Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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Device, Dressing or Drug	Indication(s)	Traffic Light and *Joint Formulary* Status
Shortec Liquid - oxycodone 5mg/5ml oral solution (Qdem Pharmaceuticals Ltd)	For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid.	.GREEN All oxycodone products should be prescribed by brand name to avoid any confusion.
Shortec Concentrate - oxycodone 10mg/ml oral solution (Qdem Pharmaceuticals Ltd)	For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid.	GREEN All oxycodone products should be prescribed by brand name to avoid any confusion
Shortec solution for injection or infusion oxycodone 10mg/ml (1ml & 2ml ampoules) & 50mg/ml (1ml ampoules) (Qdem Pharmaceuticals Ltd)	For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid.	GREEN All oxycodone products should be prescribed by brand name to avoid any confusion
Alprostadil 300mcg in 100mg cream.(Victaros) (Ferring Pharmaceuticals Ltd)	Treatment of men ≥ 18 years of age with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance	RED/RED not approved for inclusion in the *Lincolnshire Joint Formulary.* Not to be used for new patients. Treatment of those patients already receiving alprostadil cream may continue until they and their NHS clinician consider it appropriate to stop.

RED-RED: This signifies that a product is **not recommended** for prescribing in **either** primary or secondary care. All new products are classified as RED-RED pending assessment by PACEF.
RED: This signifies that a product has been approved for use within secondary care, tertiary care or a primary care hosted specialist service only and **should not be routinely prescribed in primary care**. RED drugs may be used within ULHT or LPFT subject to approval for use within each Trust. ULHT and LPFT reserve the right to determine whether or not RED drugs will be used within their Trusts. RED classification does not automatically signify that a drug will be available within secondary/tertiary care.
AMBER 1: Medicines that should be initiated by a specialist and prescribed by primary care prescribers only under a shared care protocol. Prior agreement must be obtained by the specialist from the primary care provider before prescribing responsibility is transferred.
AMBER 2: Medicines suitable to be prescribed in primary care after specialist* recommendation or initiation
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care.**

Other Headlines:

- **Changes to Amber Classification (refer to table above)**
- **MHRA Drug Safety Update - SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation (mainly toes).**
- **Rivastigmine patches - actions to take to reduce risk of medication errors.**
- **Introduction of AMBER 1 & 2 Traffic light classification to replace amber with or without shared care.**

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Rapid cost comparison Shortec Liquid (oxycodone 5mg/5ml oral solution) Shortec Concentrate (oxycodone 10mg/ml oral solution) and Shortec injection 10mg/ml (1ml & 2ml ampoules) & 50mg/ml 1ml ampoules (Qdem Pharmaceuticals Ltd)

Shortec have recently extended their range of immediate release products to include oxycodone injection 10mg/ml & 50mg/ml and two strengths of oxycodone solution 5mg/5ml and 10mg/ml.

Oxycodone product	strength	Cost (£)
Oxynorm liquid (Napp Pharmaceuticals Ltd)	5mg/5ml soln	£9.71 (250ml)
OxyNorm Conc (Napp Pharmaceuticals Ltd)	10mg/ml soln	120ml=£46.63
OxyNorm Injection (Napp Pharmaceuticals Ltd)	10mg/ml injection 50mg/ml	£8.00 5 x 1ml amps £16.00 5 x 2ml amps £70.10 5 x 1ml amps
Shortec liquid (Qdem pharmaceuticals ltd)	5mg/5ml oral soln,	£8.25 (250ml)
Shortec Conc (Qdem pharmaceuticals ltd)	10mg/ml oral soln,	£39.64 (120ml)
Shortec injection (Qdem pharmaceuticals ltd)	10mg/ml 50mg/ml	£6.90 (5 x 1ml) £13.60 (5 x 2ml) £59.59 (5 x 1ml)

Potential annual cost savings if all oral solutions and injections are prescribed as Shortec brand.

CCG	Potential annual saving
LECCG	£3,036
LWCCG	£6,666
SLCCG	£1,332
SWLCCG	£2,028

- The Shortec brand of oxycodone tablets is already included on the Lincolnshire Joint Formulary as one of the preferred lower cost brands when use of a standard release oxycodone tablet is indicated.
- PACEF has approved the extended range of Shortec products for inclusion onto the Lincolnshire Joint Formulary designated as GREEN, when use of oxycodone liquid and injection are required.

Review of Alprostadil 300 microgram in 100mg cream (Vitaros)

Following a review of alprostadil cream has been removed from the Lincolnshire Joint Formulary and reclassified RED/RED.

- PACEF first assessed alprostadil 300 microgram in 100mg cream (Vitaros) in September 2014.
- Alprostadil is an established second line treatment for erectile dysfunction used for the 25% of men who fail to respond to oral phosphodiesterase type 5 inhibitors. Until 2014 it was only available as either an intracavernosal injection (Caverject/Viridal) or as a pellet for urethral application (MUSE).
- Vitaros was a new cream based formulation of alprostadil available as single dose units, for direct application to the tip off the penis within 5 to 30 minutes of attempted sexual intercourse. The product was promoted as having a less invasive method of administration than alternative alprostadil formulations (injection & urethral sticks), at a comparable price.
- PACEF designated alprostadil 300 microgram in 100mg cream as RED (hospital only) drug approved for specialist use only. The United Lincolnshire Hospital trust (ULHT) based urology service had requested an opportunity to evaluate the new formulation against alternative treatments over a period of time.
- The ULHT urology service reported back to the April 2017meeting of PACEF that they had assessed alprostadil cream and that the response to treatment was poor compared to alternative therapies. They therefore no longer used this treatment..
- PACEF has therefore reviewed the formulary status of alprostadil cream based on the unfavourable assessment by the ULHT urology services have re-designated it as a RED/RED drug no longer approved for use for new patients.
- Treatment of those patients already receiving alprostadil cream may continue until they and their NHS clinician consider it appropriate to stop.

