Lincolnshire Prescribing and Clinical Effectiveness Bulletin – Vol 13 No 9

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Optum in association with Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services, United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

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DRUG ASSESSMENT SUMMARY

Product	Summary	Decision
Semglee® insulin (insulin glargine biosimilar)	**Introduction:** Semglee® is a new biosimilar insulin glargine which has identical licensed indications as the originator product (Lantus®). The prefilled pen delivery device is similar in design to that of Lantus the SoloSTAR® device. Semglee® NHS reference price is 20% lower than that for the reference product Lantus® - Insulin Glargine. It is the second biosimilar insulin glargine. Abasaglar®, the first biosimilar is approved for use on the Lincolnshire formulary classed as GREEN. **Further relevant information:** Semglee® has demonstrated that it is non-inferior to insulin glargine Lantus® in patients with type 1 and type 2 - diabetes. Semglee® should be used as first line in new patients, and those with suboptimal control on their existing insulin, when insulin glargine therapy is indicated.	Approved for inclusion on the formulary as GREEN.
Glycopyrronium bromide 200mcg/ml oral solution (Colonis brand)	**Introduction:** This is an oral liquid formulation of glycopyrronium bromide licensed for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. This is the second licensed glycopyrronium solution. PACEF has previously approved Sialanar® which contains 400mcg/ml of glycopyrronium bromide which is equivalent to 320mcg/ml of glycopyrronium. **Further relevant information:** The two licensed products contain different strengths of glycopyrronium bromide, with the Sialnar® brand (the current formulary product) twice the strength of the Colonis brand. The listed strength of the Sialnar® brand is also expressed in terms of the base glycopyrronium. PACEF considered the implications of having both products on the formulary and were concerned about the potential for confusion. The advantages of continuing with the existing strength preparation are: • Familiarity with prescribing and follow on prescribing by the GP. • No need to review all existing patients with a view to changing to a new preparation • No need for re-education of prescribers, suppliers and carers. PACEF agreed to endorse the use of the Sialnar® brand and not to approve the Colonis brand for inclusion onto the formulary.	Not approved for inclusion on the formulary. Classed as RED/RED.

Product	Summary	Decision
Hydventia® tablets (hydrocortisone)	**Introduction:** Recent changes have been made to the Drug Tariff reimbursement price for hydrocortisone tablets. The Drug Tariff (DT) price of generic hydrocortisone 20mg (£6.72) is now significantly less than for the brand, Hydventia® (£20.94) per 30 tablets. On the other hand, the DT price of generic hydrocortisone 10mg (£18.82) is higher than the brand, Hydventia® (£10.47) per 30 tablets. **Further relevant information:** PACEF was asked to consider the following: **Option1:** Prescribe all hydrocortisone generically. This will produce significant savings in terms of use of 20mg strength. But increase cost in terms of use of 10mg strength. **Option2:** Prescribing generic hydrocortisone 20mg for hydrocortisone 20mg strength and prescribing Hydventia® 10mg tablets for hydrocortisone 10mg strength; PACEF will need to consider if the prescribers can follow this advice accurately, or whether it would cause confusion and be difficult to implement. PACEF agreed for consistency to continue to endorse current formulary advice to prescribe hydrocortisone tablets generically.	Prescribe hydrocortisone tablets generically. Hydventia® brand are listed as RED/RED (non-formulary).
Testavan® (testoterone 20mg/g transdermal gel)	**Introduction:** Request received from endocrinologists at United Lincolnshire Hospital Trust (ULHT) to consider Testavan® for inclusion onto the formulary. Testavan® is testosterone gel 20mg/gram which is available in a pump with an applicator so the gel can be directly administered to the patient's skin. Each dose (pump actuation) is 23mg of testosterone. The licensed dose is one to three pump actuations, which can be titrated according to serum testosterone levels. **Further relevant information:** The formulation has the advantage of a "hands free" method of administration which reduces the risk of secondary transfer of testosterone. Comparing time after application of gel until time manufacturer advised the patient can shower, Testavan® has one of the shortest intervals 2 hours compared to a recommended 6 hours for Testogel® (which is currently the formulary approved item). Information provided by the manufacturers suggest that based on dosages used from clinical trials and the amount of product "wasted" during priming of the device that Testavan® is the most cost effective product. There have also recently been a number of supply problems with testosterone containing products which has also affected the current formulary recommended product – Testogel®. PACEF approved Testavan® to be added to the formulary to increase range of testosterone products that are available.	Approved for inclusion on the formulary as AMBER2.

