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Proton pump inhibitors for heartburn and dyspepsia A step down approach

Lansoprazole and omeprazole are now equal first choice proton pump inhibitors (PPIs) in the Lothian Joint Formulary (LJF), with generic versions of both available. Lansoprazole is currently cheaper than omeprazole.

PPIs provide effective control of gastro-oesophageal reflux disease and dyspepsia, but continuous use at full dose may provide more intensive therapy than required. After initial assessment, a 4-week course of PPI treatment may be appropriate to treat uncomplicated dyspepsia. After this, many patients do not require prescribed medication and strategies for managing mild or intermittent symptoms include antacids, alginates or H₂-antagonists.

If symptoms require ongoing management, a step down treatment is recommended^{1,2}. Options for therapy include:

1 As required Patients are supplied with a PPI to be taken when required on days when symptoms occur, and stopped once symptoms have resolved, often after a few days.

2 Intermittent A 2 to 4-week course of treatment is prescribed in response to recurring symptoms.

3 Continuous PPI maintenance Reduce the dose to the lowest level required to control symptoms. Review annually to determine ongoing need: if symptoms are well controlled, reduce dosage further, step down to on demand or intermittent therapy, or discuss stopping the PPI.

References

1. NHS Lothian Dyspepsia Guidelines, September 2003. http://ljpctweb/elib/2_ClinicalPractice/2_Guidelines/Guidelines/HelicobacterPylori.pdf
2. Dyspepsia - managing dyspepsia in adults in primary care. National Institute of Clinical Excellence (NICE) Clinical Guideline CG017, August 2004. <http://www.nice.org.uk/page.aspx?o=CG017>

Thanks to Anne Young, Prescribing Support Pharmacist, South Central Edinburgh LHP, for contributing to this article.



A **patient information leaflet** entitled 'Treatment of Heartburn & Dyspepsia with Proton Pump Inhibitors (PPIs)' has been developed. The leaflet is intended to be used on initiation of treatment and to support step down for patients who have been taking PPIs continuously for more than 8 weeks. A printed version of the leaflet is available from primary care pharmacists, and an electronic version can be found on the LJF website at www.ljf.scot.nhs.uk.

Enclosed with this Issue:

- ❖ Quick reference versions of the Lothian Minor Ailments Formulary for Adults and Children
- ❖ LJF Calendar 2007

LJF update - Management of skin conditions

Emollients

Emollient choice should be guided by the patient's tolerance, preference and ease of use. Ointments are the formulation of first choice and are less likely to sensitise chronic dry skin, but creams (second choice) are generally more cosmetically acceptable. Adults applying emollient to the whole body twice a day may need 500g per week, and children 250g, so it is more cost effective to prescribe by the largest pack size. Most emollients with the exception of 50/50 white soft paraffin/liquid paraffin can be used as soap substitute.

Acne and Rosacea

The first choice systemic treatments are oxytetracycline or erythromycin, with lymecycline now the second choice. Oral isotretinoin is contra-indicated in women of childbearing potential, unless all the conditions of the 'Pregnancy Prevention Programme' are met (see Summary of Product Characteristics, www.medicines.org.uk).

Calcineurin inhibitors for eczema

Tacrolimus or pimecrolimus may be used as second line for patients suffering moderate eczema uncontrolled by topical steroids, or those at risk of significant steroid-induced adverse effects.

Tacrolimus ointment may be used in patients aged over 2 years. Following a NICE appraisal in August 2004¹, the Formulary Committee agreed the use of pimecrolimus cream for those aged 2 to 16 years with moderate atopic dermatitis on the *face and neck*. These preparations are for short-term or intermittent long-term use only and can be prescribed under the guidance of a Shared Care Protocol, initiated by a specialist in dermatology.

It is important to note that the long-term safety of immunomodulation with either drug is currently unknown. To date there have been rare reports of lymphoma, skin cancers and other malignancies in a small number of patients using topical calcineurin inhibitors. A safety review by the European Medicines Agency's (EMA) Committee for Medicinal

Products for Human Use (CHMP) concluded that *"the benefit associated with the use of these [products] outweigh the risks, but that they should be used with greater caution in order to reduce potential risks of skin cancer and lymphoma as far as possible"*².

Actinic Keratoses (Solar Keratoses)

Actinic keratoses occur on sites of chronic sun exposure. They are pre-malignant but transformation to in-situ or invasive squamous cell carcinoma is rare. There is a steadily increasing demand for treatment of these common pre-malignant lesions because of the aging population.

Small non-tender keratoses can be left alone or treated with diclofenac gel 3% (Solaraze®) applied thinly twice a day for 60 to 90 days; max 8g daily.

