

# Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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## What's new this month?

- The results of a PACEF review of pen needles for pre-filled and reusable pen injectors are published. *GlucoRx FinePoint*, *Microdot Droplet*, *MyLife Penfine Classic* and *Omnican Fine* are the preferred first line lower cost products and product switching is advocated. Alternative products are recommended where safety needles or click on needles are required. A potential Lincolnshire wide saving in excess of £270,000pa is estimated (see page 4).
- Due to a product recall affecting supply of the approved first line treatment for herpes simplex keratitis, aciclovir eye ointment 3% (*Zovirax*), PACEF have granted temporary *Formulary* approval for ganciclovir 0.15% eye gel (*Virgan*) as the preferred alternative. As a result of this, ganciclovir 0.15% eye gel (*Virgan*) is designated AMBER without shared care and included temporarily in the *Lincolnshire Joint Formulary*. Prescribers are reminded that all patients presenting with herpes simplex keratitis should be referred to an ophthalmologist as a matter of urgency (see page 6).
- *Systane* eye drops are already recommended as a second line option for those who have not responded sufficiently to hypromellose or alternative first line treatments for dry eye. *Systane Ultra* eye drops should only be used for those who have not responded sufficiently to the standard *Systane* product. Both products are already included on the *Lincolnshire Joint Formulary* and are designated GREEN. ULH ophthalmologists have requested that *Systane Balance* should be added to the *Formulary* for the treatment of those with dry eyes associated with meibomian gland deficiency and/ or blepharitis. Despite reservations concerning the poor quality of the evidence base and concerns around the significantly higher price, PACEF have approved *Systane Balance* eye drops for use only on the advice of an ophthalmologist. Designation: AMBER without shared care (see page 7).
- Levonorgestrel 13.5mg T shaped intrauterine delivery system (*Jaydess*) provides effective long-term contraception for up to three years after intrauterine insertion. However, the lack of comparative data against the established product, *Mirena*, in conjunction with the lack of long-term safety data makes it difficult to recommend the product in preference. In addition, *Mirena* is also licensed for a wider range of indications. Local specialist opinion suggests that *Jaydess* may have advantages over *Mirena* in some patients, particularly those with a smaller uterus and/or tighter cervix and those considering conception within three years of insertion. As a result of this, levonorgestrel 13.5mg T shaped intrauterine delivery system (*Jaydess*) is designated RED; for insertion by specialist Sexual Health Services only. *Jaydess* is approved for inclusion in the *Lincolnshire Joint Formulary* within this context (see page 9).
- The launch of new lower cost branded sustained release formulations of galantamine offers the opportunity for CCGs to realise significant savings in the coming months. All sustained release galantamine should be prescribed as a lower cost brand such as *Galantex XL* or *Gatalin XL*. The potential saving across Lincolnshire from this singleaction is over £187,000pa. Both products are designated AMBER with shared care and are approved for inclusion in the *Lincolnshire Joint Formulary* (see page 10).
- GP responsibilities in relation to shared care or alternative prescribing arrangements around NHSE commissioned Gender Identity Clinics are defined (see page 11).

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### **FORMULARY OF PEN NEEDLES FOR PRE-FILLED AND REUSABLE PEN INJECTORS**

Pen Needle	Indication(s)	Traffic Light and Joint Formulary Status
<i>BD Autosield Duo</i> (Becton Dickinson)	Screw on safety needle for insulin pens	GREEN Should only be prescribed when healthcare workers are administering insulin or if the patient is self-administering and 'needle phobic'. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> within these criteria.
<i>GlucRx FinePoint</i> (GlucRx)	Screw on needle for insulin pens	GREEN Lower cost preferred product. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .
<i>Microdot Droplet</i> (Cambridge Sensors)	Screw on needle for insulin pens	GREEN Lower cost preferred product. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .
<i>MyLife ClickFine</i> (Ypsomed)	Snap on needle for insulin pens	GREEN Snap onto the pen with an audible click and may have advantages for people with limited vision or restricted manual dexterity. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> within these criteria.
<i>MyLife ClickFine AutoProtect</i> (Ypsomed)	Snap on safety needle for insulin pens	GREEN Should only be prescribed when healthcare workers are administering insulin or if the patient is self-administering and needle phobic. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> within these criteria.
<i>MyLife Penfine Classic</i> (Ypsomed)	Screw on needle for pre-filled and reusable insulin pens	GREEN Lower cost preferred product. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .
<i>NovoFine Autocover</i> (Novo Nordisk)	Disposable safety needle for insulin pens	GREEN Should only be prescribed when healthcare workers are administering insulin or if the patient is self-administering and needle phobic. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> within these criteria.
<i>Omnican Fine</i> (Bbraun)	Screw on needles for insulin pens	GREEN Lower cost preferred product. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .

