalamin should be administered by Intramuscular (IM) injection into the deltoid. Using the alternate arm for each dose.

Storage

Store at or below 25°C. Protected from light.

Documentation

Record using the Injections Template (Ardens) - All injections tab

Ensure the following information is included:

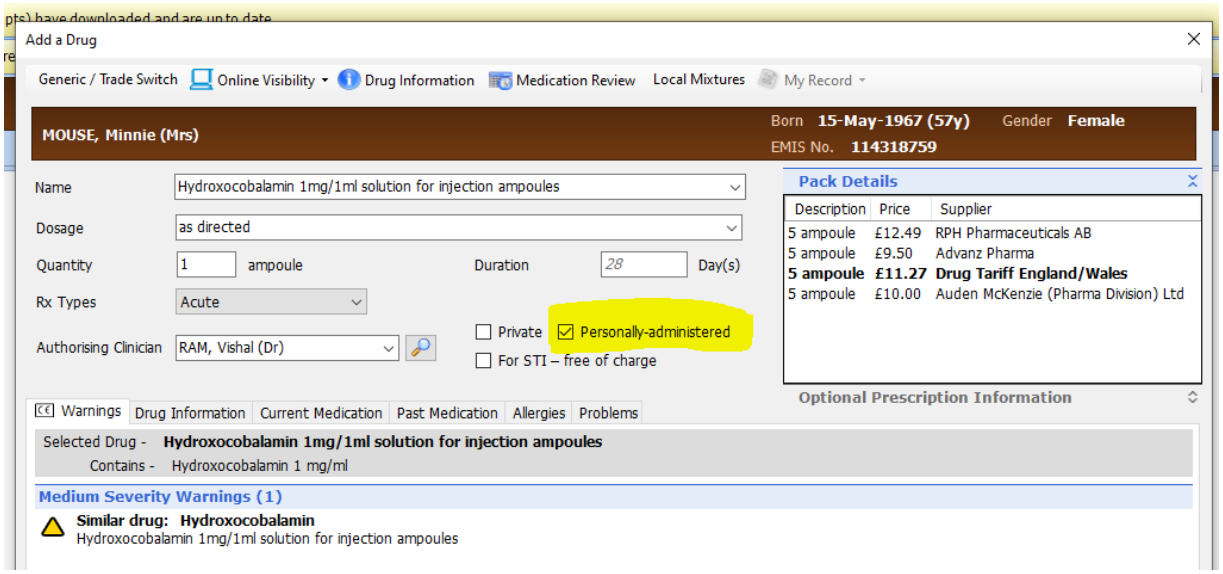
- Problem – Cobalamin deficiency/pernicious anaemia/gastrectomy/gastric bypass
- Consent
- B12 tab – procedure
- manufacturer
- expiry date
- batch number
- route
- follow-up (adjust date according to frequency of administration)

Monitoring

No follow up tests are required but review should be agreed with GP.

Claiming

Add ‘Hydroxocobalamin 1mg/1ml solution for injection’ to medication list and click ‘issue later’ so that prescriptions team can claim for this medication.



If prescription is for the community nurse team to administer this will need to be prescribed by prescribing clinician with clear instructions for District nurse administration only.

Patient Specific Direction (PSD)

A patient specific direction (PSD) is a written instruction from a prescriber for a medication to be administered to a named patient after the prescriber has assessed the patient and is satisfied that the medication to be administered serves the needs of the individual.
The minimum requirements for a PSD are:

- Patient's name
- Name, form and strength of medication (generic or brand name where appropriate)
- Route of administration
- Dose
- Frequency
- Date of treatment/ number of doses/ frequency/ date treatment ends or requires review as applicable
- Signature of prescriber and date PSD is written