Extensive thicker keratoses requires cryotherapy or treatment with fluorouracil (Efudix®) applied thinly to the affected area once or twice a day; maximum area of skin treated at one time, 500cm²; usual duration of initial therapy, 3 to 4 weeks. Topical fluorouracil can cause severe inflammatory reactions especially in fair skinned patients, and so should be used with caution.

Superficial Basal Cell Carcinoma (BCC)

BCC (rodent ulcer) is the most common skin cancer. NHS Lothian Referral Guidelines http://refhelp/dermatology/derm_home.htm advise that all patients with suspected BCC are referred to the dermatology tumour assessment team.

Topical preparations may be prescribed by specialists in the Dermatology Department where other therapies are unsuitable due to possible treatment-related morbidity, poor cosmetic outcome, large nature of lesion or recurrent lesions. Imiquimod (Aldara®) cream is in the Lothian Joint Formulary (LJF)³ as a prescribing note for the treatment of superficial BCC. Methyl-5-aminolevulinate (Metvix®) cream is available on the LJF additional list, for the treatment of both superficial BCC and nodular BCC.

References

1. Atopic dermatitis (eczema) - pimecrolimus and tacrolimus. National Institute of Clinical Excellence (NICE) Technology Appraisal TA082, August 2004. <http://www.nice.org.uk/page.aspx?o=TA82>
2. Safety reviews of tacrolimus and pimecrolimus. European Medicines Agency, March 2006. <http://www.emea.europa.eu/pdfs/general/direct/pr/9888206en.pdf> (Press Release)
3. http://www.ljf.scot.nhs.uk/exist/xml/db/ljf_v2/unified/unified13_1.xml

Thanks to Colette Burns, Clinical Pharmacist, Dermatology, for contributing to this article.

Comment on glitazones

The Lothian Prescribing Bulletin (LPB) Editorial Team would like to acknowledge that the text relating to pioglitazone in the article 'Treatment of adults with diabetes' on page 2 of LPB Issue No. 20 (April/May 2006) is potentially misleading. Pioglitazone is indicated as monotherapy and combination therapy (with either metformin or sulphonylureas) in type 2 diabetes. See www.ljf.scot.nhs.uk for further details.

Items not permitted on prescription - are you confused?

Health Boards have the right to consider whether certain items are a justifiable use of Health Service resources. Prescribers may be pressured by patients to prescribe products promoted in the media, or suggested by a complimentary therapist, who may not be connected to the NHS.

Pay and Report

Prescriptions subject to 'Pay and Report' include unlicensed medicines (e.g. herbal medicines) and items on the ACBS list (without endorsement).

In Lothian the most common 'Pay and Report' items include:

- Exorex[®] (except lotion 1%)
- Eucerin[®] cream and lotion 5%
- Glucosamine sulphate*
- Gamolenic acid capsules
- Oilatum[®] scalp treatment
- Vernage[®] sachets
- Spiroge[®] (when supplied on GP10A stock order)

Remuneration

Community pharmacists are reimbursed following dispensing but the cost of the prescription may be withheld from the prescriber's remuneration.

Appeals can be written to the Medicines Management Adviser, LPCO specifying the clinical indication and evidence of effectiveness of the product. They must demonstrate that no alternative is available on the NHS and the absolute necessity for that individual patient. A successful appeal will allow the relevant item to be prescribed **for that patient only**.

*Glucosamine is increasingly identified under 'Pay and Report':

- It is classed as a 'food supplement' not a 'medicinal product' (hence there are no statutory monitoring/good manufacturing requirements. Purity and content in different preparations may thus vary)
- There is limited clinical evidence to suggest that glucosamine is beneficial
- If such products are proven to be effective the manufacturer would tend to submit for a medicinal licence.

Disallowed Items

These are: blacklisted items; items outwith the restricted lists available to dentists and nurses; items limited to a specific form type (e.g. GP10, GP10N or GP10A); medical devices and reagents not listed in parts 2 to 6 and part 9 of the Scottish Drug Tariff; vaccines provided centrally as part of the childhood immunisation program.

In Lothian the most common disallowed items include:

- Multiple reagent urine sticks (Labstix[®])
- Certain dressing sizes (notably Tegaderm[®] 10cm x 12cm)
- Disposable scalpel blades, forceps, tongue depressors
- Products in Part 15 without SLS
- Most sterile eye lubricants, including Vis-Med[®] (if item is not in BNF Chapter 11 Section 8, it is likely to be a device)
- Colostomy disposal bags
- Sterile water for humidifiers and respirators
- Irrigation fluids, if not listed in the Tariff

Remuneration

Community pharmacists will not be reimbursed following dispensing of blacklisted items.

Key messages:

- All LJJ drugs are allowable on GP10 prescriptions.
- Be cautious of items not on the prescribing computer drug dictionary.
- Community pharmacists bear all financial implications of dispensing disallowed items.

