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## Topical Lidocaine 5% Plaster

Lidocaine plaster (Versatis®) is on the *Formulary*, restricted to specialist initiation, only for patients who are intolerant of first line therapies for post-herpetic neuralgia or where these therapies have been ineffective. It is mainly used third line after antidepressant (usually amitriptyline) and gabapentinoid therapy.

The SMC advice in 2008 showed estimates of a gross annual budget impact of £74,000 across Scotland in 2012. There were fears that this underestimated the likely impact. This has proven to be correct with spend in NHSGGC accounting for £575,000 in 2011.

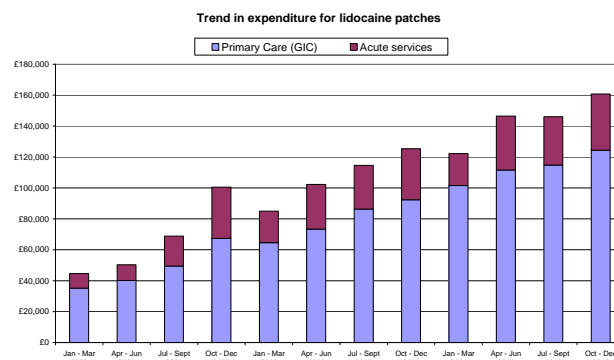
The discrepancy between anticipated impact and actual prescribing has raised concerns about prescribing patterns. There is known to be some non-*Formulary* use, eg in palliative care or other types of neuropathic pain. Use in other pain types has not been studied extensively. There are anecdotal reports of prescribing for diffuse systemic pain. As the patch works by direct contact, it is not suitable for pain that is not localised. Specialists who determine lidocaine plaster is the preferred option in a non-*Formulary* indication should acknowledge and detail the rationale in the request to the patient's GP.

Appropriate review of efficacy is vital to ensure that prescribing is stopped if the product is not effective. The SPC notes that treatment outcome should be re-evaluated after two to four weeks. If there has been no response or if any relieving effect can solely be related to the skin protective properties of the plaster, treatment must be discontinued as potential risks may outweigh benefits. Long-term use in studies showed the number of plasters used

decreased over time. Treatment should be reassessed regularly to decide if the amount of plasters covering the painful area can be reduced, or if the plaster-free period can be extended.

Some GP practices have audited this as part of the GMS contract. This shows the majority of prescribing is for off-label indications. There is also some evidence that therapy is not being reviewed on a regular basis as recommended.

The steering group of the NHSGGC Chronic Pain Managed Clinical Network plan to audit recommendations from pain clinics asking GPs to prescribe lidocaine plasters. The West of Scotland Prescribing Efficiencies Group has established a pain subproject to review potential for efficiencies. Prescribing policies in each Board will be reviewed, together with prescribing data within primary care.



## Buccal Midazolam Solution

Two batches of Epistatus® were produced with different oral syringes which measure up to 1.5ml instead of 1ml. There is a potential for overdose if not used correctly. Please ensure all users refer to the volume on the syringe not just the markings. Advice is available at <http://www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON143794>.

The newly licensed buccal midazolam solution (Buccolam®) was accepted by SMC and use is being considered in NHSGGC. Epistatus (unlicensed) is twice the strength of Buccolam, so any potential change will require careful implementation with training for all involved in prescribing, dispensing and administration. Until local assessment is complete, please continue to use midazolam 10mg/ml (Epistatus). More detail will follow soon.

## Supply of Medicines for Hospital Outpatients

New guidelines have been approved by ADTC which aim to standardise the processes across NHS GGC and ensure all parties, including patients, are aware of the expectations. The principles are:

- The hospital pharmacy will only rarely supply drugs, eg those that require specialist monitoring, are not available in primary care, part of a trial or are required immediately.
- The consultant can prescribe on an HBP pad for dispensing via a community pharmacy if the medicine is required within 48 hours
- Where a medicine is not required urgently, a recommendation will be made to the GP to prescribe.
- The GP normally continues to have clinical responsibility.
- The timescales should be made clear to both patient and GP. The goal should be to reassure patients and avoid unnecessary pressure on GP appointment schedules.

For specific advice on acute directorate procedures for the supply of medicines to hospital outpatients, please contact your local pharmacy team. GP enquires should be directed to the CH(C)P / Sector Prescribing Team or Central Prescribing Team.