## SUMMARY OF PACEF DECISIONS: OCTOBER 2014 UPDATE

Drug	Indication(s)	Traffic Light and Joint Formulary Status
Calcium acetate capsules 667 mg (equivalent to 169 mg calcium in each capsule) ( <i>PhosLo</i> ) (Stanningley)	For the prevention and treatment of hyperphosphataemia in dialysis.	AMBER without shared care. Second line for patients experiencing difficulties swallowing <i>Phosex</i> tablets. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication.
Calcium acetate tablets 986.4mg (equivalent to calcium 250mg) ( <i>Phosex</i> ) (Pharmacosmos)	Hyperphosphataemia in dialysis	AMBER without shared care. First line. Included in the <i>Lincolnshire Joint Formulary</i> for this indication.
Dimethyl fumarate 120mg and 240mg capsules ( <i>Tecfidera</i> )	For the treatment of adult patients with relapsing remitting multiple sclerosis.	RED For use by specialist MS services only. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication.
Galantamine sustained release capsules ( <i>Galantex XL</i> ) (Creo Pharma Ltd)	For the treatment of mild to moderate dementia in Alzheimer's disease	AMBER with shared care. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . Preferred lower cost brand.
Galantamine sustained release capsules ( <i>Gatalin XL</i> ) (Aspire)	For the treatment of mild to moderate dementia in Alzheimer's disease	AMBER with shared care. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . Preferred lower cost brand.
Ganciclovir 0.15% eye gel ( <i>Virgan</i> ) (Spectrum)	Acute herpetic keratitis	AMBER without shared care. Temporarily approved for inclusion in the <i>Lincolnshire Joint Formulary</i> as an alternative to acyclovir 3% eye ointment.
Levonorgestrel 13.5mg T-shaped intrauterine delivery system ( <i>Jaydess</i> )	For the prevention of pregnancy for up to three years	RED For insertion by specialist sexual health services only Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication.
Levonorgestrel 52mg T-shaped intrauterine delivery system ( <i>Mirena</i> )	For the prevention of pregnancy for up to five years For the treatment of menorrhagia. For the prevention of endometrial hyperplasia during oestrogen replacement therapy.	GREEN Included in the <i>Lincolnshire Joint Formulary</i> for these indications.
Propylene glycol 0.3%, polyethylene glycol 400 0.4% eye drops ( <i>Systane</i> ) (Alcon)	Dry eye	GREEN Recommended as a second line option for those who have not responded sufficiently to hypromellose or alternative first line treatments for dry eye. Included in the <i>Lincolnshire Joint Formulary</i> for this indication.
Polyethylene glycol 0.6% eye drops ( <i>Systane Balance</i> ) (Alcon)	Dry eye associated with meibomian gland deficiency	AMBER without shared care. <b>Should only be initiated on the advice of an ophthalmologist.</b> Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication.
Propylene glycol 0.3%, polyethylene glycol 400 0.4% eye drops ( <i>Systane Ultra</i> ) (Alcon)	Dry eye	GREEN Should only be used for those who have not responded sufficiently to the standard <i>Systane</i> product. Included in the <i>Lincolnshire Joint Formulary</i> for this indication.
Tocilizumab solution for infusion ( <i>RoActemra</i> ) (Roche)	For use in combination with methotrexate for the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant of, previous therapy with one or more disease modifying anti-rheumatic drugs or tumour necrosis factor antagonists.	RED Included in the <i>Lincolnshire Joint Formulary</i> for this indication.

