Arden and Greater East Midlands Commissioning Support Unit in association with Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services, United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

Lincolnshire Prescribing and Clinical Effectiveness Bulletin

Volume 10; Number 2 **January 2016**

What's new this month?

- **Following review, levonorgestrel 52mg T-shaped intrauterine system (*Mirena*) remains the first line levonorgestrel containing IUD of choice. Levonorgestrel 13.5mg T-shaped intrauterine system (*Jaydess*) is a smaller device with a 3 year replacement requirement that has been re-designated GREEN for second line use. Levonorgestrel 52mg T-shaped intrauterine system (*Levosert*) is not recommended for use at this stage; designation RED-RED (see page 4).**
- **Prescribers should ensure that oxycodone prolonged release formulations are only prescribed for patients with severe non-malignant pain requiring strong opioid analgesia in whom controlled release morphine sulphate is ineffective or poorly tolerated. New patients should not be initiated on oxycodone without having previously been tried or at least considered for controlled release morphine. To minimize the risk of confusion between immediate release and sustained release formulations, all oxycodone prescribing should be by brand name (see page 5).**
- **The preferred sustained and prolonged release oxycodone preparations are: *Abtard*, *Longtec* and *Reltebon*. All of these products are designated GREEN and approved for use through the *Lincolnshire Joint Formulary*. *Oxeltra* and *OxyContin* are premium price preparations and should not be prescribed; they are desisgnated RED-RED and are not available on the *Lincolnshire Joint Formulary*. Product switching is advocated wherever possible (see page 5).**
- **Insulin glargine 300iu/ml (*Toujeo*) is approved for use through the *Lincolnshire Joint Formulary*, designation AMBER. It should only be initiated on the advice of a diabetologist or GPSI and reserved for those experiencing an unacceptable frequency and/or severity of nocturnal hypoglycaemia or attempting to achieve better hypoglycaemia control during treatment with established insulins (see page 8).**
- **In most patients with COPD, salbutamol delivered through a dry powder inhaler or metered dose inhaler (plus spacer) is as effective as nebulised salbutamol, more convenient for the patient and available at a fraction of the cost. Prescribers are urged to review all patients on nebulised salbutamol with a view to replacing current therapy with either a salbutamol metered dose inhaler plus spacer or a dry powder inhaler where possible (see page 9).**
- **Updated shared care guidelines are published on the use of growth hormone in the management of growth failure in children and young people and the management of attention deficit hyperactivity disorder (ADHD) (see page 10).**
- **A small number of clinically important dose errors have been reported around the newly published and updated versions of the *BNF for Children 2015 -2016* and *BNF* 70. In addition, many readers have experienced difficulty finding the information they require as a result of significant changes to the format. Information is provided on the dosage errors and how to access dose correction documents from the bnf.org website. Advice and support on how to use the new BNF is available at http://www.bnf.org/using-your-new-bnf/ (see page 10).**

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SUMMARY OF PACEF DECISIONS: *DECEMBER 2015 UPDATE*

Drug	**Indication(s)**	**Traffic Light and *Joint Formulary* Status**
Daclatasvir 30mg and 60mg tablets (*Daklinza*) (Bristol-Myers Squibb Pharmaceuticals Ltd)	For use in combination with other medicines for the treatment of chronic hepatitis C virus infection in adults	RED Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Idelalisib 100mg and 150mg tablets (*Zydelig*) (Gilead Sciences Ltd)	For untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation or for chronic lymphocytic leukaemia in adults when the disease has been treated but has relapsed within 24 months.	RED Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Insulin glargine 300units/ml injection (*Toujeo*) (Sanofi)	Treatment of diabetes mellitus in adults.	AMBER without shared care Approved for inclusion in the *Lincolnshire Joint Formulary*. Should only be initiated on the advice of a diabetologist or a GP with a specialist interest in diabetes for those experiencing an unacceptable frequency and/or severity of nocturnal hypoglycaemia or attempting to achieve better hypoglycaemia control during treatment with established insulins.
Ledipasvir 90mg/ sofosbuvir 400mg tablets (*Harvoni*) (Gilead Sciences)	For the treatment of chronic hepatitis C (CHC) in adults	RED Approved for inclusion in the