## Pharmacist Intervention in Primary Care for Patients with Heart Failure

Meta-analysis of small trials suggests that pharmacist-led collaborative review and revision of pharmacological treatment may improve outcomes in heart failure. An NHS GGC team conducted an RCT to investigate whether a low-intensity, pharmacist-led collaborative intervention in primary care would improve outcomes. They found modest improvements in prescribing but did not improve clinical outcomes in a population which was relatively well treated at baseline. The study has been published in the [European Heart Journal](#). For more information contact Richard Lowrie ([richard.lowrie@ggc.scot.nhs.uk](mailto:richard.lowrie@ggc.scot.nhs.uk)).

## Paracetamol: Not So Simple?

Although commonly used and on general sale, it is still important to ensure vigilance with its use.

### Dose for Low Body Weight Adults

Previous safety alerts have highlighted the risks of overdose associated with the intravenous infusion in

low body weight adults ([PostScript Acute 1](#)), however need to use with caution also is true for oral forms.

There have been a number of recent incidents where there has been concern that inappropriately high doses of oral paracetamol have been prescribed for patients of very low body weight, eg < 30kg.

Please consider oral paracetamol dose reductions in at risk patients where treatment is not contra-indicated to a maximum of 15mg/kg/dose up to four times daily (maximum 60mg/kg/day). At risk patients include those with:

- Low body weight (< 50kg)
- Renal / hepatic impairment
- Glutathione deficiency (chronic malnourishment, chronic alcoholism)

### Formulation Choice

A recent incident occurred when paracetamol 1g four times daily by the nasogastric route was prescribed. It was administered as paracetamol soluble tablets. After several days of therapy the patient was confused and the patient's sodium level was noted to be 153mmol/L. The confusion was thought to be possibly secondary to high sodium levels.

Investigation suggested that the rise in the patient's sodium levels was due to the soluble paracetamol tablets. Each tablet contains 438mg (19mmol) of sodium, so 152mmol of sodium was being administered per day. This is more than the total daily recommended sodium intake for an adult. Paracetamol oral suspension contains a minimal sodium load (equivalent to <2mmol/day at therapeutic dose) and would have been the preferred formulation.

Please refer to the *Therapeutics Handbook* or your pharmacist for further information.

## ADTC Decisions Summary

The following were among those added to the *Formulary*:

- Boceprevir and telaprevir for hepatitis C in both treatment experienced and treatment naïve patients. Restricted to specialist consultant use in accordance with local protocol.
- Linagliptin for treatment of type 2 diabetes in combination with metformin when diet and exercise plus metformin does not provide adequate glycaemic control and where a sulphonylurea is inappropriate.
- Rivaroxaban for prevention of stroke and systemic embolism in adults with non-valvular AF with one or more risk factors restricted to patients receiving warfarin who have poor INR control despite evidence that they are complying, or patients with allergy or intolerable side effects from coumarin anticoagulants.

The following were among non-*Formulary* decisions

- Tapentadol immediate release tablets.

## Good Practice in Medicines Reconciliation

When patients are admitted to hospital it is important to ensure that medicines prescribed on admission correspond to those that the patient was taking before admission and any changes are clearly documented. This involves taking a careful medication history from the patient, using at least two of the most recently available information sources, resolving any discrepancies and documenting which medicines are to be continued, stopped, withheld or changed. Medicines to be continued should be written on the prescription chart along with any medicines started on admission.

There is evidence from the literature that unintentional variances of up to 40% can occur between the medicines patients were taking before admission and their prescriptions on admission. An audit in one NHS GGC hospital showed just over half of patients had one or more of their usual pre-admission medicines unintentionally omitted from their prescription charts.

This whole process of establishing and maintaining an accurate, up to date list of medicines and details of changes from admission to hospital, through transfer and at discharge is known as medicines reconciliation. The impact on safety has prompted medicines reconciliation to be included in the Scottish Patient Safety Programme which is being implemented in all Health Boards with roll out to primary care in 2013.

An accurate list of the patient's medicines needs to be maintained and documented on the prescription chart during their stay along with details of any changes made and the reasons for stopping a medicine.

This must be reliably communicated between teams when care is transferred to another ward or hospital and at discharge to the GP.

