Lincolnshire NHS

Prescribing and Clinical Effectiveness Bulletin

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CONTENTS

INTRODUCTION

Welcome to the first edition of the *Lincolnshire Prescribing and Clinical Effectiveness Bulletin*. This bulletin has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Steps will be taken to ensure the widest possible distribution across Lincolnshire PCT and within United Lincolnshire Hospitals Trust and Lincolnshire Partnership Trust. Both paper and electronic copies will be circulated initially with a view to evolving into complete electronic distribution as soon as we are confident that all key stakeholders can access E-mail. There are also plans to make all bulletins, guidelines, formularies, new product assessments, care pathways and other PACEF publications available through the LPCT website.

SUMMARY OF PACEF DECISIONS: JUNE UPDATE

Drug	Indication	Traffic Light Status
Exforge tabs (amlodipine/valsartan)	Hypertension	RED-RED
Natalizumab inf (Tysabri)	Highly active relapsing remitting multiple sclerosis	RED-RED
Lanthanum carbonate tabs (Fosrenol)	Hyperphosphataemia in chronic renal failure	AMBER
Sevelamer tabs (Renagel)	Hyperphosphataemia in chronic renal failure	AMBER
Testosterone patch (Intrinsa)	Women with hypoactive sexual desire disorder	RED-RED
Human Papillomavirus Vaccine (Gardasil)	Prevention of cervical cancer	RED-RED

UPDATE OF TRAFFIC LIGHTS SYSTEM

The Lincolnshire Traffic Lights System provides guidance for all prescribers in both primary and secondary care on the appropriateness of prescribing of a wide range of medicines. The update of the Traffic Lights List for 2007/8 is in process and will seek to simplify the colour coded guidance in the following way:

RED-RED: This will signify that a product is **not recommended** for prescribing in **both** primary and secondary care.
RED: This will signify that a product has been approved for use within ULHT and/or LPT **only** and has **no role in primary care**.
AMBER: This will signify a drug that has been approved for use in primary care **subject to specialist initiation** and the development of a **shared care guideline (SCG)**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities within the context of shared care. Not all AMBER drugs are currently covered by formal SCGs, although in the coming months PACEF will be working to rectify this.
GREEN: This will signify a product that is **approved for initiation in either primary or secondary care**. Specialist initiation and shared care guidelines are not considered necessary.

NEW PRODUCTS UPDATE

As a general principle, it has been agreed by PACEF that **all new products will be classified as RED-RED (i.e. not prescribable in either primary or secondary care) until they have been formally evaluated**. The PACEF New Product Assessment Group will endeavour to produce NPAs on all significant new products as soon as possible after launch. Prescribers are asked to await guidance from PACEF before prescribing any new product.

NATALIZUMAB (TYSABRI)

Natalizumab is a monoclonal antibody that is licensed for highly active relapsing remitting multiple sclerosis. It is given by IV infusion once every 4 weeks. The evidence base behind the product is derived from two key clinical trials, both of which were short-term. Concerns have been raised around the large inter-patient variability within trials and the decision to censor some of the data in the final published papers. Long term safety data and comparative trials against competitor therapies, such as beta-interferon and glatiramer acetate, are not yet available. In addition to this, natalizumab is considerably more expensive than alternatives. The drug has already been turned down pre-launch by ULHT Drug and Therapeutics Committee and the Scottish Medicines Consortium. A NICE Technology Appraisal is pending and will be reviewed on publication by PACEF.

PACEF Recommendation:
Natalizumab (Tysabri) is classified as RED-RED. It should not be prescribed in either primary or secondary care in Lincolnshire.

LANTHANUM CARBONATE (FOSRENOL)

Lanthanum carbonate is an oral non-calcium phosphate binding agent licensed for the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis. Trials suggest that lanthanum is comparable in efficacy to calcium carbonate. There are no comparative studies

against any other non-aluminium, non-calcium phosphate binder, such as sevelamer.

PACEF Recommendation:
Lanthanum (Fosrenol) is classified as AMBER. ULHT Renal Services will be using it as a third line agent in patients who cannot take calcium based phosphate binders (patients with a calcium level >2.4mmol/L) and who have subsequently tried and failed to tolerate sevelamer. Shared care guidelines are in development for both lanthanum carbonate and sevelamer; GPs should only accept prescribing responsibility within the context of these shared care guidelines.

TESTOSTERONE PATCH (INTRINSA)

Testosterone patch (Intrinsa) is the first licensed testosterone preparation for use in women with hypoactive sexual desire disorder (HSDD). Some debate has occurred within the medical press as to whether HSDD is a real clinical condition or a diagnostic label created by the pharmaceutical company in order to stimulate a perceived need for the treatment. Intrinsa is a patch formulation that releases 300 micrograms of testosterone every 24 hours; the patch is changed twice weekly. It is licensed for the treatment of HSDD in bilaterally oophorectomised and hysterectomised (surgically induced menopause) women up to the age of 60 receiving concomitant oestrogen therapy (i.e. women with severe androgen deficiency due to the removal of both ovaries). The evidence base consists of two placebo controlled RCTs conducted in women aged 20 to 70 years who had undergone bilateral salpingo-oophorectomy and hysterectomy and who were also receiving a stable dose of oestrogen. Both trials used efficacy tools that were developed by the manufacturer with no external validation (e.g. Sexual Activity Log, Personal Distress Scale). Both trials demonstrate a modest, but statistically significant increase in the 4-week frequency of satisfying sexual episodes evaluated at 24 weeks for testosterone patches compared to placebo, but the placebo response was high (35%). Both short-term and long-term side effects are potentially a concern: androgenic adverse effects, such as hirsutism and acne, are a particular problem and signs of virilisation may be irreversible if not caught in time. Long-term safety data, particularly relating to cardiovascular, breast and endometrial effects, is not yet available.