		Lincolnshire Joint Formulary for this indication.
Levonorgestrel 13.5mg T-shaped intrauterine system (*Jaydess*) (Bayer)	Contraception	Changed from RED to GREEN. Second line for women requiring a shorter duration of contraception and/or a smaller device.
Levonorgestrel 52mg T-shaped intrauterine system (Levosert) (Actavis)	Contraception Idiopathic menorrhagia.	RED-RED Not approved for inclusion in the *Lincolnshire Joint Formulary.*
Levonorgestrel 52mg T-shaped intrauterine system (*Mirena*) (Bayer)	Contraception. Idiopathic menorrhagia. Protection from endometrial hyperplasia during oestrogen replacement therapy.	GREEN – first line Available through the *Lincolnshire Joint Formulary.*
Ombitasvir 12.5mg/ paritaprevir 75mg/ ritonavir 50mg tablets (*Viekirax*) (AbbVie Ltd)	For use in combination with other medicines for the treatment of chronic hepatitis C in adults	RED Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Oxycodone sustained release tablets 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg (*Abtard*) (DB Ashbourne Ltd)	Severe pain that can only be adequately managed with opioid analgesics	GREEN Approved for use through the *Lincolnshire Joint Formulary*. Prescribe by brand.
Oxycodone sustained release tablets 5mg, 10mg, 15mg, 20mg, 40mg, 80mg and 120mg (*Longtec*) (Qdem Pharmaceuticals Ltd)	Moderate to severe cancer pain or post-op pain. Severe pain requiring a strong opioid.	GREEN Approved for use through the *Lincolnshire Joint Formulary*. Prescribe by brand.
Oxycodone sustained release tablets 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg (*Oxeltra*) (Wockhardt UK Ltd)	Moderate to severe cancer pain or post-op pain. Severe pain requiring a strong opioid.	RED-RED Not approved for use through the *Lincolnshire Joint Formulary*. Should not be prescribed.
Oxycodone sustained release tablets 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg and 120mg (*OxyContin*) (Napp Pharmaceuticals Ltd)	Moderate to severe cancer pain or post-op pain. Severe pain requiring a strong opioid.	RED-RED Not approved for use through the *Lincolnshire Joint Formulary*. Should not be prescribed.
Oxycodone sustained release tablets 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg (*Reltebon*) (Actavis UK Ltd)	Severe pain requiring an opioid analgesic.	GREEN Approved for use through the *Lincolnshire Joint Formulary*. Prescribe by brand.
Paclitaxel 100mg and 250mg infusion (*Abraxane*) (Celgene Ltd)	For use in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. For the treatment of non-small cell lung cancer (in combination with cisplatin) when surgery or radiotherapy is not appropriate	RED-RED Not approved for inclusion in the *Lincolnshire Joint Formulary.* RED-RED Not approved for inclusion in the *Lincolnshire Joint Formulary.*
Pembrolizumab 50mg powder for infusion (*Keytruda*) (Merck Sharp & Dohme Limited)	For the treatment of advanced (unresectable or metastatic) melanoma in adults.	RED Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Simprevir 150mg capsules (*Olysio*) (Janssen Cilag Ltd)	For use in combination with sofosbuvir for the urgent treatment of chronic hepatitis C infection of genotype 1 or 4 when peg interferon alfa cannot be used because of intolerance or contr-indications.	RED-RED Not approved for use through the *Lincolnshire Joint Formulary* for this indication.
Tolvaptan tablets 15mg, 30mg, 45mg and 60mg (*Jinarc*) (Otsuka)	To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease in adults with CKD stage 1 to 3 with evidence of rapidly progressing disease	RED Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication; it should be prescribed by brand to avoid confusion with an alternative tolvaptan formulation (*Samsca*) licensed for an alternative indication and not approved for use through the Formulary .

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. Back issues of the *PACE Bulletin* and other PACEF publications are available through the PACEF website (http://lincolnshire-

pacef.nhs.uk). Electronic copies of the *PACE Bulletin* are circulated to a wide readership via email. If you are not currently on our distribution list and wish to receive regular copies of PACEF publications please contact Sandra France on sandra.france@gemcsu.nhs.uk.

