Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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Summary of PACEF decisions from May 2017

PACE Short (Vol 11 No 10)

Device, Dressing or Drug	Indication(s)	Traffic Light and *Joint Formulary* Status
Budesonide 2mg/dose rectal foam (Budenofalk) (Dr. Falk Pharma UK Ltd)	For the treatment of active ulcerative colitis that is limited to the rectum and the sigmoid colon	.GREEN To be used as second line option if rectal hydrocortisone is not tolerated.
Hydrocortisone Acetate 10% w/w (Colifoam)(Meda Pharmaceuticals)	Ulcerative colitis, proctosigmoiditis and granular proctitis.	GREEN To be used as a first line option when use of a rectal corticosteroid is indicated.
Prednisolone 20mg/application foam enema foam	Proctitis, ulcerative colitis.	GREEN Not to be initiated in new patients. Approved for continued use in existing patients until reviewed by a specialist.
Insulin Degludec Trisiba 100units/ml cartridge pen fill, Tresiba 100 units/ml pre-filled pen (FlexTouch), Tresiba 200units/ml pre-filled pen (FlexTouch) Novo Nordisk	Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year	Amber 2. Should only be initiated by either the community hosted specialist services or consultant diabetologists Restricted as AMBER2 •for patients with type 1 DM who have recurrent admissions with diabetic ketoacidosis due to poor adherence •for patients with type 1 DM with problematic or recurrent nocturnal hypoglycaemia on other long-acting analogues and are not suitable for insulin pump therapy •for a small number of patients with type 2 DM with significant insulin resistance who might otherwise need large doses of Humulin R U500 insulin

Other news

Valproate updated drug safety alert and neurodevelopmental disorder

Ponatinib (Iclusig) risk of vascular occlusive events

Nicotine Replacement Therapy (NRT) change in provision from June 1st 2017.

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Rapid Drug Assessment Budenofalk 2mg Rectal Foam (Budesonide Rectal Foam) (Dr. Falk Pharma UK Ltd)

Request had been made from ULHT gastroenterology service, to include budesonide rectal foam onto the Lincolnshire Joint Formulary. It is proposed that budesonide becomes the second line choice for the treatment of active left sided ulcerative colitis for those intolerant to or who experience side effects from using rectal hydrocortisone. Evidence suggests equivalence between the alternative options.

product	Number of doses	Cost (£) (doses in pack)
Budesonide 2mg foam enema (Budenofalk)	1 metered application (2mg) once daily for up to 8 weeks.	£57.11 (14)
Hydrocortisone acetate 10% w/w (Colifoam)	Initially 1 metered application 1–2 times a day for 2–3 weeks then reduced to 1 metered application once daily on alternate days, to be inserted into the rectum.	£9.33 (14)
Prednisolone 20mg Foam Aerosol	1 metered application 1–2 times a day for 2 weeks, continued for further 2 weeks if good response, to be inserted into the rectum, 1 metered application contains 20 mg prednisolone.	£187.00 (14)

Savings is all prednisolone rectal foam is switched to budesonide from prednisolone, based on 11 months activity.

CCG	Potential annual saving
LECCG	£35,460
LWCCG	£22,860
SLCCG	£18,054
SWLCCG	£8,962

- Currently the two rectal steroids on the formulary are hydrocortisone 10% w/w (Colifoam) and Prednisolone 20mg foam aerosol (Chemidex). The price of prednisolone rectal foam is considerably more than for the alternative products.
- If Budesonide is used as an alternative to prednisolone there is a potential annual saving of £90k+ across the four CCGs. Although this saving is unlikely to be realized within year as product switching should only be at the discretion of a specialist following patient review.
- PACEF approved Budesonide rectal foam as GREEN for inclusion on the Lincolnshire Formulary as second line option if rectal hydrocortisone is not tolerated.
- Prednisolone 20mg rectal foam should remain on this product classed as GREEN but use should be reserved for existing patients.

Review of Insulin Degludec (Tresiba)

Following a review of Insulin Degludec it remains as should remain as AMBER 2 . Treatment with insulin degludec can now be initiated by a wider group of clinicians consultant diabetologists, GPSI (Diabetes) and Diabetes Specialist Nurses.

- PACEF first reviewed insulin degludec in June 2013 approving it for use for the following patient groups:
- 1) for patients with type 1 DM who have recurrent admissions with diabetic ketoacidosis due to poor adherence
- (2) for patients with type 1 DM with problematic or recurrent nocturnal hypoglycaemia on other long-acting analogues who are not suitable for insulin pump therapy
- (3) for a small number of patients with type 2 DM with significant insulin resistance who might otherwise need large doses of Humulin R U500 insulin.
- To ensure managed introduction of the new therapy and to mitigate any risk of confusion with existing therapies PACEF restricted initiation of therapy to consultant diabetologists only.
- The community based Diabetes Specialist nurses (DSNs) and GP with Specialist Interest (GPSI) for Diabetes with the support of the ULHT consultant endocrinologists had requested that the formulary status for insulin degludec was reviewed and whilst staying as AMBER 2 the category of specialist able to initiate treatment is extended to include GPSi's and the community based DSNs.
- Capacity within the hospital based service is limited and it is viewed as an unnecessary use of a referral that patients previously being managed by the community based service are having to be referred to secondary care hosted service for initiation onto insulin degludec

- There is a need for insulin degludec initiation to remain with those with experience in the initiation of insulin therapy and the knowledge of differences between injectable therapies.
- PACEF approved this request and agreed also to extend the criteria for those eligible for treatment to include housebound patients, who have had previously difficulties responding to alternative insulin preparations and who would benefit from a long acting analogue.