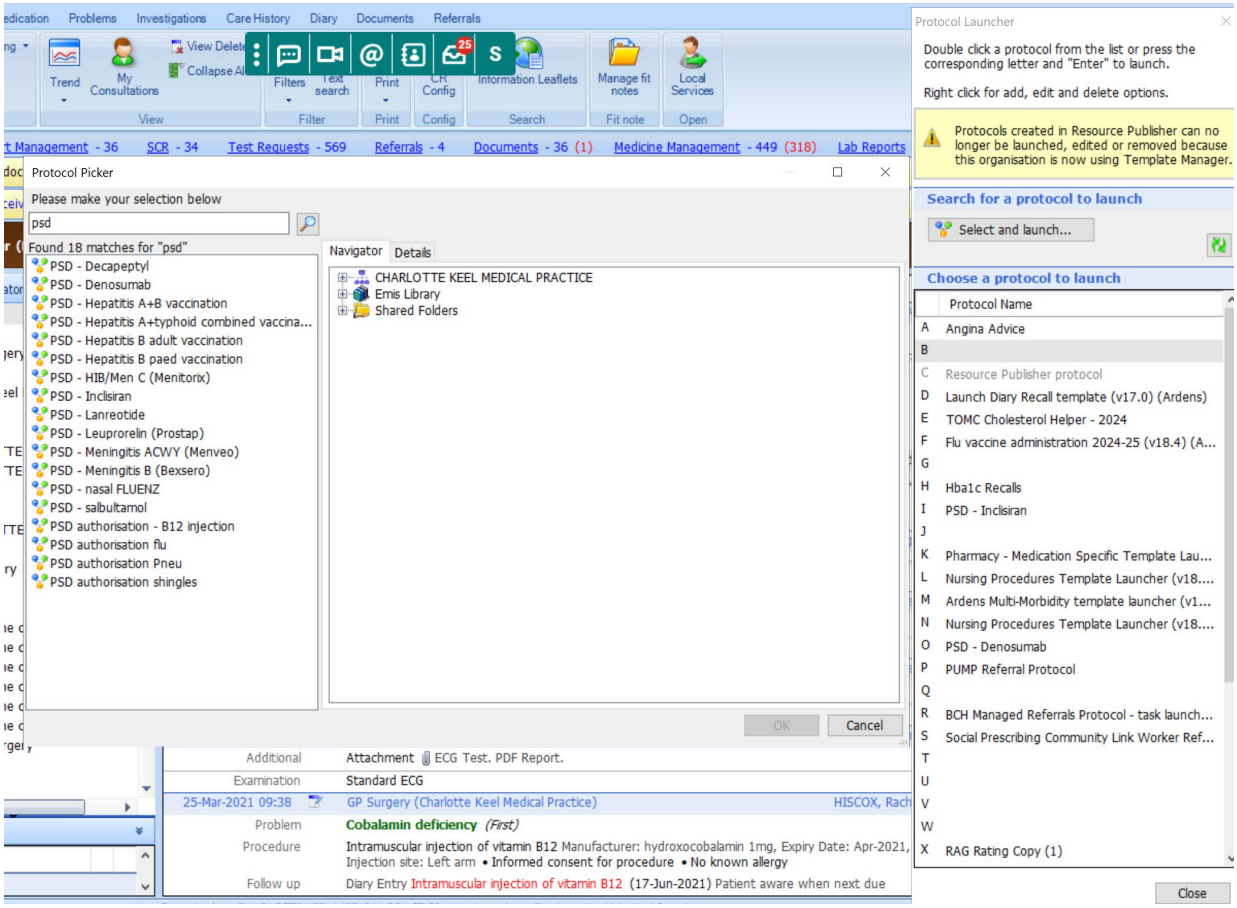
Writing a Vitamin B12 injection PSD in EMIS

A shortcut F12 key has been developed to facilitate generating a PSD for Vitamin B12 injection.

How to add the F12 key

- Make sure you are on the EMIS screen and type the F12 key on your keyboard.
  - This will open the Protocol Launcher
- Click on a blank letter to add the Vitamin B12 PSD shortcut
  - This will be highlighted.
- Right click and click 'Add'
  - This will open the protocols available.
- Type 'PSD' in the search box
  - A list of PSD protocols will be displayed.

- Select ‘PSD authorisation – B12 injection’ and double click on this or click OK.
- This will be added to your F12 protocol list.
- You can then close your F12 list.