Google searching can be a quick and effective way of finding back numbers of the *PACE Bulletin* relevant to a specific topic of interest. Searchers are advised to use the official version of the *Bulletin* available from the PACEF website rather than depend on a potentially unreliable draft or variant found through Google or an alternative search engine.
The *Lincolnshire Joint Formulary* is available on line and is fully searchable; it can be accessed at www.lincolnshirejointformulary.nhs.uk

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: This signifies that a drug has been approved for use in primary care **subject to specialist initiation; a shared care guideline (SCG) may also be required**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities. Not all AMBER drugs that require SCGs are currently covered by formal documents; PACEF are working to rectify this.
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care.**

RAPID DRUG ASSESSMENT: *LEVONORGESTREL 52MG T-SHAPED INTRAUTERINE SYSTEM (LEVOSERT)*

Following review, levonorgestrel 52mg T-shaped intrauterine system (*Mirena*) remains the first line levonorgestrel containing IUD of choice. Levonorgestrel 13.5mg T-shaped intrauterine system (*Jaydess*) is a smaller lower dose device with a 3 year replacement requirement that has been re-designated GREEN for second line use. Levonorgestrel 52mg T-shaped intrauterine system (*Levosert*) is not recommended for use at this stage.

The *Levosert* 52mg T-shaped intrauterine system is the third levonorgestrel containing IUD to receive a UK marketing authorisation. It is authorised for use both as a contraceptive and as a treatment for heavy menstrual bleeding.

PACEF reviewed evidence from two clinical trials. The first of these was a multicentre, open-label partially randomised trial that provided evidence of effectiveness and safety in over 1600 women, both nulliparous and parous, over a 3 year period. This trial will continue to run and is expected to report again after 5 and 7 years. Subject to satisfactory results, this is likely to extend the life of the product beyond the current recommendation of 3 years.

A second one year randomised active comparator trial demonstrated that *Levosert* was as effective as *Mirena* in the treatment of heavy menstrual bleeding; both IUDs had similar safety profiles and were well tolerated.

A cost comparison reveals the following:

Product	Releasing	Indications	Replace after	Cost per pack	Cost per year
Levonorgestrel 52mg T-shaped intrauterine system (*Levosert*) (Actavis)	20 microgram in 24 hours	Contraception. Idiopathic menorrhagia.	3 years	£66.00	£22.00 per year
Levonorgestrel 52mg T-shaped intrauterine system (*Mirena*) (Bayer)	20 microgram in 24 hours	Contraception. Idiopathic menorrhagia. Protection from	5 years	£88.00	£17.60 per year

		endometrial hyperplasia during oestrogen replacement therapy.			
Levonorgestrel 13.5mg T-shaped intrauterine system (*Jaydess*) (Bayer)	6 microgram in 24 hours	Contraception	3 years	£69.22	£23.07 per year.

Despite the fact that *Levosert* is the lowest cost per pack, the longer replacement life of *Mirena* means that the *Mirena* IUS still emerges as the most cost-effective product. This may change in the future as the ongoing clinical trial involving *Levosert* is extended beyond 3 years to 5 and then 7 years, potentially extending the replacement life of the product.

The Faculty of Sexual and Reproductive Healthcare assessment of *Levosert* could see no additional benefits of using the product compared to the *Mirena* IUD at this stage.

Jaydess was recently evaluated by PACEF and approved for inclusion on the *Lincolnshire Joint Formulary* designation RED for use by specialist sexual health services only. The product was approved to offer the option of a smaller IUD compared to *Mirena* and also as an option for women requiring a shorter period of levonorgestrel therapy. It can be seen from the table that *Levosert* has a wider range of licensed indications than *Jaydess*.

PACEF Recommendations:

Levonorgestrel 52mg T-shaped intrauterine system (*Mirena*) still emerges from this evaluation as the first line product of choice on the grounds of effectiveness, safety, cost-effectiveness and range of authorised indications. It is designated GREEN and available through the *Lincolnshire Joint Formulary*. At the request of Sexual Health Services, PACEF have reconsidered primary care access to levonorgestrel 13.5mg T-shaped intrauterine system (*Jaydess*) and have changed the designation of the product from RED to GREEN. *Jaydess* is recommended as a second line option for women requiring a shorter duration of contraception and/or a smaller device or lower dose. In the absence of data beyond 3 years and with a relatively high cost per year, levonorgestrel 52mg T-shaped intrauterine system (*Levosert*) is designated RED-RED and not approved for inclusion in the *Lincolnshire Joint Formulary* at this stage, pending the publication of further trial data on longer-term use.