Tocilizumab subcutaneous injection 162mg/0.9ml pre-filled syringe (RoActemra) (Roche)	For use in combination with methotrexate for the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant of, previous therapy with one or more disease modifying anti-rheumatic drugs or tumour necrosis factor antagonists.	RED Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication. Delivered to the patient through Homecare.
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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 NHS in Lincolnshire website ([www.lincolnshire.nhs.uk](http://www.lincolnshire.nhs.uk)); follow the commissioning link to PACEF. Electronic copies of both the *PACE Bulletin* and our sister publication *PACE Shorts* (a short summary 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](mailto:sandra.france@gemcsu.nhs.uk).

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The *Lincolnshire Joint Formulary* is available on line and is fully searchable; it can be accessed at [www.lincolnshirejointformulary.nhs.uk](http://www.lincolnshirejointformulary.nhs.uk)

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### **REVIEW: NEEDLES FOR PRE-FILLED AND REUSABLE PEN INJECTORS**

The prescribing of pen needles for pre-filled and reusable pen injectors in Lincolnshire primary care costs over £580,000pa. PACEF have reviewed the range of products available and have concluded that there are a number of lower cost, high quality products that should be preferred. These are:

- *Glucorx FinePoint*
- *Microdot Droplet*
- *MyLife Pentfine Classic*
- *Omnican Fine*

**These products are between 30 to 50% lower in cost than market leaders and their wider use could reduce primary care prescribing costs by £270,000pa.** For comparative costs see Appendix 1 at the end of this *Bulletin*:

Estimated annual savings for each of the Lincolnshire CCGs assuming a complete switch to the lower cost products are as follows:

	<b>Potential Annual Saving</b>
Lincolnshire East CCG	£95,530
Lincolnshire West CCG	£74,750
South Lincolnshire CCG	£64,350
South West Lincolnshire CCG	£39,440
Lincolnshire	£274,070

The majority of products are screw- on pen needles and are available in various needle lengths and gauges. After review of the range of products available with the Diabetes Specialist Nurses it was agreed that in most clinical situations the lower cost preferred products should be prescribed. However, there are exceptions to this:

## **(1) Safety needles**

There are a number of safety needles available on NHS prescription that incorporate automatic safety locks to avoid needle stick injury. These are:

- *BD Autoshield Duo*
- *MyLife ClickFine AutoProtect*
- *NovoFine Autocover*

These products should only be prescribed when healthcare workers are administering insulin or if the patient is self-administering and 'needle phobic'. Although these products are relatively high cost, they are unlikely to be suitable for a switch to a lower cost product.

## **(2) Click on needles**

*MyLife Clickfine* needles and *Novo Twist* needles snap onto the pen with an audible click and may have advantages for people with limited vision or restricted manual dexterity.

When reviewing prescribing of insulin pen needles, key principles from Diabetes Care UK *The First UK Injection Technique Recommendations* (2<sup>nd</sup> Edition) should be applied:

- For adults there is no clinical reason for recommending needles longer than 8mm.
- For children and adolescents there is no clinical reason for using needles longer than 6mm.
- 4mm, 5mm and 6mm needles are suitable for all people regardless of body mass index (BMI); they may not require a lifted skin fold and can be given at 90 degrees to the skin.
- Using shorter needles (6mm or less) helps to prevent inadvertent IM injection of insulin.
- If leakage of insulin occurs with shorter needles, injection technique should be reviewed. The individual should count slowly to 10 before withdrawing the needle.
- All needles are single use only.