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

Valproate and developmental disorders: new alert asking for patient review and further consideration of risk minimisation measures.
Babies born to mothers who take valproate medicines (Epilim, Depakote) during pregnancy have a 30-40% risk of developmental disability and a 10% risk of birth defects.
The MHRA has issues communications to prescribers in January 2015 and February 2016 on the magnitude of the risk but there is evidence that 1 in 5 women taking valproate are still not aware of any of its risks in pregnancy.
The MHRA has updated it advice to health care professionals:

- Do not prescribe valproate medicines for epilepsy or bipolar disorder in women and girls unless other treatments are ineffective or not tolerated; migraine is not a licensed indication.
- Ensure women and girls taking valproate medicines understand the 30-40% risk of neurodevelopmental disorders and 10% risk of birth defects and are using effective contraception.
- Valproate use in women and girls of child bearing potential must be initiated and supervised by specialists in the treatment of epilepsy or bipolar disorder.
- There are a number of resources which can assist a clinician in the review of valproate containing medication and provide information to both health care professionals and patients. Links to these are contained below and information on support materials can also be obtained from the Optum Medicines Management & Optimisation Service.
- PACEF advise that all women and girls currently receiving valproate therapy are identified and reviewed using appropriate MHRA resources to support them in making an informed choice.

Resources

Patient Safety alert -
https://improvement.nhs.uk/uploads/documents/Patient_Safety_Alert_-_Resources_to_support_safe_use_of_valproate.pdf

Guidance on using valproate tool kit
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/606618/Guidance_on_using_the_valproate_toolkit_for_those_prescribing_and_dispensing_valproate.pdf

Change in supply of provision of Nicotine Replacement Therapy to support smoking cessation

From 1st June there will be a change in the provision of the supply of Nicotine Replacement Therapy (NRT) for those who are undertaking a supported smoking cessation QUIT attempt through Quit 51 services.

- Lincolnshire County Council (LCC) Public Health Service has sent information detailing the proposed change in provision of NRT to all GPs and community pharmacies.
- From the 1st June there will be a gradual roll-out across the area covered by the four Lincolnshire CCGs with NRT being directly provided to people accessing smoking cessation services provided by Quit 51.
- New clients will be informed and if appropriate provided with NRT at their first appointment by the smoking cessation advisor.
- Client's already in the service will move onto direct supply at the next scheduled appointment following 1/6/17, subject to their advisor having read, understood and competent with the NRT protocol.
- Until informed otherwise GPs are requested to continuing to prescribe NRT products to patients at request of Quit 51 contracted services until arrangements are in place for direct supply.
- The provision of prescription only medicine i.e. Varenicline (Champix) and Bupropion (Zyban) remains the responsibility of primary care.

NICE Update

NICE Technology Appraisal	Guidance	PACEF recommendation
NICE TA 440. Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine (26th April 2017)	Pegylated liposomal irinotecan, in combination with 5-fluorouracil and leucovorin, is not recommended, within its marketing authorisation, for treating metastatic adenocarcinoma of the pancreas in adults whose disease has progressed after gemcitabine-based therapy.	Designated RED/RED and not approved for use through the Lincolnshire Joint Formulary for this indication.
NICE TA 441. Daclizumab for treating relapsing–remitting multiple sclerosis. (26th April 2017)	Daclizumab is recommended as an option for treating multiple sclerosis in adults, only if: •the person has active relapsing–remitting multiple sclerosis previously treated with disease-modifying therapy, or rapidly evolving severe relapsing–remitting multiple sclerosis (that is, at least 2 relapses in the previous year and at least 1 gadolinium-enhancing lesion at baseline MRI) and •alemtuzumab is contraindicated or otherwise unsuitable and •the company provides the drug with the discount agreed in the patient access scheme	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.

NICE TA 442 Ixekizumab for treating moderate to severe plaque psoriasis. (26th April 2017)	Ixekizumab is recommended as an option for treating plaque psoriasis in adults, only if: •the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 •the disease has not responded to standard systemic therapies, for example, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or these treatments are contraindicated or the person cannot tolerate them, and •the company provides the drug with the discount agreed in the patient access scheme.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication
NICE TA 443 Obeticholic acid for treating primary biliary cholangitis (26th April 2017)	Obeticholic acid is recommended, within its marketing authorisation, as an option for treating primary biliary cholangitis in combination with ursodeoxycholic acid for people whose disease has responded inadequately to ursodeoxycholic acid or as monotherapy for people who cannot tolerate ursodeoxycholic acid. Obeticholic acid is recommended only if the company provides it with the discount agreed in the patient access scheme. Assess the response to obeticholic acid after 12 months. Only continue if there is evidence of clinical benefit.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.

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Medicines Management & Optimisation Service
Optum Commissioning Support Unit
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T 020 7121 0560 I E info@optum.co.uk I **optum.co.uk**
10th Floor, 5 Merchant Square, Paddington, London, W2 1AS