NSW PHARMACIST PRACTICE STANDARDS FOR GASTRO-OESOPHAGEAL REFLUX AND GASTRO-OESOPHAGEAL REFLUX DISEASE

A. APPROVED MEDICINES

Approved Medicines as listed in the NSW Health Authority (dated 30 January 2025) are:

- Famotidine
- Nizatidine
- Esomeprazole
- Lansoprazole
- Omeprazole
- Pantoprazole
- Rabeprazole

B. GENERAL REQUIREMENTS

Pharmacists must hold general registration under the Health Practitioner Regulation National Law and have successfully completed the training requirements detailed in the NSW Health Authority (dated 30 January 2025).

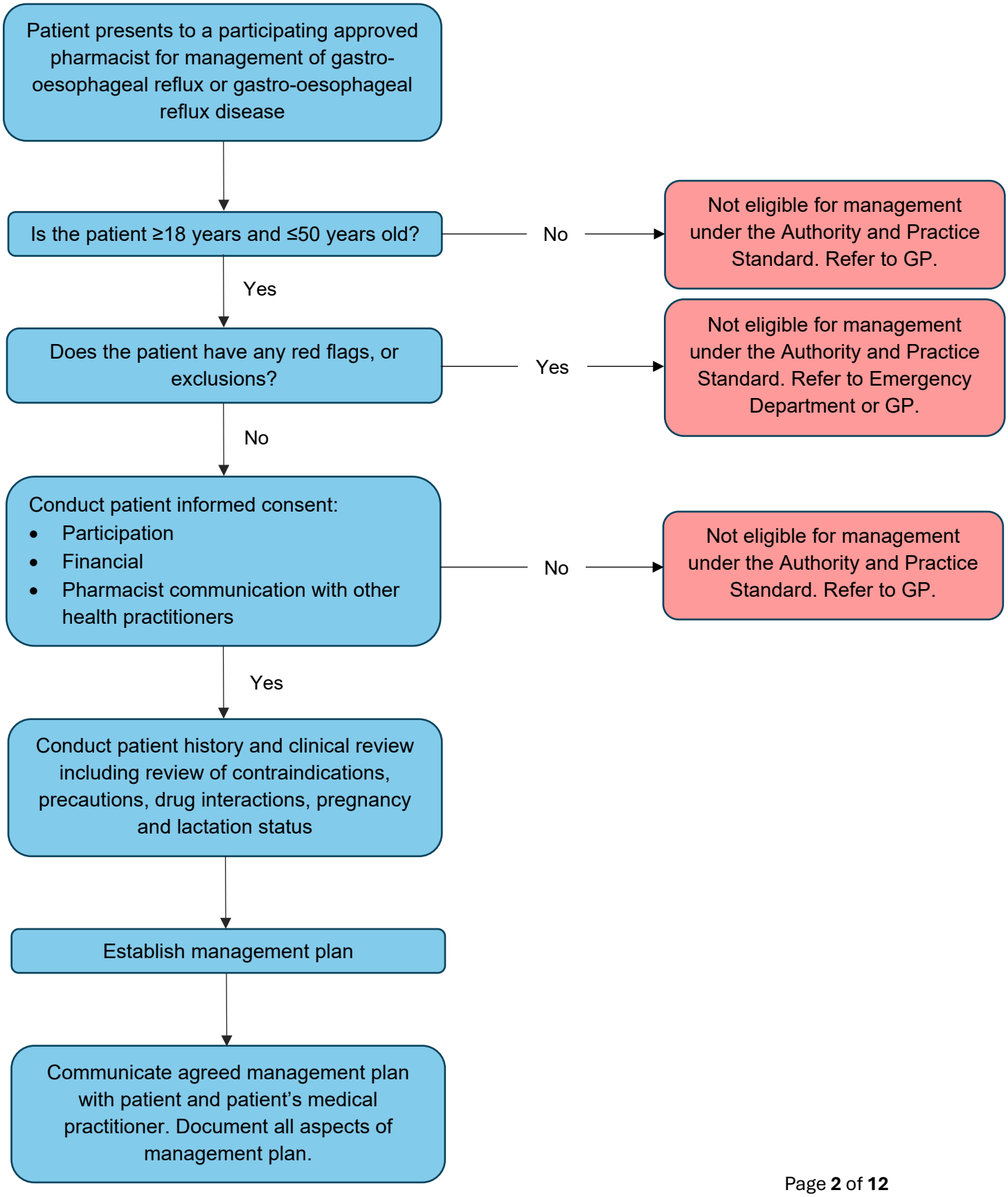
C. ADVERSE EVENTS

If the treating pharmacist becomes aware of an uncommon, unexpected or serious adverse event following treatment with an Approved Medicine, this should be reported to the Therapeutic Goods Administration. This should be conducted via the usual processes, by reporting online at https://aems.tga.gov.au/.