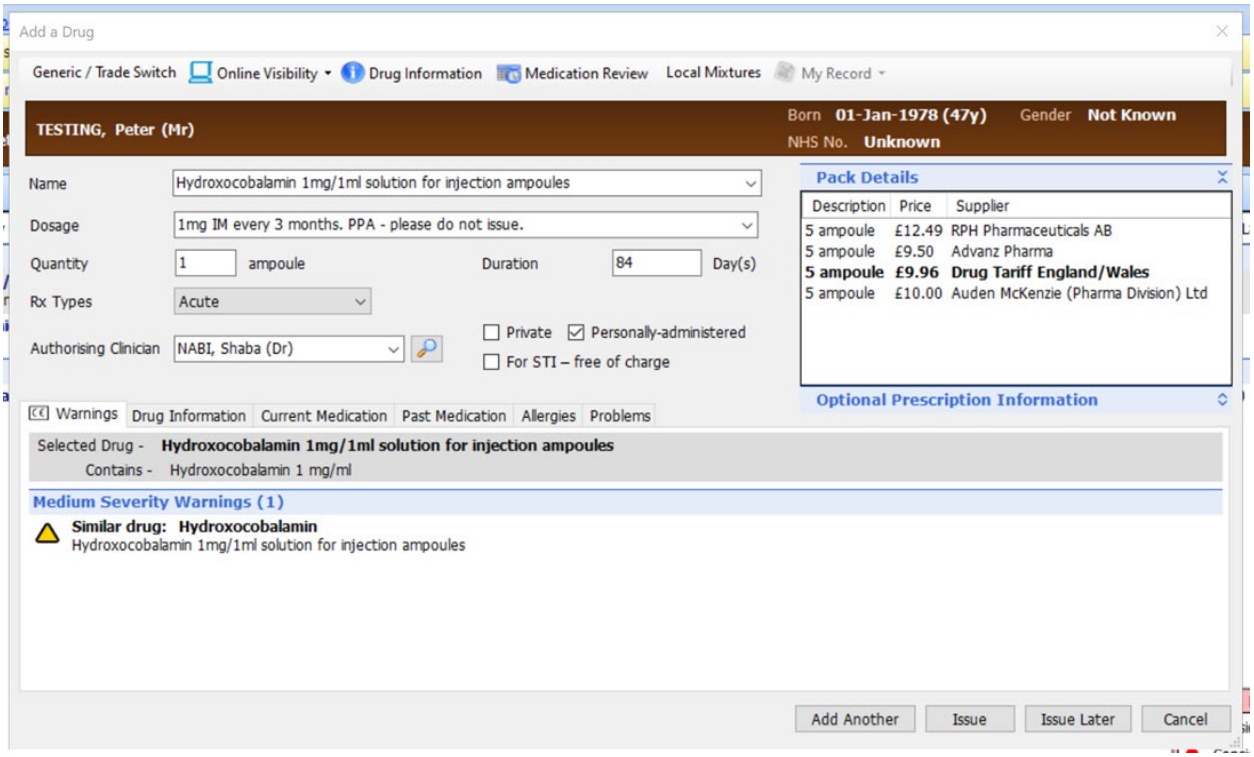


How to Write a Vitamin B12 injection PSD

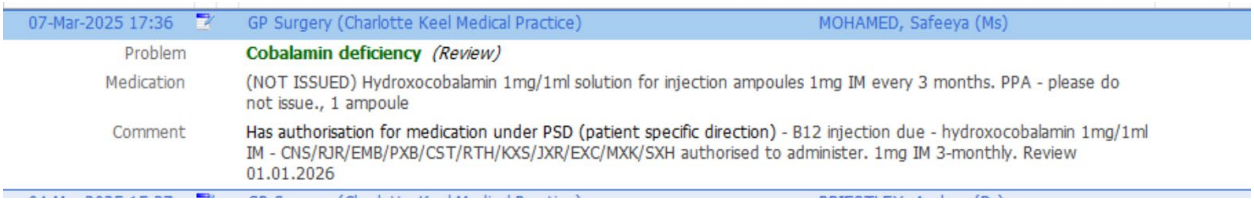
1. Open a new consultation
2. Add the Problem ‘Cobalamin deficiency’
3. Type on the F12 key on your keyboard to open the Protocol Launcher

4. Select the ‘PSD authorisation – B12 injection’ and double click on this – this will open a prepopulated PSD authorisation.
5. Click on the box next to PSD, and free type the dose, frequency and length of time that you would like the patient to have the injection, and the review date (there is not specified length of time, so this would be based on clinical judgement).
6. e.g. 1mg IM on alternate days for 6 doses, then every 3 month. Review 31.12.2026.
7. Save the template.

8. Add Vitamin B12/ Hydroxocobalamin injection to the medication list as an acute medication single dose (quantity 1) unless a prescription needs to be issued for administration by the district nurses, in which case the quantity will depend on the frequency of administration and will need to be printed or issued to the pharmacy electronically.
9. Tick the box 'personally administered' to avoid the prescription being issued electronically to the pharmacy, but do not issue the prescription. This will be printed during the claims process at the end of the month.



10. Save your consultation.



Version Control

Date	Version	Author	Change Details
17/07/2025	1.0	Safeeya Mohamed, Dr Heather Saxby, Dr Shaba Nabi	New SOP

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