Having accurate up to date information about a patient's medication supports safe and effective clinical decisions. This should:

- prevent avoidable harmful errors such as drug interactions, unintended omissions and duplication
- assist when constructing the differential diagnosis, since medicines can cause illness/disease directly or as a result of an interaction
- help in planning future treatment
- assist the interpretation of results since medicines can mask clinical signs and alter the results of investigations
- ensure prompt and appropriate treatment while patients are in hospital

Inaccurate or incomplete medication lists in hospital lead to medication errors and patient harm which may in turn lengthen the stay. Poor communication of medicines information and changes at discharge leads to patient harm in the community and an increased risk of re-admission.

If medicines reconciliation is to be performed reliably for every patient then a systematic approach with clear responsibilities is required. Good practice guidance for safe and reliable medicines reconciliation in hospitals across NHS GGC has been approved by the ADTC. It relates to medicines reconciliation on admission, during the patient's stay and at discharge and outlines the respective roles and responsibilities of medical, pharmacy and nursing staff. There are resources to support implementation of medicines reconciliation. You can find advice at [http://www.ggcprescribing.org.uk/media/uploads/policies/section\\_10/med\\_reconciliation\\_guidance\\_-\\_1203.pdf](http://www.ggcprescribing.org.uk/media/uploads/policies/section_10/med_reconciliation_guidance_-_1203.pdf).

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## New Pathway for Management of Erectile Dysfunction

New arrangements are now in place for men residing in NHSGGC who present with erectile dysfunction (ED). This was triggered by the change in restrictions on prescribing medical therapies for ED announced on 9 Jan 2011 in PCA(M)(2011) 4 *Treatment of Erectile Dysfunction: Patients with Severe Distress* [http://www.sehd.scot.nhs.uk/pca/PCA2011\(M\)04.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2011(M)04.pdf)

Primary care prescribers can continue to issue GP10s, annotated "SLS", for men who meet the medical criteria for NHS prescribing:

- all prostate cancer
- spinal cord injury
- MS
- diabetes
- renal failure
- severe pelvic injury
- spina bifida
- single gene neurological disease
- polio
- Parkinson's disease

Prescribing for men with severe distress can be undertaken in primary care only after referral to specialist services. This is available through SCI Gateway. All severe distress referrals will be reviewed by a consultant psychiatrist with approval in writing. A face-to-face consultation may be offered. The GP must include sufficient information to justify NHS prescribing.

Severe distress consists of at least one of the following:

- significant disruption to normal, social and occupational activity
- marked effect on mood, behaviour, social and environmental awareness
- marked effect on interpersonal relationships

The full NHSGGC pathway for ED with no obvious iatrogenic cause is available at

<http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGC%20Referral%20Guidance/Referral%20GuidanceForms/Erectile%20Dysfunction%20Referral%20pathway%20061211.pdf>.

Referral criteria have been agreed by the Referral Management Group and LMC.

The *Formulary* status of PDE-5 inhibitors has been reviewed and now states that NHS prescribing by GPs is limited to nationally determined patient groups and schedule 11 restrictions.

## Levothyroxine: Withdrawal of Teva Brand

The licence for Teva levothyroxine 100microgram (marketed as Teva and Numark) has been suspended while reports of reduced efficacy are investigated. It is possible that a change in a patient's symptoms and TSH status may be attributed to switching between Teva levothyroxine 100microgram tablets and another product.

- Most patients are unlikely to notice any difference or incur serious consequences so can wait until their next prescription for a change of product.
- Patients who experience a significant change in symptoms should have their TSH status checked and their dose of levothyroxine adjusted and reviewed as usual practice.

The following patients may be particularly susceptible to changes in TSH and may require close monitoring:

- Pregnant women, throughout pregnancy but especially in the first trimester:
  - Pregnant women with thyroid disease are monitored routinely through the antenatal period by specialist services.
- Those with heart disease
  - Specialists have intimated that the risk is low. GPs should be vigilant for patients with heart disease showing signs or symptoms which are suggestive of levothyroxine overdose and should investigate appropriately.
- Those under treatment with TSH suppressive doses of levothyroxine after treatment for thyroid cancer
  - Local specialists have suggested this is a relatively small group who are regularly monitored.

The CHM advise that patients in the above groups should be contacted and, if they are taking Teva tablets, be given an early appointment for a clinical review and blood test. The difficulty in practice is that patients may switch between brands many times and the timing of that is unpredictable. Any patients who report a change in symptoms should be advised to see their doctor.

Community pharmacies and hospitals have withdrawn the affected products and are now using other brands. Further information is available from <http://www.mhra.gov.uk/home/groups/comms-po/documents/news/con143690.pdf>