RAPID DRUG ASSESSMENT: *OXYCODONE SUSTAINED RELEASE (ABTARD AND OXELTRA)*

Whenever prolonged or sustained release oxycodone tablets are indicated a lower cost brand should be specified on the prescription. Preferred options are *Abtard*, *Longtec* and *Reltebon*.

Following the launch of two new oxycodone sustained release formulations, an updated cost comparison of the available brands reveals that the lowest cost sustained release products currently available are: *Abtard*, *Longtec* and *Reltebon* (highlighted in bold in the table below).

Sustained and prolonged release oxycodone preparations (Abtard, Longtec, Oxeltra, Reltebon, OxyContin)

Drug	Dose	Cost
Oxycodone sustained release tablets 5mg (*Abtard*) (DB Ashbourne Ltd)	**5mg every 12 hours**	**£12.52 (2x28)**
Oxycodone sustained release tablets 10mg (*Abtard*)	**10mg every 12 hours**	**£12.52**
Oxycodone sustained release tablets 15mg (*Abtard*)	**15mg every 12 hours**	**£19.06**
Oxycodone sustained release tablets 20mg (*Abtard*)	**20mg every 12 hours**	**£25.04**
Oxycodone sustained release tablets 30mg (*Abtard*)	**30mg every 12 hours**	**£38.11**
Oxycodone sustained release tablets 40mg (*Abtard*)	**40mg every 12 hours**	**£50.09**
Oxycodone sustained release tablets 60mg (*Abtard*)	**60mg every 12 hours**	**£76.24**
Oxycodone sustained release tablets 80mg (*Abtard*)	**80mg every 12 hours**	**£100.19**
Oxycodone prolonged release tablets 5mg (*Longtec*) (Qdem)	**5mg every 12 hours**	**£17.74 (2x28's)**
Oxycodone prolonged release tablets 10mg (*Longtec*)	**10mg every 12 hours**	**£17.50**
Oxycodone prolonged release tablets 15mg (*Longtec*)	**15mg every 12 hours**	**£26.25**
Oxycodone prolonged release tablets 20mg (*Longtec*)	**20mg every 12 hours**	**£35.00**
Oxycodone prolonged release tablets 40mg (*Longtec*)	**40mg every 12 hours**	**£70.00**
Oxycodone prolonged release tablets 80mg (*Longtec*)	**80mg every 12 hours**	**£140.00**
Oxycodone prolonged release tablets 120mg (*Longtec*)	**120mg every 12 hours**	**£210.00**
Oxycodone sustained release tablets 5mg (*Oxeltra*) (WockhardtUK Ltd)	5mg every 12 hours	£27.18
Oxycodone sustained release tablets 10mg (*Oxeltra*)	10mg every 12 hours	£27.19
Oxycodone sustained release tablets 15mg (*Oxeltra*)	15mg every 12 hours	£41.39
Oxycodone sustained release tablets 20mg (*Oxeltra*)	20mg every 12 hours	£54.37
Oxycodone sustained release tablets 30mg (*Oxeltra*)	30mg every 12 hours	£82.76
Oxycodone sustained release tablets 40mg (*Oxeltra*)	40mg every 12 hours	£108.78
Oxycodone sustained release tablets 60mg (*Oxeltra*)	60mg every 12 hours	£165.56
Oxycodone sustained release tablets 80mg (*Oxeltra*)	80mg every 12 hours	£217.57
Oxycodone sustained release tablets 5mg (*Reltebon*) (Actavis)	**5mg every 12 hours**	**£15.02 (2x28)**
Oxycodone sustained release tablets 10mg (*Reltebon*)	**10mg every 12 hours**	**£15.02**
Oxycodone sustained release tablets 15mg (*Reltebon*)	**15mg every 12 hours**	**£22.87**
Oxycodone sustained release tablets 20mg (*Reltebon*)	**20mg every 12 hours**	**£30.05**
Oxycodone sustained release tablets 40mg (*Reltebon*)	**40mg every 12 hours**	**£60.11**
Oxycodone sustained release tablets 60mg (*Reltebon*)	**40mg every 12 hours**	**£91.49**
Oxycodone sustained release tablets 80mg (*Reltebon*)	**80mg every 12 hours**	**£120.23**
Oxycodone prolonged release tablets 5mg (*OxyContin*) (Napp)	5mg every 12 hours	£25.04