### **PACEF Recommendation:**

Having reviewed the full range of pen needles for pre-filled and reusable pen injectors, PACEF have approved the following lower cost products for first line use: ***GlucorX FinePoint, Microdot Droplet, MyLife Penfine Classic and Omnican Fine***. All of these products are approved for inclusion in the ***Lincolnshire Joint Formulary*** and are designated GREEN. PACEF recognize that safety needles that incorporate automatic safety locks to avoid needle stick injury are necessary where healthcare workers are administering insulin or if the patient is self-administering and needle phobic. Within this context preferred products are: ***BD Autoshield Duo, MyLife ClickFine AutoProtect and NovoFine Autocover***. All of these products are approved for inclusion in the ***Lincolnshire Joint Formulary*** for these indications only and are designated GREEN. Where the patient has limited vision or restricted manual dexterity, needles that snap onto the pen with an audible click should be used. The preferred products designated GREEN within criteria and approved for inclusion in the ***Lincolnshire Joint Formulary*** are: ***MyLife Clickfine*** and ***Novo Twist***. Practices are urged to review their prescribing of pen needles in accordance with Diabetes Care UK principles with a view to switching appropriate patients to the lower cost preferred products. Technician support with implementation is available from the Prescribing and Medicines Optimisation Service.

### **References**

Diabetes Care in the UK: The First UK Injection Technique Recommendations, 2<sup>nd</sup> Edition, (October 2011)  
Lincolnshire Community Health Services, *Administration of Insulin Injections, Guidelines and Procedures* (September 2014)  
*Drug Tariff* (October 2014)

## **PRODUCT RECALL: ACICLOVIR 3% EYE OINTMENT (ZOVIRAX)**

In conjunction with the MHRA, GlaxoSmithKline have announced that they are recalling some batches of *Zovirax eye ointment* due to contamination of the active pharmaceutical ingredient with metal particles above the upper limit for particle size. As a result of this *Zovirax Eye Ointment* is unlikely to be available for several months and alternatives will need to be prescribed.

Prescribers are reminded that all patients presenting with herpes simplex keratitis should be referred to an ophthalmologist as a matter of urgency. The standard licensed alternative to aciclovir 3% eye ointment in the UK is ganciclovir 0.15% eye gel (*Virgan*) in a dose of one drop five times daily until epithelial healing occurs. Treatment should not exceed 21 days.

Other possible alternatives include:

- Oral aciclovir 400mg 5 times a day for 10 to 14 days.
- Imported unlicensed aciclovir 3% eye ointment.
- Unlicensed trifluorothymidine 1% eye drops (trifluridine, *Viroptic*).

### **PACEF Recommendation:**

**Due to a product recall affecting supply of the approved first line treatment for herpes simplex keratitis, aciclovir eye ointment 3% (*Zovirax*), PACEF have granted temporary *Formulary* approval for ganciclovir 0.15% eye gel (*Virgan*) as the preferred alternative. As a result of this, ganciclovir 0.15% eye gel (*Virgan*) is designated AMBER without shared care and included temporarily in the *Lincolnshire Joint Formulary*. Prescribers are reminded that all patients presenting with herpes simplex keratitis should be referred to an ophthalmologist as a matter of urgency.**

## **NEW DRUG ASSESSMENT: CALCIUM ACETATE CAPSULES (PHOSLO)**

*PhosLo* is a phosphate binder containing anhydrous calcium acetate 667 mg (equivalent to 169 mg calcium) in each capsule. It holds a marketing authorisation for the prevention and treatment of hyperphosphataemia in dialysis. NICE Clinical Guideline 157:

*Hyperphosphataemia in chronic kidney disease* (March 2013) recommends calcium acetate as the first line phosphate binder of choice to control serum phosphate in adults (in addition to dietary management).

At present, calcium acetate tablets 986.4mg (equivalent to calcium 250mg) (*Phosex*) are the only approved formulation of calcium acetate on the *Lincolnshire Joint Formulary*.

Unfortunately, some patients struggle to swallow *Phosex* tablets due to their size. NICE have acknowledged that palatability and size of calcium acetate formulations can create problems for some patients and that patient preference and ease of administration should be taken into account as part of treatment selection.