Product	Summary	Decision
Optive Fusion® eye drops	**Introduction:** Optive Fusion® eye drops is a combination preparation of sodium hyaluronate 0.1%, carboxymethylcellulose 0.5% and glycerine formulated in a preserved ophthalmic solution stable for 3 months after opening. The combination product offers a cost advantage compared to the use of single components - Hylo-tears 0.1% (multidose) plus carmellose 0.5% (single use eye drops). **Further relevant information:** PACEF approved the use of Optive fusion only for when use of a combination of sodium hyaluronate 0.1%, carboxymethylcellulose 0.5% is clinically indicated. The combination product is not intended to replace monotherapy with either of the individual components. Prescribers are reminded that NHSE advice on products which can be purchased over the counter states; that most cases of sore tired eyes resolve and patients with this condition and mild-moderate dry eye syndrome should be encouraged to manage the condition with good eyelid hygiene, avoiding environmental causes alongside treating the issue e.g. with suitable lubricant products. A variety of ophthalmic products can be purchased from pharmacies and other retail outlets for dry/sore tired eyes. Prescribing of lubricating eye products should be reserved for those with a long term chronic condition e.g. moderate to severe dry eyes. (PACE Bulletin Vol 12 No 8)	Approved for inclusion on the formulary as GREEN. Restricted for use when a combination of sodium hyaluronate 1% and carboxy-methylcellulose 0.5% is required.
Menthoderm Cream® (Menthol in Aqueous cream 0.5%, 1%, 2%)	**Introduction:** Menthoderm® has been requested by ULHT dermatologists to replace Dermacool® on the formulary. Menthoderm® is more cost effective than Dermacool® based on acquisition cost, and cost savings are anticipated through consultant-led prescribing in primary care. Dermacool® will be classed as RED/RED (non-formulary) for new patients.	Approved for inclusion on the formulary as GREEN (to replace Dermacool®).
Betesil® medicated plasters	**Introduction:** Betesil® 2.25g medicated 7.5 x 10cm topical plaster impregnated with betamethasone valerate, classified as a potent corticosteroid. It is licensed for the treatment of inflammatory skin disorders which do not respond to less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. It is particularly indicated for application to difficult to treat areas such as knees and elbows etc. ULHT dermatologists have requested that Betesil® replaces the current formulary product fludroxycortide Tape 4micrograms per cm^2 (Haelan tape). Fludroxycortide Tape 4micrograms per cm^2 (Haelan tape) will be classed as RED/RED (non-formulary) for new patients.	Approved for inclusion on the formulary as AMBER 2 (to replace fludroxycortide)

Product	Summary	Decision
Paliperidone M/R tablets (Invega®)	**Introduction:** Lincolnshire Partnership Foundation Trust (LPFT) have requested a review of the formulary status of paliperidone M/R tablets. These were previously classed as RED/RED (non-formulary). Paliperidone tablets are licensed for the treatment of schizophrenia in adults and adolescents 15 years and older and for the treatment of schizoaffective disorders. Safety profile and pharmacokinetics of paliperidone are similar to risperidone. It is recommended that it is initiated by secondary mental health services and then is able to be handed back to the GP once the patient is on a maintenance dose and stable. The monitoring required would be that of risperidone which is currently prescribed in primary care. **Further relevant information:** LPFT clinicians are requesting that paliperidone tablets are added to the formulary as a treatment options for a small number of patients in whom alternative oral antipsychotics are not tolerated or are not clinically effective.	Approved for inclusion on the formulary as AMBER 2
DEKAs Essential 60 capsules **DEKAs Plus 60 chewables** **DEKAs Plus 60 softgels** **DEKAs Plus 60ml liquid**	**Introduction:** Request received from Nottinghamshire University Hospitals, Cystic Fibrosis Team to include this product on the formulary for patients who have been seen and manged by that service. The ACBS has approved all four forms of DEKAs 'For the dietary management of patients with cystic fibrosis on the specific recommendation of a specialist in cystic fibrosis. **Further relevant information:** This new product offers a reduction in medication burden as some people with cystic fibrosis can take a combination of vitamins requiring 15 separate tablets which could be reduced to only two medications daily. DEKAs also offer the product in safe forms i.e. beta carotene over retinol. Retinol can be linked with vitamin A toxicity and also should be used with caution in pregnancy. DEKAs also utilise phytomendaione, which is the preferred form of vitamin K, as recommended in both UK and European guidelines. To follow guidelines of prescribing all people with cystic fibrosis would increase costs due to the expense of menadiol sodium phosphate, by being able to obtain an all in one form the costs are offset by the reduction in use of other vitamin A, D, E and K products.	Approved for inclusion on the formulary as AMBER 2