Reclassification AMBER traffic light classification

The current Amber traffic light classification has generated some confusion and PACEF was asked to review this. Following discussion the following changes have been made:

- AMBER with shared care is to be changed to AMBER 1.
- AMBER 1 medicines are products that should be initiated by a specialist and prescribed by primary care prescribers only under a shared care protocol. Prior agreement must be obtained by the specialist from the primary care provider before prescribing responsibility is transferred.
- Amber without shared care will become AMBER 2
- AMBER 2 medicines are products suitable to be prescribed in primary care after specialist recommendation or initiation.
- The joint formulary entry where necessary, will further define what is meant by the term specialist, to provide clarification if necessary e.g. if the term specialist refers to hospital based medical consultants only, nurse specialists or community based services.

MEDICINES AND HEALTHCARE REGULATORY AGENCY: DRUG SAFETY UPDATE (March 2017)

SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation (mainly toes).

Canagliflozin may increase the risk of lower-limb amputation (mainly toes) in patients with type 2 diabetes. Evidence does not show an increased risk for dapagliflozin and empagliflozin, but the risk may be a class effect. Preventive foot care is important for all patients with diabetes.

MHRA has issued the following advice:

- Carefully monitor patients receiving canagliflozin who have risk factors for amputation, such as poor control of diabetes and problems with the heart and blood vessels.
- Consider stopping canagliflozin if patients develop foot complications such as infection, skin ulcers, osteomyelitis, or gangrene.
- Advise patients receiving any sodium-glucose co-transporter 2 (SGLT2) inhibitor about the importance of routine preventive foot care and adequate hydration.
- Continue to follow standard treatment guidelines for routine preventive foot care for people with diabetes.
- Report any suspected side effect with SGLT2 inhibitors or any other medicine on a Yellow Card.

The United Lincolnshire Hospital NHS Trust Diabetic service has advised that in addition to the MHRA advice all three SGLT2 inhibitors (canagliflozin, dapagliflozin and empagliflozin) should be used with caution in all patients with known diabetic foot disease.

Risk of medication errors with rivastigmine patches.

The UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals have produced a Medicines Q&A highlighting the risk of medicine errors associated with the use of rivastigmine patches.

- The aim of the Q&A is to raise awareness on the types of medication errors reported with rivastigmine patches, as well as highlighting strategies to improve medication safety on the prescribing and administration of these patches.
- Rivastigmine patches are currently classed as AMBER 1 on the Lincolnshire Joint formulary. The use of patches should only be considered in patients taking rivastigmine who develop or experience swallowing difficulties. PACEF currently recommends that if transdermal patches are required than a low cost brand should be used such as Alzest.
- The following actions should be considered to support safe use of rivastigmine patches:

Correct and timely application

- Patients and caregivers should be given clear instructions on the frequency of patch removal and renewal, and appropriate areas for application. They should be encouraged to keep a record of when the patch was removed and when it was replaced, for example by using the manufacturer provided medication record dairies or writing the day of the week or date on the patch with a thin ball point pen.
- Robust systems should be in place in healthcare settings e.g. care homes and hospitals, to ensure correct application of patches at the scheduled time.
- Pharmacy dispensing labels should make the frequency of patch removal and renewal clear e.g. "*Apply ONE patch every TWENTY-FOUR hours. Remove and discard old patch before applying a new patch to a different location.*"

Review prescribing and storage systems

- Strategies to mitigate the risk of dispensing errors of wrong product (i.e. confusion between rivastigmine and *rotigotine* patches) and strength should be considered. These may include review of the stock's location in pharmacy departments, community pharmacies and dispensaries.

Copies of the UKMI Q&A which contains further details of the type of medication incidents associated with the use of rivastigmine patches can be obtained from the Optum Medicines Management and Optimisation team.

NICE Update

NICE Technology Appraisal	Guidance	PACEF recommendation
NICE TA 180 Ustekinumab (Stelara®) for treating psoriasis in adults.(last updated March 2017)	**Ustekinumab (Stelara®)** is recommended as a treatment option for adults with plaque psoriasis when the following criteria are met. The disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) score of 10 or more and a Dermatology Life Quality Index (DLQI) score of more than 10. The psoriasis has not responded to standard systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or the person is intolerant of or has a contraindication to these treatments.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.

NICE Technology Appraisal	Guidance	PACEF recommendation
NICE TA 340 Ustekinumab for treating active psoriatic arthritis.(last updated March 2017)	1.1 Ustekinumab(Stelara®) is recommended as an option, alone or in combination with methotrexate, for treating active psoriatic arthritis in adults only when: Treatment with tumour necrosis factor (TNF) alpha inhibitors is contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis and golimumab for the treatment of psoriatic arthritis) Or The person has had treatment with 1 or more TNF–alpha inhibitors.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.
NICE TA 439 Cetuximab (Erbitux) and panitumumab (Vectibix) for previously untreated metastatic colorectal cancer	Cetuximab is recommended, within its marketing authorisation, as an option for previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults in combination with: • 5-fluorouracil, folinic acid and oxaliplatin (FOLFOX) or • 5-fluorouracil, folinic acid and irinotecan (FOLFIRI). Panitumumab is recommended, within its marketing authorisation, as an option for previously untreated RAS wild-type metastatic colorectal cancer in adults in combination with: FOLFOX or FOLFIRI.	Cetuximab (Erbitux) and panitumumab (Vectibix will be classed as RED for this indication

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