A cost comparison reveals that the two products are similar in price:

*Phosex* costs £19.79 per 180 tablets (11p per 1000mg calcium acetate)

*PhosLo* costs £14.40 per 200 capsules (10.8p per 1000mg calcium acetate)

### **PACEF Recommendation:**

**PACEF acknowledge that the size of *Phosex* tablets can present a problem to some patients who have difficulty swallowing them. Where these problems occur, calcium acetate 667 mg (equivalent to 169 mg calcium) tablets (*PhosLo*) are approved for inclusion in the *Lincolnshire Joint Formulary* for second line use; designation AMBER without shared care.**

**NEW DRUG ASSESSMENT: TOCILIZUMAB SUBCUTANEOUS INJECTION (ROACTEMRA) FOR RHEUMATOID ARTHRITIS**

Tocilizumab subcutaneous injection 162mg/0.9ml in a pre-filled syringe (*RoActemra*) was launched earlier in the summer for the treatment of moderate to severe active rheumatoid arthritis (RA). NICE have previously approved intravenous infusion of tocilizumab for this indication, but have yet to issue guidance on the role of the SC formulation. PACEF compared the two formulations and the results are tabulated below:

	Tocilizumab SC injection	Tocilizumab IV injection
Marketing authorisation	For use in combination with methotrexate for the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant of, previous therapy with one or more disease modifying anti-rheumatic drugs or tumour necrosis factor antagonists.	For use in combination with methotrexate for the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant of, previous therapy with one or more disease modifying anti-rheumatic drugs or tumour necrosis factor antagonists.
Dose	162mg by SC injection every week.	8mg/kg body weight given once every four weeks.
NICE guidance	Tocilizumab is approved for IV use within this context but no appraisal of the SC formulation has yet been published.	NICE approved.
Efficacy	Similar	Similar
Safety profile	Similar, but more injection site problems with SC injection.	Similar
Patient convenience	Delivered by the Homecare provider to the patient at home. Patient self-administers after training if specialist considers that this is appropriate.	Delivered through a specialist clinic every four weeks. More inconvenient to the patient due to clinic time, travelling, time off work etc.
Cost	Similar	Similar

**PACEF Recommendation**

**Tocilizumab subcutaneous injection 162mg/0.9ml pre-filled syringe (*RoActemra*) is approved for use within marketing authorisation and is designated RED. It is approved for inclusion in the *Lincolnshire Joint Formulary* and will be provided to patients through a Homecare provider subject to appropriate commissioning arrangements.**

**RAPID DRUG ASSESSMENT: PROPYLENE GLYCOL 0.6% EYE DROPS (SYSTANE BALANCE)**

Polyethylene glycol 0.6% eye drops (*Systane Balance*) are indicated for the treatment of dry eye conditions, specifically dry eye associated with meibomian gland disorders.

Supporting evidence comes from three small, short-term studies, two of which compared the effectiveness of *Systane Balance* against another ocular lubricant not available in the UK (*Soothe XP*). The third study included only 28 patients and compared symptomatic relief with previously used unnamed treatments with *Systane Balance*. These studies concluded that: (1) *Systane Balance* demonstrates improvements in tear film lipid layer thickness and tear stability up to two hours after instillation; (2) *Systane Balance* increased meibomian gland function and; (3) induced less haze upon instillation. PACEF were disappointed by the sparsity and poor quality of the evidence presented.

A comparison of the products in the *Systane* range is tabulated below. Propylene glycol 0.3%, polyethylene glycol 400 0.4% eye drops (*Systane* and *Systane Ultra*) are currently the only products in the range included in the *Lincolnshire Joint Formulary*:

Drug	Indication	Inactive ingredients	Manufacturers' notes	Cost per 10ml bottle
Propylene glycol 0.3%, polyethylene glycol 400 0.4% eye drops ( <i>Systane</i> ) (Alcon)	Dry eye	Boric acid, calcium chloride, hydroxypropyl guar, magnesium chloride, poly quaternium-1 as a preservative, potassium chloride, sodium chloride, zinc chloride.	Lubricant eye drops for the temporary relief of burning and irritation due to dryness of the eye	£4.66 (10ml)
Propylene glycol 0.3%, polyethylene glycol 400 0.4% eye drops ( <i>Systane Ultra</i> ) (Alcon)	Dry eye	Aminomethylpropanol, boric acid, hydroxypropyl guar, POLYQUAD® (polyquaternium-1) 0.001% preservative, potassium chloride, sodium chloride, sorbitol	Lubricant eye drops for the temporary relief of burning and irritation due to dryness of the eye. Can be used to lubricate and rewet daily extended wear and disposable silicone hydrogel and soft (hydrophilic) contact lenses. The only product in the <i>Systane</i> range that can be used without the patient removing their contact lenses	£6.69 (10ml)
Propylene glycol 0.6%, eye drops ( <i>Systane Balance</i> ) (Alcon)	Dry eye associated with meibomian gland deficiency.	Boric acid, dimyristoyl phosphatidylglycerol, edetate disodium, hydroxypropyl guar, mineral oil, polyoxyl 40 stearate, POLYQUAD® (polyquaternium-1) 0.001% preservative, sorbitan tristearate and sorbitol.	Lubricates the ocular surface, supplements and stabilizes the lipid layer of the tear film and reduces excessive tear evaporation.	£7.49 (10ml)