Product	Summary	Decision
Paravit CF® capsules and liquid	**Introduction:** Request received from Nottinghamshire University Hospitals, Cystic Fibrosis Team to include this product on the formulary for patients who have been seen and manged by that service. To be used in infants, children, adolescents and adults (over 16 years) with cystic fibrosis. This medication will be used to normalise and maintain fat soluble vitamins with the aim to also reduce treatment burden. **Further relevant information:** Paravit CF capsules are lactose, egg, peanut, nut free and suitable for Halal/Kosher diets. Paravit CF liquid is allergen free and suitable for vegetarian/Halal/Kosher diets. This new product offers a reduction in medication burden as some people with cystic fibrosis can take a combination of vitamins requiring 15 separate tablets which could be reduced to only two medications daily. Paravit CF capsules also utilise phytomendaione which is the preferred form of vitamin K, as recommended in both UK and European guidelines.	Approved for inclusion on the formulary as AMBER 2
Nadolol tablet	**Introduction:** Request received from Nottinghamshire based cardiology services to include nadolol on the formulary to be used in patients with congenital long QT syndrome on the specific request of a cardiologist. **Further relevant information:** Nadolol is a non-cardioselective long acting beta blocker that is recommended as an option to treat long QT syndrome. It has been shown in a small study, along with propranolol, to be superior to metoprolol at reducing the risk of breakthrough cardiac events. Similar studies are not available for other beta-blockers such as bisoprolol. Its long half-life prevents wide fluctuations in blood levels and means that it can be given once a day. However, other beta blockers also have half-lives that allow once daily dosing with small fluctuations in blood levels e.g. bisoprolol and propranolol MR. Nadolol is less lipid soluble than propranolol which reduces the incidence of nightmares and hallucinations.	Approved for inclusion on the formulary as AMBER 2

Product	Summary	Decision
Alkindi® (Hydrocortisone granules)	**Introduction:** Alkindi® is licensed for the replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old). Alkindi is the only dose appropriate preparation of hydrocortisone licensed for use in cortisol replacement therapy for children with adrenal insufficiency. It is available as granules in capsules for opening with the following strengths: 0.5mg. 1mg, 2mg and 5mg. Doses are calculated based on surface area and are given on waking, in the middle of the day and early evening. The granules must be given orally and should not be chewed. **Further relevant information:** The capsule shell must not be swallowed but carefully be opened as follows: - The capsule is held so that the printed strength is at the top, and tapped to ensure all the granules are in the lower half of the capsule. - The bottom of the capsule is gently squeezed. - The top of the capsule is twisted off. The granules are either poured directly onto the child's tongue, or the granules are poured onto a spoon and placed in the child's mouth. For children who are able to take soft food, the granules may be sprinkled onto a spoonful of cold or room temperature soft food (such as yoghurt or fruit puree) and given immediately. Whichever method is used, the capsule is tapped to ensure all the granules are removed. Immediately after administration a drink such as water, milk, breast-milk, or formula-milk should be given to help ensure all granules are swallowed. If the granules are sprinkled onto a spoonful of soft food this should be given immediately (within 5 minutes) and not stored for future use.	Approved for inclusion on the formulary as AMBER2

UPDATES

Antimicrobial Guidelines

Lead Consultant microbiologist from ULHT has confirmed that the NICE /PHE summary is intended to be used as resource for clinicians and can be adapted by NHS organisations taking into local formulary restrictions, treatment guidelines, care pathways and based on knowledge of local resistance and sensitivity patterns where known.

A Lincolnshire primary care antimicrobial guideline is updated periodically and the latest update will be available on PACEF website shortly.

Quick reference guide inhalers for COPD

A quick reference guide inhaler for COPD has been produced.

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