Additionally, you must notify the patient's usual medical practitioner (if they have one).

D. PRACTICE STANDARD OVERVIEW

The following guideline should be used in consultations to assess the eligibility, identity and govern supply of suitable treatments, and guide associated referral requirements.



E. USE OF THIS PRACTICE STANDARD

This Practice Standard provides guidance for pharmacists delivering the Community Pharmacy Gastro-oesophageal Reflux and Gastro-oesophageal Reflux Disease (GORD) Service. It is to be used together with the training modules and other resources provided by education providers.

Key points

- The Community Pharmacy Gastro-oesophageal Reflux and Gastro-oesophageal Reflux Disease (GORD) Practice Standard provides a framework for appropriately trained approved pharmacists to manage eligible patients as part of the NSW Health Authority (dated 30 January 2025).
- To receive management for GORD under this service, the patient must fulfill the eligibility requirements of the Practice Standard. Patients who have requested the service but are not eligible for management should be referred to their regular medical practitioner or health service.
- Pharmacists can supply up to 4 weeks of therapy before referring patient to a medical practitioner.
- Pharmacists must only supply formulations listed in the Authority.
- Patients must be physically present in the pharmacy to be eligible for management.
- Patients are required to have a consultation with an approved pharmacist before a medication can be supplied under the Authority.
- Pharmacists must make a full clinical record of the consultation and the details of all consultations and outcomes must be recorded using secure digital software. Records must be stored securely for minimum seven (7) years.
- Pharmacists must exercise professional discretion and judgement when applying the information within this Practice Standard. The Practice Standard does not override the responsibility of the pharmacist to make decisions appropriate to the circumstance of the individual, in consultation with their patient.

F. PATIENT CONSENT

Informed clinical and financial consent must be obtained from the patient prior to providing care under this practice standard.

The pharmacist must seek the patient's consent to share a record of the consultation and any subsequent consultations (including adverse events) with the patient's usual treating medical practitioner or medical practice, where the patient has one. If the patient consents to the disclosure, the record must be shared within a week following the consultation

G. PATIENT ELIGIBILITY AND REFERRAL CRITERIA

- Patients must be aged 18 years or over and up to and including aged 50 years to be eligible for the service.
- Patients who meet any of the referral criteria below are not eligible for this service and must be referred to their regular medical practitioner or health service, or in instances of urgent care to the Emergency Department. Note that these are not exhaustive lists.
- Pharmacists must apply clinical judgement and refer any patient considered appropriate for medical care for any reason.
- Pharmacists must consult the Therapeutic Guidelines and other relevant references to confirm management is appropriate, including for:
    - Contraindications and precautions
    - Drug interactions
    - Pregnancy and lactation

'Red flag' warning signs that require immediate referral to a medical practitioner:

- Chest pain[1]
- Signs or symptoms of myocardial infarction
- Any new symptoms or a change in symptoms in patients over the age of 50
- Symptoms of anaemia including fatigue, shortness of breath, weakness, dizziness, or an irregular heartbeat
- Difficult or painful swallowing
- Haematemesis
- Malaena
- Vomiting
- Jaundice
- Unexplained weight loss
- Severe, frequent, or changing symptoms
- Abdominal pain[1]
- Diaphoresis

Patients must be referred to a medical practitioner if they meet any of the following criteria:

- The patient has any 'red flag' warning sign (see box above)
- A clear diagnosis of gastro-oesophageal reflux or GORD cannot be made
- The patient is aged under 18 or over 50 years
- The patient is being managed by a gastroenterologist
- The condition is having a marked negative emotional or social effect on the patient
- There is inadequate response to treatment/symptom control is inadequate after 4 weeks of PPI therapy at the standard dose
- Symptoms worsens
- Atypical symptoms or signs
- Patient requires long-term therapy with PPI and has not been investigated or reviewed by a medical practitioner
- Patients with a stoma

[1] Assessment of chest pain and abdominal pain is complex, therefore maintain a high index of suspicion for differential conditions. Be aware of cognitive bias, focus on excluding red flags and early referral to a medical practitioner.