**PACEF Recommendation:**

***Systane* eye drops are already recommended as a second line option for those who have not responded sufficiently to hypromellose or alternative first line treatments for dry eye. *Systane Ultra* eye drops should only be used for those who have not responded sufficiently to the standard *Systane* product. Both products are already included on the *Lincolnshire Joint Formulary* and are designated GREEN. ULH ophthalmologists have requested that *Systane Balance* should be added to the *Formulary* for the treatment of those with dry eyes associated with meibomian gland deficiency and/ or blepharitis. Despite reservations concerning the poor quality of the evidence base and concerns around the significantly higher price, PACEF have approved *Systane Balance* eye drops for use only on the advice of an ophthalmologist. Designation: AMBER without shared care and approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.**

## **NEW DEVICE ASSESSMENT: LEVONORGESTREL 13.5MG INTRAUTERINE DELIVERY SYSTEM (JAYDESS)**

*Jaydess* is a new progesterone only T shaped intrauterine delivery system containing levonorgestrel 13.5mg. It is licensed to provide contraception for a period of up to three years after insertion into the uterine cavity.

Supporting evidence comes from one phase III randomised controlled trial which compared two low dose intrauterine systems containing levonorgestrel 13.3mg and 19.5mg; the comparator product levonorgestrel 19.5mg is not licensed and is not available commercially. The trial demonstrated that the 13.3mg levonorgestrel device was effective as a contraceptive with similar failure rates to those seen with correct use of other long-acting reversible contraception.

There is no head to head data comparing *Jaydess* with the established leading levonorgestrel T shaped intrauterine system *Mirena* or any other intra-uterine devices (copper based coils) or alternative long acting contraceptives, such as medroxyprogesterone injections or etonorgestrel implant (*Nexplanon*). As a result of this, it remains uncertain as to whether *Jaydess* is as effective as *Mirena* in terms of contraceptive efficacy.

Levonorgestrel 52mg T shaped intrauterine system (*Mirena*) is licensed to provide contraception for a period of up to five years after insertion. It also holds additional licenses for the treatment of menorrhagia and the prevention of endometrial hyperplasia during oestrogen replacement therapy.

In a recent review of *Jaydess* published by the Faculty of Sexual and Reproductive Healthcare (FSRH), it was claimed that *Jaydess* may be easier to insert and result in less pain on insertion than *Mirena* due to its smaller size. However, there is a lack of comparative data to confirm this at this stage. There are also differences in both the initial and average release rates of levonorgestrel delivered by the two different devices; in the absence of comparative data, the clinical significance of this and any advantages and disadvantages that result require further investigation. There is also a lack of long term safety data with *Jaydess* and some concern over possible increased contraceptive failure, increased expulsion rates and increased ectopic pregnancy rates in real life studies.

A cost comparison reveals the following:

	<b>Cost</b>	<b>Cost per year*</b>
Levonorgestrel 13.5mg T-shaped intrauterine system ( <i>Jaydess</i> )	£69.22 per device	£23.07 (assuming replacement after 3 years)
Levonorgestrel 52mg T-shaped intrauterine system ( <i>Jaydess</i> )	£88.00 per device	£17.60 (assuming replacement after 5 years).

\*Comparing cost per year may not accurately reflect real world practice as many women who use the *Mirena* device request early removal if they wish to conceive.

