Lincolnshire Prescribing and Clinical Effectiveness Bulletin

Volume 11 No 11, August 2017

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

Summary of PACEF decisions from June 2017

PACE Short (Vol 11 No 11)

Device, Dressing or Drug	**Indication(s)**	**Traffic Light and *Joint Formulary* Status**
Ulipristal acetate 5mg tablets (Esyma)	For intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age	Amber 2 To be initiated by GP following initial assessment by a specialist in line with locally agreed treatment pathway.
Sereflo - Salmeterol (as xinafoate) 25 microgram with fluticasone propionate 125 or 250 microgram, metered dose inhaler (Fannin Ltd).	It is licensed for the treatment of adult patients with asthma not adequately controlled on an ICS and as needed SABA or patients already adequately controlled on both an ICS and a LABA.	GREEN Approved as low cost alternative to Seretide Evohaler.
Aerivio Spiromax, 50 microgram/500 microgram inhalation powder. Each metered dose contains 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms of fluticasone propionate. (Teva Pharma B.V.)	licensed for both the treatment of severe asthma and COPD when use of a high strength LABA and ICS combination is indicated	GREEN Approved as a low cost alternative to Seretide Accuhaler
Paliperidone Palmitate 3 monthly Injection TREVICTA 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection	a 3-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product	RED Lincolnshire partnership trust approved drug to be used as an option in patient stabilised on 1monthly paliperidone injection

Other news

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

Reports of depression and, in rare cases, suicidal thoughts in men taking finasteride 1 mg (Propecia) for male pattern hair loss.

Table of contents

Guidelines approved to support the use of Ulipristal acetate (Esmya) for the intermittent treatment of women with symptomatic uterine fibroids.

Ulipristal acetate (Esmya®) has now been approved for inclusion onto the Lincolnshire Joint Formulary for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Ulipristal acetate (Esmya®) had previously been approved for inclusion onto the formulary for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Ulipristal acetate is classed as AMBER 2 for both indications.

- NICE Heavy Menstrual Bleeding Guidelines (CG44) were updated in 2016 to include the following recommendations:

1.5.11 Offer ulipristal acetate 5 mg (up to 4 courses) to women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level of 102 g per litre or below.

1.5.12 Consider ulipristal acetate 5 mg (up to 4 courses) for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter, and a haemoglobin level above 102 g per litre.

- Ulipristal acetate should be administered as a 5 mg dose, orally once daily for up to 3 months with or without food.
- United Lincolnshire Hospital Trust (ULHT) have developed treatment guidelines to support the use of ulipristal acetate for the management of intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.
- Patients will be assessed by a hospital based specialist to ensure that patient is eligible for ulipristal acetate (NICE Heavy Menstrual Bleeding Guidelines CG44).
- Specialist will counsel the patient regarding administration, contraception, potential side effects and the need for treatment free intervals. The specialist will then provide the patient's GP with a copy of the treatment guidelines.
- The specialist service is also responsible for arranging follow up appointments with an ultrasound scan after the second course of treatment is completed (approximately 9-10 months after initial review).
- The first treatment course should start during the first week of menstruation.
- The treatment guidelines provide details of the follow-up required following the initial course and the future management of the patient.
- A copy of the guideline will be included on the Lincolnshire PACEF website. http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-pacef

Rapid Drug Assessment Sereflo - Salmeterol (as xinafoate) 25 microgram with fluticasone propionate 125 or 250 microgram, metered dose inhaler

A new low cost metered dose inhaler containing a fixed dose combination of salmeterol & fluticasone propionate licensed for the treatment of adult patients with asthma not adequately controlled on an ICS and as needed SABA or patients already adequately controlled on both an ICS and a LABA.

product	Strength	Cost (£) (doses in pack)
Sereflo	25/125 25/250	£23.50 (120) £39.95 (120)
Seretide Evohaler	25/125 25/250	£35.00 (120) £59.48 (120)
Sirdupla	25/125 25/250	£26.25 £44.61

- This licensed indication for Sereflo is comparable to that for Sirdupla which is currently the preferred first-line product when a salmeterol & fluticasone propionate combination inhaler is required.
- Sereflo MDI's currently costs £2.75 less per device compared to Sirdupla for the 25/125 strength and £4.66 less per device in the higher strength 25/250.
- It is not licensed for use in those aged less than 18 years of age. This is in line with the approach taken for all of the lower cost devices recently launched - all are licensed for adult use only.

- Whilst there has been significant switching to Sirdupla there are still significant savings to be realised in primary care from using lower cost salmeterol/fluticasone combinations
- Savings can only be realised if the inhalers are prescribed by brand.

  If the remaining MDIs prescribed generically are switched to Sereflo potential annual cost savings are:

CCG	Potential annual saving
LECCG	£41,059
LWCCG	£41,243
SLCCG	£32,259
SWLCCG	£32,369

- To avoid confusion and to maximise any potential savings all inhalers should be prescribed by brand.
- Sereflo is approved for inclusion onto the Lincolnshire joint Formulary as GREEN.
- Prescribing of MDI salmeterol/fluticasone combination inhalers should be reviewed and all prescriptions changed to branded prescribing.
- Contact your embedded pharmacist for advice on switching products.