Oxycodone prolonged release tablets 10mg (*OxyContin*)	10mg every 12 hours	£25.04
Oxycodone prolonged release tablets 15mg (*OxyContin*)	15mg every 12 hours	£38.12
Oxycodone prolonged release tablets 20mg (*OxyContin*)	20mg every 12 hours	£50.08
Oxycodone prolonged release tablets 30mg (*OxyContin*)	30mg every 12 hours	£76.23
Oxycodone prolonged release tablets 40mg (*OxyContin*)	40mg every 12 hours	£100.19
Oxycodone prolonged release tablets 60mg (*OxyContin*)	60mg every 12 hours	£152.49
Oxycodone prolonged release tablets 80mg (*OxyContin*)	80mg every 12 hours	£200.39
Oxycodone prolonged release tablets 120mg (*OxyContin*)	120mg every 12 hours	£305.02

PACEF Recommendation:
Prescribers should ensure that oxycodone prolonged release formulations are only prescribed for patients with severe non-malignant pain requiring strong opioid analgesia in whom controlled release morphine sulphate is ineffective or poorly tolerated. New patients should not be initiated on oxycodone without having previously been tried or at least considered for controlled release morphine. To minimize the risk of confusion between immediate release and sustained release formulations, all oxycodone prescribed should be by brand name.
The preferred sustained and prolonged release oxycodone preparations are: *Abtard*, *Longtec* and *Reltebon*. All of these products are designated GREEN and approved for use through the *Lincolnshire Joint Formulary*. *Oxeltra* and *OxyContin* are premium price preparations and should not be prescribed; they are designated RED-RED and are not available of the *Lincolnshire Joint Formulary*. Product switching is advocated wherever possible. All of the *OxyContin* strengths are now available as lower cost equivalents. Prescribers may wish to standardize prescribing around brands that signify to some extent through their product name the sustained release characteristics of the formulation (i.e. *Abtard* or *Longtec*).

NEW PRODUCT ASSESSMENT: *INSULIN GLARGINE 300IU/ML (TOUJEO)* (AMENDED VERSION)

Insulin glargine 300iu/ml (*Toujeo*) is approved for use through the *Lincolnshire Joint Formulary*, designation AMBER. It should only be initiated on the advice of a diabetologist or GPSI and reserved for those experiencing an unacceptable frequency and/or severity of nocturnal hypoglycaemia or attempting to achieve better hypoglycaemia control during treatment with established insulins.

Insulin glargine 300iu/ml (*Toujeo*) is a new higher strength insulin glargine formulation available in a pre-filled pen with a maximum dial dose of 80iu. It is claimed to form a more compact subcutaneous depot on administration which allows for more prolonged release over a 24 hour period. PACEF reviewed a series of four clinical trials known as the EDITION studies. The primary outcome of the trials confirmed that insulin glargine 300iu/ml is non-inferior in terms of efficacy to the established 100iu/ml preparation. Secondary outcome data suggests that the 300iu/ml preparation may be superior to 100iu/ml in terms of reduced rates of nocturnal hypoglycaemia due to a slower more prolonged release, although the EDITION studies were not powered to prove this. The Scottish Medicines Consortium have recently approved insulin glargine 300iu/ml (*Toujeo*) for use in NHS Scotland 'for those at risk of experiencing unacceptable frequency and/or severity of nocturnal hypoglycaemia or attempting to achieve better hypoglycaemia control during treatment with established insulins'. A NICE Evidence Summary of New Medicines review states that *Toujeo* offers no

benefit over *Lantus* in terms of reduced hypoglycaemic events on the basis that the EDITION studies do not demonstrate statistical significance around the secondary outcome.