PACEF consulted local specialists in Sexual Health who suggested that *Jaydess* could be considered in: (1) Younger nulliparous women; (2) Women planning to have a baby in the nearer future (e.g. in less than 3 years' time); (3) Women with a smaller uterus (on sounding) and/or a tighter cervix; (4) Women who are concerned about hormonal side effects.

### **PACEF Recommendation:**

**Levonorgestrel 13.5mg T shaped intrauterine delivery system (*Jaydess*) provides effective long-term contraception for up to three years after intrauterine insertion.**

However, the lack of comparative data against the established product, *Mirena*, in conjunction with the lack of long-term safety data makes it difficult to recommend the product in preference. In addition, *Mirena* is also licensed for a wider range of indications. Local specialist opinion suggests that *Jaydess* may have advantages over *Mirena* in some patients, particularly those with a smaller uterus and/or tighter cervix and those considering conception within three years of insertion. As a result of this, levonorgestrel 13.5mg T shaped intrauterine delivery system (*Jaydess*) is designated RED; for insertion by specialist Sexual Health Services only. *Jaydess* is approved for inclusion in the *Lincolnshire Joint Formulary* within this context.

**RAPID COST COMPARISON: LOWER COST GALANTAMINE MODIFIED RELEASE FORMULATIONS (GALANTEX XL/GATALIN XL)**

Galantamine is a reversible inhibitor of acetylcholinesterase originally marketed as *Reminyl* and licensed for the treatment of mild to moderate Alzheimer's disease. A number of lower cost modified release formulations are now available; a cost comparison is provided below:

Product	Strength	Cost (£) (28 days)
Galantamine sustained release capsules ( <i>Galantex XL</i> ) (Creo Pharma Ltd)	8mg	£25.42
	16mg	£31.80
	24mg	£39.10
Galantamine sustained release capsules ( <i>Gatalin XL</i> ) (Aspire)	8mg	£25.94
	16mg	£32.45
	24mg	£39.90
Galantamine sustained release capsules ( <i>Acumor XL</i> ) (Mylan)	8mg	£49.26
	16mg	£61.65
	24mg	£75.81
Galantamine sustained release capsules ( <i>Reminyl XL</i> ) (originator brand) (Shire)	8mg	£51.88
	16mg	£64.90
	24mg	£79.80
Galantamine sustained release capsules ( <i>Elmino XL</i> ) (Zentira)	8mg	£51.88
	16mg	£64.90
	24mg	£79.80
Galantamine sustained release capsules ( <i>Lotprosin XL</i> ) (Actavis)	8mg	£51.88
	16mg	£64.90
	24mg	£79.80
Galantamine sustained release capsules (Category C generic reimbursement price)	8mg	£51.88
	16mg	£64.90
	24mg	£79.80

Potential savings in each of the Lincolnshire Clinical Commissioning Groups (CCGs) if all sustained release galantamine was prescribed as a low cost brand (*Galantex XL* or *Gatalin XL*) are as follows:

	<b>Annual saving</b>
Lincolnshire East CCG	£84,060
Lincolnshire West CCG	£62,201
South Lincolnshire CCG	£21,794
South West Lincolnshire CCG	£19,304
Lincolnshire	£187,359

**PACEF Recommendation:**

The launch of new lower cost branded sustained release formulations of galantamine offers the opportunity for CCGs to realise significant savings in the coming months. All sustained release galantamine should be prescribed as a lower cost brand such as *Galantex XL* or *Gatalin XL*. The potential saving across Lincolnshire from this single action is over £187,000pa. Both products are designated AMBER with shared care and are approved for inclusion in the *Lincolnshire Joint Formulary*.

**NICE TECHNOLOGY APPRAISAL TA320: DIMETHYL FUMARATE FOR TREATING RELAPSING-REMITTING MULTIPLE SCLEROSIS (AUGUST 2014)**

Dimethyl fumarate is recommended as an option for treating adults with active relapsing-remitting multiple sclerosis (normally defined as 2 clinically significant relapses in the previous 2 years), only if:

- they do not have highly active or rapidly evolving severe relapsing-remitting multiple sclerosis and
- the manufacturer provides dimethyl fumarate with the discount agreed in the patient access scheme.