Rapid Drug Assessment Aerivio Spiromax, 50 microgram/500 microgram inhalation powder. Each metered dose contains 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms of fluticasone propionate.

A new dry powder inhaler device launched as a lower cost alternative to the Seretide Accuhaler. This is a fixed dose combination of salmeterol & fluticasone propionate licensed for licensed for both the treatment of severe asthma and COPD when use of a high strength LABA and ICS combination is indicated.

product	Strength	Cost (£) (doses in pack)
Aerivio Spiromax	50/500	£29.97(60)
AirFluSal Forspiro	50/500	£32.74
Seretide Accuhaler	50/500	£40.92

- The licensed indications for Aerivio Spiromax are comparable to that for both AirFluSal Forspiro and Seretide Accuhaler.
- Aerivio Spiromax currently costs £2.77 less per device compared to AirFluSal Forspiro for 25/125 and £10.95 less per device compared to Seretide Accuhaler.

- Whilst there has been significant switching to Sirdupla there are still significant savings to be realised in primary care from using lower cost salmeterol/fluticasone combinations
- Savings can only be realised if the inhalers are prescribed by brand.
- Although on the formulary there has been little use of the AirFluSal Forspiro device although it is included in the QIPP actions for practices for 2017/18.

  If the remaining dry powder inhalers prescribed generically are switched to either AirFluSal Forspiro or Aerivio Spiromax potential annual cost savings are estimated to be :

CCG	Potential annual saving
LECCG	£96,097
LWCCG	£52,823
SLCCG	£35,084
SWLCCG	£24,220

- Aerivio Spiromax was approved for inclusion onto the Lincolnshire joint Formulary classed as GREEN on traffic light list.

Rapid Drug Assessment Paliperidone 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection (Trevicta)

This is a new 3-monthly injection of paliperidone palmitate licensed for the maintenance treatment of adults with schizophrenia who are clinically stable on 1-monthly paliperidone palmitate (Xeplion).

- The Lincolnshire Partnership Foundation Trust (LPFT) are advising this prolonged released product should only be used for patients who have been maintained and stable on 1-monthly paliperidone palmitate injections for 6 months.
- This is to allow clinicians to assess response and tolerability. The response should be assessed before switching as dose adjustments can only be made every 3 months, and the patient's response may not be apparent for several months.
- As it has a slow release profile, it is not proposed for acutely unwell patients or those transitioning from oral or other long acting antipsychotic injections. The advantage is its convenience in the frequency of injections.
- The one disadvantage is that it has a very long half-life once steady state is achieved, the paliperidone plasma levels can last for an average of 395 days from the last 3 monthly paliperidone palmitate injection. It is therefore essential to assess tolerability to reduce risk of adverse effects before switching to the 3-monthly paliperidone palmitate injections.
- Although the cost of the 3 month option is the same as 3 x the cost of the monthly injection, , the significant benefit is the reduction in outpatient appointments from twelve a year, to four.

- This will be a significant cost saving. LPFT have approved this product as a RED hospital only product. All prescribing of this drug should remain the responsibility of LPFT.

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

The MHRA have received reports of depression and, in rare cases, suicidal thoughts in men taking finasteride 1 mg (Propecia) for male pattern hair loss.
Finasteride is a 5α-reductase-type-2 inhibitor. In the 1 mg dose (Propecia), it is indicated for the treatment of male pattern hair loss (androgenetic alopecia). In the 5 mg dose (Proscar), it is indicated for the treatment and control of benign prostatic hyperplasia
Finasteride 1mg (Propecia) is classed as RED/RED and is a non-formulary drug
The MHRA has updated it advice to health care professionals:
Advice for healthcare professionals:

- Since finasteride has been marketed there have been a number of spontaneous adverse drug reaction reports suggesting a possible link to depression, and in rare cases, suicidal thoughts
- Advise patients to stop finasteride 1 mg (Propecia) immediately if they develop depression and inform a healthcare professional
- Be aware that the product information for finasteride 5 mg (Proscar) already lists depression as a possible adverse reaction

NICE Update

NICE Technology Appraisal	Guidance	PACEF recommendation
NICE TA 445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs(24th May)	1.1 Certolizumab pegol alone, or in combination with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults only if: •it is used as described in the NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or •the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has stopped responding after the first 12 weeks. Certolizumab pegol is only recommended if the company provides it as agreed in the patient access scheme. 1.2 Secukinumab alone, or in combination with methotrexate, is recommended as an	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.

	option for treating active psoriatic arthritis in adults only if: •it is used as described in the NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or •the person has had a TNF‑alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after 12 weeks or •TNF‑alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis). Secukinumab is only recommended if the company provides it as agreed in the patient access scheme.	

Produced by
Medicines Management & Optimisation Service
Optum Commissioning Support Unit
July 2017

T 020 7121 0560 l E info@optum.co.uk l **optum.co.uk**
10th Floor, 5 Merchant Square, Paddington, London, W2 1AS