PACEF Recommendation:
On the basis of current evidence, testosterone patch (Intrinsa) has been classified as RED-RED. It should not be prescribed in either primary or secondary care in Lincolnshire. An SMC review is due in September 2007 and may provide useful additional information on cost-effectiveness. Any additional information emerging from the SMC review will be reviewed by PACEF later in the year.

NICE UPDATES

NICE CLINICAL GUIDELINE 46: VENOUS THROMBOEMBOLISM

- This CG aims to reduce the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in all hospital inpatients undergoing surgery.
- It identifies patient-related risk factors for venous thromboembolism (VTE) (e.g. age over 60, obesity, use of oral contraceptives or HRT, continuous

travel of more than 3 hours in the 4 weeks before or after surgery etc) and advocates risk assessment.

- The CG provides tabulated recommendations for prophylaxis in each surgical speciality. Recommendations usually differ depending on whether the patient has one or more risk factors.
- Mechanical prophylaxis, in the form of **thigh-length graduated compression/anti-embolism stockings**, should be offered to all surgical inpatients, unless contra-indicated (e.g. in PAD or diabetic nephropathy). **Patients should be encouraged to wear them from admission until they return to usual levels of mobility**. If thigh length stockings are inappropriate, knee length may be used.
- Patients at increased risk of VTE (one or more risk factors) and those having orthopaedic surgery (hip replacement, hip fracture or other) should be offered **low molecular weight heparin (LMWH)**. **Fondaparinux** is an alternative. The LMWHs are bemiparin sodium (Zibor), dalteparin sodium (Fragmin), enoxaparin sodium (Clexane) and tinzaparin sodium (Innohep). The local LMWH of choice is enoxaparin.
- Fondaparinux sodium is a synthetic pentasaccharide that inhibits activated factor X. It is licensed for prophylaxis of VTE in medical patients and in patients undergoing major orthopaedic surgery of the legs or abdominal surgery.
- **LMWH or fondaparinux should be continued for 4 weeks after hip replacement or hip fracture surgery.** This means continuation of treatment after discharge. All of the drugs are administered by subcutaneous injection and patients can be taught to self administer.

As a result of this, these patients will be discharged from ULHT with sufficient LMWH or fondaparinux to cover the 4 week post-operative period. This 4 week course of treatment will be prescribed as discharge medication from within ULHT. GPs will not be expected to prescribe and should reject all approaches to do so.

NICE CLINICAL GUIDELINE 47: FEVERISH ILLNESS IN CHILDREN

- In assessing a child with fever, the Clinical Guideline (CG) advocates checking for immediately life-threatening features (compromise of the **A**irway, **B**reathing or **C**irculation, or **D**ecreased level of consciousness).
- A traffic light system, based on the presence or absence of signs/ symptoms, is advocated to predict the risk of serious illness.
- The CG advocates measurement of body temperature to detect fever in children aged 4 weeks to 5 years. An electronic or chemical dot thermometer in the axilla or an infra-red tympanic thermometer are all advocated as options. An electronic thermometer in the axilla is advocated in children younger than 4 weeks. The CG cautions against routine use of oral or rectal temperature measurement or the use of forehead chemical thermometers.
- Healthcare professional should measure and record temperature, heart rate, respiratory rate and capillary refill time as part of routine assessment. The child should also be assessed for signs of dehydration.
- The CG offers a care pathway and treatment algorithms for remote assessment, management by a non-paediatric prescriber and management by a paediatric specialist.
- Oral antibiotics should not be prescribed to children with fever without apparent source.

- Antipyretic agents do not prevent febrile convulsions and should not be used specifically for this purpose. Antipyretic agents should not be given to a child with fever with the sole aim of reducing body temperature. Do not rely on a change in temperature after 1 to 2 hours to differentiate between serious and non-serious illness.
- Paracetamol or ibuprofen should be considered if the child appears distressed or unwell. Do not give paracetamol and ibuprofen at the same time; use one as an alternative to the other.
- If meningococcal disease is suspected, give parenteral antibiotics at the earliest opportunity (either benzylpenicillin or a third-generation cephalosporin). More detailed guidance on antibiotic treatment of suspected bacterial infection is also provided within the CG.

HUMAN PAPILLOMA VIRUS VACCINATION

Readers will be aware of the recent announcement by the Department of Health that Human Papilloma Virus (HPV) vaccine is likely to be introduced into the national immunisation programme. The Joint Committee on Vaccination and Immunisation (JCVI) have advised the DoH that vaccination should be introduced for girls aged around 12 to 13 years. Subject to a favourable independent peer review of a cost-benefit analysis, routine vaccination could begin in autumn 2008.

Prescribers are reminded that HPV vaccine (Gardasil) remains classified as RED-RED and is likely to remain so until the national HPV vaccination programme begins.

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