Notes

Dimethyl fumarate 120mg and 240mg capsules (*Tecfidera*) are licensed for the treatment of adult patients with relapsing remitting multiple sclerosis. The starting dose is 120 mg twice a day. After 7 days, the dose is increased to the recommended dose of 240 mg twice a day. Treatment should be initiated under supervision of a physician experienced in the treatment of the disease.

**PACEF Recommendation:**

Dimethyl fumarate 120mg and 240mg capsules (*Tecfidera*) are designated RED within licensed indications. Treatment should be initiated, monitored and supplied from within specialist services. Any approaches to GPs to prescribe dimethyl fumarate capsules (*Tecfidera*) should be refused. Dimethyl fumarate (*Tecfidera*) is approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.

**SPECIALIST SERVICES CIRCULAR: PRIMARY CARE RESPONSIBILITIES IN RELATION TO THE PRESCRIBING AND MONITORING OF HORMONE THERAPY FOR PATIENTS UNDERGOING OR HAVING UNDERGONE GENDER DYSPHORIA TREATMENTS (MARCH 2014)**

Since April 2013, NHS England has been responsible for commissioning the specialised element of the gender dysphoria care pathway, currently delivered through seven specialised Gender Identity Clinics (GICs). In this circular NHSE make plain their expectations of GPs in relation to commissioned GICs. GPs are expected to:

- cooperate with the GIC and prescribe the hormone therapy recommended for their patients.
- cooperate with the GIC in terms of patient safety monitoring by providing basic physical examinations (within competence) and blood tests (where requested).

Conversely, the GIC is expected to assist GPs by providing relevant information and support, including the interpretation of blood test results. Hormone therapy should be monitored at least 6 monthly in the first 3 years and yearly thereafter, dependant on clinical need.

Typical drugs recommended by GICs include oestradiol preparations (e.g. transdermal oestradiol gels and patches and oral oestradiol preparations), testosterone preparations (e.g.gels, *Sustanon* and *Nebido* injection) and gonadotrophin releasing hormone analogues.

Apart from *Sustanon*, there are no licensed products with an approved indication for the treatment of gender dysphoria. However, there is extensive clinical experience in the use of these products in the treatment of gender dysphoria over decades.

**PACEF Comment:**

**Following the publication of this Circular, GPs are encouraged to participate in shared care or alternative prescribing arrangements in conjunction with NHSE commissioned Gender Identity Clinics and their specialist teams.**

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 November 2014

## Appendix 1: Comparative cost of pen needles

Length	Gauge	BD Micro-Fine+	BD Micro-Fine Ultra	Comfort Point	IME-FINE	Insupen	MyLife Clickfine	Nanopass	NovoFine	NovoTwist	Unifine Pentips	Unifine Pentips Plus	GlucoRx FinePoint	MyLife Penfine Classic	Microdot Droplet	Omnican Fine
4mm	31			£9.95									£5.95			£5.95
	32		£12.69			£12.05	£12.32				£11.75			£5.94	£5.95	
	32.5							£12.25								
	33					£12.69										
5mm	30															
	31	£12.69				£10.28					£12.00	£12.74	£5.95			
	32									£12.99						
6mm	31			£9.95	£11.20	£10.28	£12.84		£13.02		£11.75	£12.74	£5.95		£5.95	£5.95
	32					£12.05								£5.94		
8mm	29															
	30								£9.24							
	31	£9.00		£6.60	£8.20	£8.98	£9.11				£8.25	£8.95	£5.95	£5.94	£5.95	£5.95
	32					£11.50										
	32.5							£8.85								
10mm	29						£9.11						£5.95			
	30															£5.95
12mm	28								£9.40							
	29			£6.60		£8.98	£9.11				£8.25	£8.95	£5.95			£5.95

**The pen needles highlighted in GREEN are the lower cost products.**

MyLife Clickfine & NovoTwist do not screw on. Unifine Pentips Plus have a built in needle remover. Omnican Fine pen needles do not have an inner sheath.

**Prices taken from Drug Tariff October 2014**