Medication Review - Quality and Outcomes Framework

Guidance on the Organisational Indicators (nGMS2) for Medicines Management has been revised. It is expected that at least a Level 2 medication review will occur. These are medication reviews defined as *"under the direction of a doctor, nurse or pharmacist, in the absence of the patient, but with reference to the patient's clinical record with the full patient's notes but not in the presence of the patient"*.

It is suggested in Lothian that these may include medication reviews that take place in a community

pharmacy, with the details being communicated to the practice to ensure that these are incorporated into the clinical record.

This information is included in the 'Don't Panic Guide', the latest version of which has recently been distributed to practices.

It is also available on the intranet at http://pctweb/elib/8_nGMS%20Contract/2_DP%20Guide/DPGMF_vs7.pdf.

Medicines for the doctor's bag

Guidance for the use of medicines in Lothian during normal working hours

"The choice of what to include in the GP's bag is determined by the medical conditions likely to be met; the medicines the GP is confident in using; the storage requirements, shelf-life and costs of such treatments; the extent of ambulance paramedic cover; the proximity of the nearest hospital; and the availability of a 24-hour pharmacy"¹.

For some time, but particularly since the introduction of the new General Medical Services contract, there have been increasing instances notified to the GP Sub-Committee where locums, Retainers, Registrars and others have had difficulty obtaining medicines for their doctor's bag.

Following discussions co-ordinated by the GP Sub-Committee, a list of core drugs was drafted, in line with the Lothian Joint Formulary², the Lothian Unscheduled Care Service stock list, and recent references^{1,3-5}. Peer review was sought from Lothian GPs and most of those consulted agreed that provision of such a bag with a uniform set of core drugs would reduce clinical risk and aid the doctors who work between different practices.

A list of drugs has now been agreed and Lothian practices are encouraged to hold a bag containing this list of drugs for use by 'non-principals'. These medicines are intended for immediate use. These bags will be used at times when community pharmacies are open.

References

1. Drugs for the doctor's bag: 1 - Adults. Drug & Therapeutics Bulletin. September 2005;43(9):65-8.
2. Lothian Joint Formulary www.ljf.scot.nhs.uk
3. Drugs for the doctor's bag: 2 - Children. Drug & Therapeutics Bulletin. November 2005;43(11):81-84.
4. A guide to good practice in the management of controlled drugs in primary care (England). First edition. NHS. National Prescribing Centre. December 2005. http://www.npc.co.uk/publications/Controlled_Drugs.pdf
5. Providing medicines out-of-hours. Achieving safe practice. A guide for PCTs and organised providers. July 2005. <http://www.npa.co.uk/publications/nhsdev/ASP-Oct-05.pdf>



1 Gastro-intestinal

ranitidine 150mg tablets
oral rehydration salts (Electrolade[®]) sachets
loperamide 2mg capsules
glycerol 4g suppositories

2 Cardiovascular

aspirin 300mg tablets
glyceryl trinitrate 400 micrograms spray
furosemide 40mg tablets & 10mg/mL injection
atropine injection 600 micrograms/mL

3 Respiratory

salbutamol 100 micrograms CFC-free inhaler
Volumatic[®] spacer device
prednisolone 5mg tablets
hydrocortisone 100mg/1mL injection
chlorphenamine 4mg tablets & 10mg/mL injection
adrenaline (epinephrine) 1mg/1mL (1 in 1000)

4 Central Nervous System

diazepam 2mg tablets
chlorpromazine 25mg tablets & 25mg/mL injection
prochlorperazine 12.5mg/mL injection,
3mg buccal tablets, 5mg suppositories
hyoscine butylbromide (Buscopan[®]) 20mg/mL injection

Moderate pain

co-codamol 30/500mg tablets
diclofenac 25mg/mL injection

Severe pain

cyclimorph 10mg/mL injection CD

Reversal of opioid-induced respiratory depression

naloxone 400 micrograms/mL injection

Status epilepticus

diazepam 5mg/2.5mL rectal tubes

Parkinsonism and related disorders

procyclidine 5mg/mL injection

5 Infections

amoxicillin 250mg capsules & 125mg/5mL suspension
benzylpenicillin 600mg injection
cefotaxime 1g injection
cefalexin 250mg capsules
water for injection 2mL and 10mL

6 Endocrine

glucagon 1mg injection
hydrocortisone 100mg/1mL injection
prednisolone 5mg tablets
Diasix[®]
Ketostix[®]

7 Obstetrics and Gynaecology

ergometrine 500 micrograms with oxytocin 5 units/mL
(Syntometrine[®]) injection

11 Eye

Ocular diagnosis
fluorescein 1% eye drops

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