H. BACKGROUND

- The Therapeutic Guidelines defines GORD as gastro-oesophageal reflux symptoms that are frequent (2 or more episodes per week) and severe enough to impair quality of life, or people who have complications of gastro-oesophageal reflux. However, the clinical definition of GORD may differ between resources used in clinical practice.
- The causes of gastro-oesophageal reflux and GORD are multifactorial and may involve dysfunctional peristalsis, delayed gastric emptying and impaired or transient relaxation of lower oesophageal sphincter resting tone.
- The cardinal symptoms of gastro-oesophageal reflux are heartburn and regurgitation. For adults who have typical symptoms and no red flag/alarm symptoms, response to a trial of PPI therapy can help to confirm the diagnosis of GORD.
- The symptoms of GORD are common to multiple other conditions but can often be differentiated using the patient's history.
- Atypical symptoms attributed to reflux include:
    - Belching
    - Epigastric pain
    - Dyspepsia
    - Acid brash
- Extra-oesophageal symptoms that are associated with, but not specific to gastro-oesophageal reflux may include those listed below. These patients need to be referred to a medical practitioner for investigation and assessment.
    - Tooth sensitivity, enamel erosion (particularly on palatal surface of upper incisors) and halitosis
    - Pharyngeal and laryngeal signs and symptoms such as hoarseness and throat clearing, persistent cough, sore throat, pharyngitis and sinusitis
    - Chest pain
    - Sleep disturbance
    - Nausea
    - Asthma-like symptoms (cough, wheeze, shortness of breath)
- Red flag symptoms (also known as alarm symptoms, listed in the table above) are suggestive of other serious conditions and require immediate referral to a medical practitioner for assessment.
- Assessment of chest pain and abdominal pain is complex; therefore it is important for pharmacist to maintain a high index of suspicion for differential conditions. Be aware of cognitive bias, focus on excluding red flags and early referral to a medical practitioner.
- Both GORD and acute myocardial infarction (AMI) can cause similar signs and symptoms, and frequently co-exist. Extreme caution must be exercised by pharmacists managing patients with suspected presentations of AMI. Pharmacists are required to immediately refer these patients to an emergency department for urgent medical assessment.

- Some patients with features of GORD need to be referred to a medical practitioner for endoscopic investigation to rule out alternative aetiologies, confirm diagnosis of GORD and assess for complications (e.g. Barrett's oesophagus).
- The presumptive clinical diagnosis of gastro-oesophageal reflux and GORD are primarily based on patient reported symptoms. However, response to a trial of proton pump inhibitors (PPI) can be used to diagnose GORD. A trial of high dose PPIs has a sensitivity of 80% as a diagnostic test for GORD.
- The initial management of gastro-oesophageal reflux and GORD is based on the severity of symptoms; symptom control is the aim for most patients. Mild intermittent symptoms may be managed with diet and lifestyle modification only, however on-demand drug therapy may be used.
- Approximately one third of patients reflux symptoms have some form of mucosal damage, ranging from minor erosions to circumferential ulceration or metaplasia (e.g. Barrett's oesophagus). GORD may lead to oesophageal strictures in a minority of patients or on rare occasions, malignancy.
- Ranitidine is permitted under this practice standard.

I. PATIENT ASSESSMENT

A patient history and examination that is tailored to the patient's presentation is required to inform the management approach, including appropriate referral. The prompts provided below are not exhaustive, pharmacists should maintain an open mind and be aware of cognitive bias.

PATIENT HISTORY

Sufficient information must be obtained from the patient to assess the safety and appropriateness of management. The My Health Record should be reviewed where appropriate and available.

The patient history should include:

- Age
- Weight
- Pregnancy and lactation status
- Onset, nature, duration, frequency, severity, and pattern of symptoms
- Precipitating and relieving factors
- Underlying medical conditions and conditions that may complicate diagnosis
- Dietary patterns
- Current medication use (including prescribed medications, vitamins, herbs, supplements, over the counter medicines)
- Pharmacological and non-pharmacological (dietary and lifestyle) strategies trialled to treat symptoms and response
- Drug allergies and adverse drug reactions
- Smoking and vaping status
- Alcohol and drug history.