PACEF Recommendation:
Insulin glargine 300iu/ml (*Toujeo*) is designated AMBER without shared care and should only be initiated on the advice of a diabetologist or a GP with a specialist interest in diabetes. It is approved for inclusion in the *Lincolnshire Joint Formulary* for those experiencing an unacceptable frequency and/or severity of nocturnal hypoglycaemia or attempting to achieve better hypoglycaemia control during treatment with established insulins. For updated NICE guidance on the prescribing of insulin analogues in type 2 diabetes mellitus see below.

TRENT MEDICINES INFORMATION, QIPP DETAIL AID: *SALBUTAMOL – DOES IT REALLY NEED TO BE NEBULISED?*

In most patients with COPD, salbutamol delivered through a dry powder inhaler or metered dose inhaler (plus spacer) is as effective as nebulised salbutamol, more convenient for the patient and available at a fraction of the cost.

Salbutamol given by nebuliser is sometimes used long-term in patients with more severe forms of Chronic Obstructive Pulmonary Disease (COPD). There is little objective evidence to support this. Nebulisation delivers only a small fraction of the administered dose of salbutamol (around 10%) to the airways. NICE guidance on the treatment of COPD advises that, in most cases, bronchodilator therapy is best delivered by a hand held inhaler. Where a metered dose inhaler is prescribed, a spacer can help to maximize the dose delivered and remove the need for coordination of actuation with inhalation.

NICE also recommend that patients with COPD should not continue on nebulised treatment unless, after assessment, it is confirmed that nebulised salbutamol:

- reduces symptoms and/or
- increases ability to undertake activities of daily living and/or
- increased exercise activity and/or
- improves lung function.

Nebulisers and associated equipment also need regular cleaning and servicing. The mask, nebuliser and tubing should be washed at least daily and need replacing at intervals. The compressor used to drive the nebuliser should be serviced annually.

A cost comparison of nebulised salbutamol with salbutamol MDI plus spacer and salbutamol dry powder inhaler reveals that nebulised salbutamol costs 5 to 10 times more even without taking into account the associated costs for compressor, nebuliser chamber, mask and tubing. The annual prescribing costs of salbutamol nebuliser solution in Lincolnshire are as follows:

	Annual Cost of Nebulised Salbutamol
Lincolnshire East CCG	£20,245
Lincolnshire West CCG	£20,450
South Lincolnshire CCG	£8,343
South West Lincolnshire CCG	£8,446
Lincolnshire	£57,484

PACEF Recommendation:
All patients currently prescribed nebulised salbutamol should be reviewed with a view to replacing current therapy with salbutamol delivered through a hand held inhaler wherever possible. If a metered dose inhaler is preferred, a spacer should also be provided.

Reference: Trent Medicines Information Services, QIPP Detail Aid, *Salbutamol – Does it really need to be nebulised?* (November 2015)

SHARED CARE GUIDELINES: *GROWTH HORMONE IN THE MANAGEMENT OF GROWTH FAILURE IN CHILDREN AND YOUNG PEOPLE AND THE MANAGEMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER*

PACEF have approved the following shared care guidelines for use:

- Nottinghamshire Area Prescribing Committee, *Management of Growth Failure in Children and Young People with Growth Hormone (Somatropin)*
- Lincolnshire Shared Care Guideline, *Methylphenidate, atomoxetine, dexamfetamine and lisdexamfetamine in the management of Attention Deficit Hyperactivity Disorder*

Further information is available from Cathy Johnson, Interface lead Pharmacist (cathy.johnson@ardengemcsu.nhs.uk)

Copies of the SCGs are available through the PACEF website:

http://lincolnshire-pacef.nhs.uk

CLARITY AROUND THE NEW EDITIONS OF THE *BRITISH NATIONAL FORMULARY* PUBLICATIONS

A small number of clinically important dose errors have been reported around the newly published and updated versions of the *BNF for Children 2015 -2016* and *BNF* 70. In addition, many readers have experienced difficulties finding the information they require as a result of the significant changes to the format.

Three documents have been posted on bnf.org detailing the corrections to the two publications and a summary document of all of the issues raised with the *BNF* team to date. Clinicians are urged to print off the dose correction documents from the bnf.org website and insert/attach them to their print copy.

