PRESCRIBING SUPPORT TEAM AUDIT

ESOMEPRAZOLE PRESCRIBING REVIEW / SWITCH PROTOCOL

DATE OF AUTHORISATION: _________________

AUTHORISING GP: _________________________________

PRESCRIBING SUPPORT TECHNICIAN: __________________________

(Please see PPI prescribing review audit for further information and references*)

SUMMARY
£156k was spent on esomeprazole (2007/08) at a cost of £0.85 per DDD compared to an average £0.18 per DDD for the formulary choices omeprazole and lansoprazole. Such expenditure is not cost effective as esomeprazole is comparable to double strength omeprazole at more than “quadruple” the cost with no clinical benefit.

OBJECTIVE
To ensure the appropriate prescribing of Proton Pump Inhibitors in Dumfries and Galloway*

RATIONALE
All Proton Pump Inhibitors (PPIs) consist of a racemic mixture of both active and inactive isomers except esomeprazole, which consists of only the active isomer of omeprazole. When a PPI dose is reduced or stopped a rebound surge in acid output is triggered. This is usually most significant after 4-10 days (increased acid output in the region of 82% above baseline has been published). The severity of the acid rebound is dependant on the dose and duration of PPI treatment. Patients on esomeprazole 40mg can be first reduced to two 20mg omeprazole (to be taken before breakfast). Esomeprazole 20mg is equivalent to omeprazole 40mg.

To protect the oesophagus from rebound effects, a suitable raft-forming alginate should be used in combination with the PPI. After a PPI dose reduction, patients should preferably be allowed to stabilise for at least 2 to 4 weeks (while using alginate cover before any further dose reductions or discontinuing PPI altogether) Appropriate patients should thereafter be encouraged to self-manage their symptoms using alginate when required, and only requesting PPI treatment for flare up situations not alleviated by regular alginate use.
Practices have the option of reviewing those patients currently receiving esomeprazole (see below) or by switching the patient to the equivalent omeprazole dose. Inclusion and exclusion as listed below apply.

**SWITCH OPTION**

Eligible patients as agreed by the practice will be sent a letter (Appendix 1) and invited to contact the surgery if they wish to discuss the switch with a GP or Practice Nurse. Some practices may decide to send patients a similar letter informing the patient of the intended switch and inviting them to contact the surgery if they have concerns before the actual switch takes place. GPs should be informed of those patients who meet exclusion criteria and those where the initial prescription was on recommendation by a consultant.

**REVIEW OPTION**

**Step 1 - Search**

Computer search will be undertaken to identify patients on esomeprazole. The following inclusion and exclusion detailed below will be applied to those patients identified by the search and a register of patients eligible to attend a dyspepsia clinic will be compiled. Computer records will be cross-checked with patient’s paper notes and any read codes found to be incorrectly recorded will be notified to the Practice and amended. When the patients register is completed, it will be distributed to all partners in the Practice for approval.

**Inclusion criteria**

- All patients who have been taking esomeprazole for more than 8 weeks.

**Exclusion criteria**

- Patients on healing doses of esomeprazole for treatment of duodenal ulcers for less than 4 weeks
- Patients on healing doses of esomeprazole for treatment of gastric ulcers for less than 8 weeks
- Patients currently on Helicobacter Pylori eradication therapy
- Patients currently under review at GI clinic or awaiting referral to one
- Patients awaiting gastroscopy or review
- Patients who have been diagnosed with Zollinger-Ellison Syndrome
- Patients who have been diagnosed with Barrett’s Oesophagus
- Patients over 90 years of age
- Patients with a terminal illness
- Patients with grade 3 or 4 oesophagitis
- Patients on high dose corticosteroids for a life-threatening or chronic illness
- Patients receiving immunosuppression therapy
- Patients undergoing chemotherapy or radiotherapy
- Patients with oesophageal strictures or oesophageal dilation
- Patients with a history of oesophageal varices
- Unstable psychiatric patients
- Known alcohol abusers
- Patients under 18 years of age
- Any other criteria as specified by the Practice
Step 2 – Patient Invitations
A letter (Appendix 2) will be sent out to eligible patients asking them to contact the Practice to make an appointment to attend the dyspepsia clinic. Appointments will be made via Practice reception staff. To encourage clinic attendance, Practices may choose to state in the patient letter that repeats for current medication may not be renewed, unless the patient attends the clinic.

Step 3 – The Clinic Process and Patient Management Options
The patient will be given full verbal information about the purpose of the clinic and signed consent obtained prior to any assessment being carried out.
If any of the following alarm features are present then the patient will be referred to a GP for an immediate consultation:
- Anaemia
- Vomiting
- Weight loss
- Dysphagia
- Epigastric mass
- Haematemesis
- Jaundice
- Progressively worsening symptoms
- Any other feature as specified by the Practice