EXAMINATION

- Physical examination of patient as required
- Assessment of vital signs

J. MANAGEMENT AND TREATMENT PLAN

- The initial management of gastro-oesophageal reflux and GORD is based on the severity of symptoms and endoscopic findings (if known):
    - Mild intermittent symptoms require only diet and lifestyle modification or on-demand drug therapy
    - Frequent or severe symptoms that significantly impair quality of life require regular therapy and may require further specialist intervention. These patients require a referral to a medical practitioner.
- For most patients, the aim of therapy is to control symptoms.
- Advise all patients with reflux symptoms to trial diet and lifestyle modification
- Pharmacist management of gastro-oesophageal reflux and GORD involves:
    - Non-pharmacological/general measures
        - Advice regarding dietary and lifestyle modification as per the Therapeutic Guidelines: Diet and lifestyle modification for the management of gastro-oesophageal reflux in adults.
    - Pharmacotherapy
        - Therapeutic Guidelines: Management of mild intermittent symptoms of gastro-oesophageal reflux in adults
        - Therapeutic Guidelines: Management of frequent or severe symptoms of gastro-oesophageal disease (GORD) in adults
        - Therapeutic Guidelines: Gastro-oesophageal reflux during pregnancy.
- PPIs in pregnancy have different levels of evidence. Pharmacists must be guided by the most up to date evidence on the safety and efficacy of PPIs when providing management to pregnant and breastfeeding women.
- The efficacy and availability of PPIs has led to PPI overuse. Long-term regular PPI therapy is only recommended for a limited number of indications and should be reviewed regularly. PPI therapy should be stopped if there is no ongoing indication.
- Where regular drug therapy is required and a patient has not been previously reviewed by a medical practitioner, a referral to a medical practitioner is required.
- If initial PPI therapy provides adequate symptom control, therapy should be titrated down and continued at the lowest dose and frequency that controls symptoms, or eventually stopped — this is known as step-down therapy. Regular attempts should be made to further reduce the dose.
- If there is an inadequate response to treatment or symptom control is inadequate after 4 weeks of PPI therapy at the standard dose, the patient is required to be referred to a medical practitioner.

- Comprehensive advice and counselling (including supporting written information when required) as per the Therapeutic Guidelines, Australian Medicines Handbook, and other relevant references should be provided to the patient regarding:
    - Individual product and medicine use, including initial dosing, maintenance and step-down therapy
    - How to manage adverse effects
    - When to seek further care and/or treatment from a medical practitioner
- The agreed management plan must be documented in the patient electronic clinical record and shared with members of the patient's multidisciplinary team, in accordance with the Authority.
- Where a patient has a My Health Record, the pharmacist must ensure the details of the supply are uploaded to My Health Record, unless requested otherwise by the patient.

FOLLOW-UP CARE AND REVIEW

- Clinical review with the pharmacist
    - If initial PPI therapy provides adequate symptom control, therapy should be titrated down and continued at the lowest dose and frequency that controls symptoms, or eventually stopped — this is known as step-down therapy. Regular attempts should be made to further reduce the dose.
    - Where a patient requires long-term therapy for GORD, the patient must be referred to their medical practitioner for review and assessment.
    - Patients who have been appropriately reviewed and investigated for GORD by their medical practitioner and are presenting for repeat scripts can continue clinical reviews by the pharmacist.
- If the condition does not improve or resolve after 4 weeks of PPI therapy at the standard dose, the patient should be advised to see a medical practitioner for review and further investigation.

K. CLINICAL DOCUMENTATION AND COMMUNICATION

- The pharmacist must make an electronic clinical record, and a record in a pharmacy dispensing system regarding the supply of any medications under these services, in accordance with the Authority.
- Where a patient has a My Health Record, the pharmacist must ensure the details of the supply are uploaded to My Health Record, unless requested otherwise by the patient.

L. RESOURCES

Patient information/resources:

- It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources provided to patients.

- Emergency Care Institute: ED fact sheets: Gastro-oesophageal reflux disease (GORD)
- Gastroenterological Society of Australia (GESA) Patient Resources: Information about reflux
- Healthdirect: GORD (reflux)
- Pharmaceutical Society of Australia: Heartburn and indigestion patient information card
- Royal Hospital for Women: MotherSafe factsheets: Heartburn in Pregnancy and Breastfeeding

Pharmacist resources:

- Therapeutic Guidelines: Gastrointestinal
  - Oesophageal disorders
  - Functional gastrointestinal disorders
- Australian Medicines Handbook
  - Drugs for dyspepsia, reflux and peptic ulcers
- Gastroenterological Society of Australia (GESA)
- Australian Prescriber: Management of GORD
- Best Practice Advisory Centre New Zealand: Managing gastro-oesophageal reflux disease (GORD) in adults: an update
- Emergency Care Institute: The emergency care assessment and treatment (ECAT) protocols:
  - Abdominal pain
  - Gastrointestinal bleeding (suspected)
- Step down therapy
  - Therapeutic Guidelines: Maintenance and step-down therapy for GORD in adults
  - Canadian Family Physician: Evidence based practice guideline: Deprescribing proton pump inhibitors

M. ACKNOWLEDGEMENTS

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NSW Health emergency care assessment and treatment (ECAT) protocols developed by the ECAT Working Group, led by the Agency for Clinical Innovation, have been used to inform relevant aspects of this Practice Standard.

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Approved

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