Entries effected in *BNF* 70 relate to the following medicines: aciclovir, clindamycin, erythromycin, pyrimethamine, ceftriaxone and vecuronium bromide.

Entries effected in *BNF for Children 2015 -2016* relate to the following medicines: aciclovir, co-amoxiclav 400/57 suspension, erythromycin, magnesium glycerophosphate, pyrimethamine, tranexamic acid, paraldehyde, ceftriaxone and vecuronium bromide.

Readers confused by the new format are advised to consult the FAQ document available at http://www.bnf.org/using-your-new-bnf/

NICE UPDATE

NICE Technology Appraisal	Guidance	PACEF Recommendation
TA 358 *Tolvaptan for treating autosomal dominant polycystic kidney disease* (October 2015)	Tolvaptan is recommended as an option for treating autosomal dominant polycystic kidney disease in adults to slow the progression of cyst development and renal insufficiency only if: (1) they have chronic kidney disease stage 2 or 3 at the start of treatment (2) there is evidence of rapidly progressing disease.	**Tolvaptan tablets 15mg, 30mg, 45mg and 60mg (*Jinarc*) are classified RED for the treatment of autosomal dominant polycystic kidney disease. *Jinarc* is approved for inclusion in the *Lincolnshire Joint Formulary* for this indication; it should be prescribed by brand to avoid confusion with an alternative tolvaptan formulation (*Samsca*) licensed for an alternative indication.**
TA 359, *Idelalisib for treating chronic lymphocytic leukaemia* (October 2015)	Idelalisib, in combination with rituximab, is recommended: for untreated chronic lymphocytic leukaemia in adults with a 17p deletion or TP53 mutation or for chronic lymphocytic leukaemia in adults when the disease has been treated but has relapsed within 24 months.	**Idelalisib 100mg and 150mg tablets (*Zydelig*) are classified as RED and approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.**
TA 360, *Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer* (October 2015)	Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine is not recommended within its marketing authorisation for adults with previously untreated metastatic adenocarcinoma of the pancreas.	**Paclitaxel (*Abraxan*) is designated RED-RED for this indication and not recommended for inclusion in the *Lincolnshire Joint Formulary.***
TA 361, *Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C* (terminated appraisal) (October 2015)	NICE is unable to make a recommendation because no evidence submission was received from the manufacturer	**Simprevir 150mg capsules (*Olysio*) are designated RED-RED and are not approved for use through the *Lincolnshire Joint Formulary* for this indication.**
TA 362, *Paclitaxel as albumin-bound nanoparticles with carboplatin for untreated non-small-cell lung cancer (terminated appraisal)* (October 2015)	NICE is unable to make a recommendation because no evidence submission was received from the manufacturer	**Paclitaxel infusion (*Abraxan*) is designated RED-RED for this indication and not recommended for inclusion in the *Lincolnshire Joint Formulary.***
TA 363 *Ledipasvir–sofosbuvir for treating chronic hepatitis C* (November 2015)	Ledipasvir–sofosbuvir is recommended as an option for treating chronic hepatitis C in adults.	**Ledipasvir 90mg/ sofosbuvir 400mg tablets (*Harvoni*) are designated RED and approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.**
TA 364 *Daclatasvir for treating chronic hepatitis C* (November 2015)	Daclatasvir is recommended as an option for treating chronic hepatitis C in adults	**Daclatasvir 30mg and 60mg tablets (*Daklinza*) are designated RED and**

		approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
TA 365 *Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C* (November 2015)	Ombitasvir – paritaprevir – ritonavir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults,	**Ombitasvir 12.5mg/ paritaprevir 75mg/ ritonavir 50mg tablets (*Viekirax*) are designated RED and approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.**
TA 366 *Pembrolizumab for advanced melanoma not previously treated with ipilimumab* (November 2015)	Pembrolizumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma that has not been previously treated with ipilimumab, in adults,	**Pembrolizumab 50mg powder for infusion (*Keytruda*) is designated RED and approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.**

Acknowledgements

Many thanks to: Cathy Johnson, Interface Lead Pharmacist, Arden GEM Commissioning Support Unit for her help with the preparation of this *Bulletin.*

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