PostScRxipt – PrimaRxy Care

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GENERIC PRESCRIBING OF IMMUNOSUPRESSANTS IN RENAL PATIENTS: During the last 12 months a number of drugs used in renal disease have come off patent. The emergence of generic alternatives could have considerable cost benefits but concerns surround the non bioequivalence of generic versions of immunosuppressants and possible clinical risks especially when 'critical dose' drugs are involved.

Tacrolimus and Ciclosporin:

- These are 'critical dose' drugs where therapeutic drug monitoring is required.
- Different formulations are widely recognised to have distinct pharmacokinetic characteristics and thus may not be interchangeable.
- Inadvertent switching in primary care is an issue if prescribers do not specify brands.
- Small changes in bioavailability may reduce their efficacy (risking transplant loss) or cause drug toxicity (including renal impairment, hepatic dysfunction and high blood pressure).

The renal transplant unit at the Western is advising that tacrolimus and ciclosporin should be prescribed by brand and **NOT** be changed without hospital monitoring.

Mycophenolate Mofetil

The patent for mycophenolate mofetil (Cellcept®) expired at the beginning of November 2010 and a large number of generics are anticipated.

Whether mycophenolate mofetil is a 'critical dose' drug is under clinical debate. The unit at the Western Infirmary does not routinely undertake therapeutic drug monitoring and adjusts doses according to side effects (diarrhoea or decreasing white blood counts).

No real evidence indicates that the different formulations are not interchangeable; it is advisable, however, to be cautious in transplant patients and the unit will monitor patients for problems. If GP's prescribe generically then patients should be alert to any new health problems and inform the renal unit.

NHS Greater Glasgow and Clyde

Conclusions

Tacrolimus and ciclosporin are critical dose drugs and brands should not be interchanged without careful monitoring by the transplant unit. Inadvertent switching in primary care is an issue if prescribers do not specify brands. Patients are key and should be fully informed of the issues, including what to do if a different formulation is prescribed or dispensed. The Renal Unit issues formulation identification cards to all new transplant patients.

Generic mycophenolate mofetil may not have the same issues but renal units are keen to monitor patients for problems.

Care should be taken to ensure that the same product is supplied to patients to reduce problems mentioned above. In the event of a problem in sourcing a particular brand, especially with current quotas and "direct to pharmacy" arrangements, the community pharmacist should contact the hospital renal pharmacy team or renal consultant for advice.

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COMMUNITY PHARMACY UNSCHEDULED CARE PGD: The majority of pharmacies in GG&C provide the Unscheduled Care PGD for patients who have run out of their medication and cannot access a prescription because the surgery is closed or the GP is otherwise unavailable. This is mainly used to support out of hours, bank holidays and weekends. The pharmacist can provide up to a full prescription cycle using a CPUS form but should then fax a copy to the patient's GP alerting them to the supply. If the patient had already requested a prescription from the practice, but had been unable to collect it and had accessed the pharmacy in the interim, it is advisable that the GP10 is not supplied, as this could potentially result in double quantities issued over a short period of time.

Practices are requested to action the faxes as soon as reasonably possible. Community pharmacists have also been asked to contact their local practices to agree any arrangements for dealing with any GP10s issued after a CPUS supply.

I-CAPS: I-Caps® are a dietary supplement containing several vitamins, minerals and lutein, an antioxidant found in the eye naturally. Currently there does not seem to be any conclusive evidence that supplementation with lutein is effective in Age-related Macular Degeneration (AMD).

I-Caps® and similar antioxidants are not blacklisted, and in the strictest sense they can be prescribed on a GP10, however, the prescription may be subject to 'pay and report' which is where the prescriber would need to justify the prescription in order to receive payment. These preparations are considered food supplements and are not licensed medicinal products. The recommendation of the Prescribing Team is that these preparations are not prescribed on the NHS.

They can be bought by the patient directly, but many ophthalmologists simply recommend that patients with AMD eat a healthy diet with plenty fresh fruit and vegetables (lutein is contained in many green and brightly coloured vegetables as well as eggs) and refrain from smoking.

PULMICORT CFC FREE INHALER DISCONTINUED: AstraZeneca UK Ltd has discontinued production of **Pulmicort® CFC–free Inhaler 100 & 200micrograms and NebuChamber Spacer®** with immediate effect due to complex manufacturing issues. The NebuChamber spacer® is only licensed for use with these two inhaler presentations. This issue does not apply to any other AstraZeneca inhalers or components which will remain in normal supply and use.

Patients can continue using PULMICORT CFC-free Inhaler 100 & 200 micrograms until their current supply is finished. At that time, patients should be changed to an appropriate alternative inhaled corticosteroid treatment for their specific medical condition. Guidance on equipotent doses of alternative inhaled corticosteroids can be found in the BTS/SIGN British Guideline on the management of asthma

DABIGATRAN: **Dabigatran: Application for New Indication for Use**

The manufacturer of dabigatran has submitted an application for marketing authorisation for a new indication of prevention of stroke and systemic embolism in adults with atrial fibrillation to the European Medicines Agency (EMA). This medicine is currently licensed for thromboprophylaxis following elective hip/knee replacement but is non-Formulary in NHSGGC as rivaroxaban is the preferred option.

If a market authorisation (commonly known as a licence) is granted, SMC will assess the product and make recommendations for use in Scotland. This advice will be considered by ADTC and given the projected budget impact it will also be considered by PMG. Should there be a decision to use this product; a local implementation plan will be required before NHSGGC *Formulary* status is formalised.

Until the sequence of events from licence to *Formulary* status is complete all NHSGGC prescribers should refrain from using this medicine. Negligible prescribing is expected while dabigatran remains unlicensed for this indication. Once licensed, initiation by hospital specialists should only be in exceptional circumstances (through the non-*Formulary* process) until local *Formulary* status, prescribing protocols and implementation arrangements are in place.

The potential budget impact for dabigatran poses an unprecedented challenge to the NHS and, subject to SMC advice, a managed introduction is essential. Your support to ensure this is effectively managed is appreciated.

ERECTILE DYSFUNCTION: Prescribing for patients with severe distress PCA(M)(2011) 4 *Treatment of Erectile Dysfunction:Patients with Severe Distress* confirms some relaxation of current restrictions on prescribing of these treatments. Currently, all prescribing must be carried out by the specialist service. In future, all eligible patients will be able to receive treatment on NHS prescription from their GP following assessment or advice by the relevant consultant. Before changes are made to the way in which these patients are treated, the Clinical Services Subgroup of the Sexual Health Planning Group is identifying the relevant consultants who will provide that assessment and advice and the Primary Care Prescribing Management Group is confirming that clinical capacity and funding are in place.

Until the new services are finalised, all clinicians involved in the treatment of these patients are requested to maintain the status quo.

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