Patients should be informed that it is “normal” to have a low gastric pH. The relative achlorhydria induced by esomeprazole-use has implications for Vit B12 absorption, possible bacterial “super-infections” and a potential increased risk of hip fractures in the over 50s.
This clinical assessment will follow a structured plan. Data obtained from the clinic will be recorded on a register and will be used suggest appropriate non-drug changes in patient management and prepare the final surgery report. Part of the assessment will include evaluating the suitability for stepping the patient down to a lower PPI dose or stepping them off PPI therapy altogether and replacing it with an alginate based reflux suppressant. At the end of each clinic, the lead GP will be provided with completed patient assessment forms and patient notes.
All medication changes will be approved by the GP.
Each appointment at the clinic will be scheduled to last 15 minutes and during this time the following information will be recorded:
- patient name and identification code
- sex
- date of birth
- age
- current upper GI medication (drug name, dose, frequency, duration, concomitant NSAID use)
- diagnosis (PUD, GORD, Erosive Reflux Oesophagitis, dyspepsia, other)
• previous investigations (date, endoscopy, Barium studies, H.Pylori status, pH monitoring, other)
• current level of symptom control
Patients who have been prescribed esomeprazole healing dose for more than 8 weeks and do not meet any of the exclusion criteria will be recommended for a step down to a maintenance dose omeprazole 40mg (2 x 20mg) then to omeprazole 20mg or lansoprazole 30mg.
To improve symptom control and increase the likelihood of success of this dosage reduction, an alginate based reflux suppressant may be recommended. The alginate would be used to prevent and/or treat occasional breakthrough symptoms caused by rebound acid hypersecretion. These patients will then be reviewed in 2 – 3 months with a view to stepping them off esomeprazole/omeprazole therapy completely.
Patients who have been prescribed esomeprazole 20mg (maintenance dose) for more than 8 weeks and do not meet any of the exclusion criteria will be counselled and recommended for stepping off PPI therapy. Alginate based reflux suppressant therapy will be the recommended alternative treatment. PPI therapy will still be indicated in these patients for the treatment of occasional flare-ups of GORD. In such cases, the maximum duration of PPI treatment is 8 weeks and lansoprazole/omeprazole are the formulary choices. Patients requiring long-term acid suppression (e.g. on concurrent NSAID therapy) can remain on reduced doses of either omeprazole or lansoprazole.
All patients assessed at the clinic will receive advice on lifestyle modifications that may relieve GORD symptoms. (see PIL)

Step 4
All patients referred to their GP for medication review will be followed up within 3 – 6 months of completion of the dyspepsia clinic. Information collected at the follow-up will be included in the end of programme final report. An open clinic commencing 2 – 4 weeks after completion of the initial clinics will also be run. This clinic is aimed at patients experiencing problems that have arisen as a result of their medication change.

Step 5
On completion of the project, a final report providing a detailed analysis of the information collated from the register and patient reviews will be presented to the Practice. The report will show the result of all medication changes and will allow the Practice to review the success of the programme. Recommendations for continued PPI reviews will also be made and a summary of patient’s questions and concerns will be included if applicable.
CHANGES TO REPEAT PRESCRIBING

1. The audit must be checked and agreed with a GP in the practice prior to work being undertaken by the Prescribing Support Technician/LHP pharmacist (PST).
2. Agreement is made between the Practice and the PST for a suitable date for implementation.
3. It is recommended that the PST member notifies local community pharmacies of the impending change in prescribing of esomeprazole.
4. The PST member conducts a search of the Practice Clinical System to identify patients currently prescribed esomeprazole.
5. The patient list is checked to ensure that all patients are still undergoing treatment (also to avoid letters being sent to recently deceased patients).
6. No patient may be changed beyond the scope of the relevant SPC unless authorised by the prescriber.
7. All changes to prescribing must be recorded within the prescribing field and, wherever possible, an indication recorded for any medication added.
8. Each patient should be informed of any changes made in accordance with the Practice’s preferred mode of communication. The Prescribing Support Team recommends personalised written communication sent from the Practice. Additional information e.g. patient leaflets may be included wherever possible.
9. The PST member will communicate information about the review to relevant personnel within the practice e.g. receptionists, nurses and will, if appropriate, create on-screen reminders on the Clinical System.
10. A project file is retained by the Practice containing a list of patients involved, patient letter templates and any individual information sent, a copy of the protocol and contact details for the Prescribing Support Team.
11. The PST member will record statistics of the review for report purposes and analysis of the review. No information regarding individual patients leaves the practice.
12. A follow-up audit will take place within 12 months.
Dear Mr/Mrs __________

We have recently been reviewing patients who are receiving PPI (proton pump inhibitor) therapy with a medicine called esomeprazole (Nexium). PPIs are used to treat gastric and duodenal ulcers, dyspepsia (indigestion) and gastro-oesophageal reflux disease; they also protect the stomach if you are taking anti-inflammatory treatment. There is little to choose between the different PPIs which are available to prescribe except for cost, as they all work well with very few side effects. Esomeprazole costs around 10 times more than either of the other PPIs which we recommend in Dumfries and Galloway. Many patients taking esomeprazole would do just as well with an alternative PPI such as omeprazole or lansoprazole. As a result we are proposing to discontinue your esomeprazole prescription and commence you on ............

This change in your medication regimen will take place with your next prescription. In the meantime, please finish your existing tablets as normal.

Should you have any queries, please contact the Surgery on the number above or, alternatively, you can contact a member of the Prescribing Support Team on ............

Yours sincerely

Partner’s names     Prescribing Support Team

Always finish your existing supply of medicine before starting on the new drug or dosage unless otherwise instructed by your GP.
Dear

**Dyspepsia Clinic Appointment**
We are continually working to improve the healthcare offered to our patients and to ensure that you receive the most appropriate medication for your condition.

We are currently reviewing patients receiving repeat prescriptions for their acid related disorders (heartburn, hiatus hernia etc.) and patients on medication after ulcer healing.

We would like to invite you to attend the dyspepsia clinic where the prescribing support pharmacist will review your condition and ensure that you continue to receive the best and most appropriate treatment.

Your individual appointment is for 15 minutes, during which you will be asked to complete a simple questionnaire. It is also an ideal opportunity to ask questions that you may have.

We would be grateful if you would attend your surgery for your clinic appointment.

**AT:** [Insert Time]  
**ON:** [Insert Time]

Please inform the surgery if you are unable to attend and another appointment can be arranged for you.

Thank you for your co-operation.

Yours faithfully,