

Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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What's new this month?

- *Eloine* was the first lower dose ethinyloestradiol 20mcg/drospirenone 3mg COC to reach the UK market rapidly followed by *Daylette*, a lower cost equivalent. Both products are effective and well tolerated oral contraceptives with the potential for reduced heaviness of withdrawal bleeding. Due to a comparatively higher price, *Eloine* is designated RED-RED and is not approved for use through the *Lincolnshire Joint Formulary*. Where an ethinyloestradiol 20mcg/drospirenone 3mg tablet is indicated, the lower cost equivalent *Daylette* should be prescribed; it is designated GREEN and approved for use through the *Lincolnshire Joint Formulary* (see page 3).
- There are currently two fentanyl immediate release formulations approved for use on the *Lincolnshire Joint Formulary* and designated GREEN. These are fentanyl sublingual tablets (*Abstral*) and fentanyl buccal tablets (*Effentora*). Treatment should only be initiated by a physician experienced in the management of opioid therapy in cancer pain (this could be a GP or a member of the palliative care team) and should be closely monitored (see page 5).
- At the request of the palliative care team, PACEF have also approved fentanyl nasal spray 100mcg/dose and 400mcg/dose (*PecFent Nasal Spray*) as the preferred fentanyl nasal preparation on the *Lincolnshire Joint Formulary*; designation GREEN. *PecFent Nasal Spray* is significantly lower in cost per dose than the alternative fentanyl nasal spray (*Instanyl*) and should be used in preference where a nasal spray formulation is indicated (see page 5).
- Wherever on demand quick acting opioid therapy is indicated, oral immediate release morphine should be considered first line. Immediate release oxycodone should be reserved for second line use. Fentanyl immediate release products should only be considered when a patient is unable to take immediate release morphine for breakthrough cancer pain, or where breakthrough pain is of rapid onset and not controlled by oral morphine. Immediate release oxycodone should be considered as a second line option after morphine, before considering immediate release fentanyl (see page 5).

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SUMMARY OF PACEF DECISIONS: FEBRUARY 2015 UPDATE

Drug	Indication(s)	Traffic Light and Joint Formulary Status
Apremilast 10mg, 20mg and 30mg tablets (<i>Otezla</i>) (Celgene)	For the treatment of moderate to severe chronic plaque psoriasis in adults who have failed to respond to, have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA.	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication.
Apremilast 10mg, 20mg and 30mg tablets (<i>Otezla</i>) (Celgene)	For the treatment of active psoriatic arthritis in patients with an inadequate response or intolerance to DMARDs.	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication.
Bortezomib 3.5mg injection (<i>Velcade</i>) (Janssen-Cilag Ltd)	For use, in combination with rituximab, cyclophosphamide, doxorubicin and prednisone in the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.	RED. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication. Also approved for use: <ul style="list-style-type: none"> as monotherapy for relapsed progressive multiple myeloma (NICE TA129) in combination with thalidomide for the first line treatment of multiple myeloma (NICE TA228). in combination with other agents for the induction therapy of previously untreated multiple myeloma (NICE TA311).
Ciclosporin 0.1% single use eye drops (<i>Ikervis</i>) (Santen UK Ltd)	For the treatment of severe keratitis in dry eye disease unresponsive to tear substitutes.	RED Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . Local treatment guidelines are in development.
Erlotinib 25mg, 100mg and 150mg tablets (<i>Tarceva</i>) (Roche Products Ltd)	For the treatment of locally advanced or metastatic non-small cell lung cancer after failure of previous chemotherapy.	RED Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication. NB Erlotinib is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-negative.
Ethinylestradiol 0.02mg/ drospirenone 3 mg tablets (<i>Daylette</i>) (Consilient Health Ltd)	Contraception	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .
Ethinylestradiol 0.02mg/ drospirenone 3 mg tablets (<i>Eloine</i>) (Bayer)	Contraception	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .
Fentanyl sublingual tablets 100mcg, 200mcg, 300mcg, 400mcg, 600mcg,800mcg (Abstral) (ProStrakan)	Breakthrough pain in opioid therapy for chronic cancer pain.	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . Third line after (1) immediate release

		morphine and (2) immediate release oxycodone.
Fentanyl lozenges 200mcg,400mcg, 600mcg, 800mcg, 1200mcg and 1600mcg (Actiq) (Teva UK)	Breakthrough pain in opioid therapy for chronic cancer pain	RED-RED Not approved for inclusion in the Lincolnshire Joint Formulary.
Fentanyl buccal film sachet 200mcg, 400mcg and 800mcg (Breakyl) (Meda)	Breakthrough pain in opioid therapy for chronic cancer pain	RED-RED Not approved for inclusion in the Lincolnshire Joint Formulary.
Fentanyl buccal tablets 100mcg, 200mcg, 400mcg, 600mcg and 800mcg (Effentora) (Teva UK)	Breakthrough pain in opioid therapy for chronic cancer pain	GREEN Approved for inclusion in the Lincolnshire Joint Formulary. Third line after (1) immediate release morphine and (2) immediate release oxycodone.
Fentanyl nasal spray 50mcg/dose, 100mcg/dose, 200mcg/dose (Instanyl) (Takeda)	Breakthrough pain in opioid therapy for chronic cancer pain	RED-RED Not approved for inclusion in the Lincolnshire Joint Formulary.
Fentanyl nasal spray 100mcg/dose, 400mcg/dose (PecFent) (Archimedes)	Breakthrough pain in opioid therapy for chronic cancer pain	GREEN Approved for inclusion in the Lincolnshire Joint Formulary. Third line after (1) immediate release morphine and (2) immediate release oxycodone.
Fentanyl sublingual tablets 133mcg, 267mcg, 400mcg, 533mcg and 800mcg (Recivit) (Grünenthal)	Breakthrough pain in opioid therapy for chronic cancer pain	RED-RED Not approved for inclusion in the Lincolnshire Joint Formulary.
Gefitinib 250mg tablets (<i>Iressa</i>) (AstraZeneca UK Ltd)	For the treatment of locally advanced or metastatic non-small cell lung cancer with activating mutations of epidermal growth factor receptor	Gefitinib is already included on the Lincolnshire Joint Formulary as a RED drug for the treatment of lung cancer as recommended under NICE TA 192. Gefitinib is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-positive. It is designated RED-RED for this indication.
Trastuzumab emtansine 100mg and 160mg for solution for infusion (Kadcyla) (Roche Products Ltd)	Monotherapy for the treatment of HER2-positive, unresectable, locally advanced or metastatic breast cancer, in adult patients who have previously received trastuzumab and a taxane separately or in combination.	RED-RED Not included in the Lincolnshire Joint Formulary.

RAPID DRUG ASSESSMENT: ETHINYLOESTRADIOL 0.02MG/ DROSPIRENONE 3MG TABLETS (ELOINE AND DAYLETTE)

***Eloine* was the first lower dose ethinyloestradiol 20mcg/drospirenone 3mg COC to reach the UK market, rapidly followed by *Daylette*, a lower cost equivalent. Both products are effective and well tolerated oral contraceptives with the potential for reduced heaviness of withdrawal bleeding. Due to a comparatively higher price, *Eloine* is designated RED-RED while the lower cost equivalent *Daylette* is designated GREEN.**

Bayer has recently launched *Eloine*, a new combined oral contraceptive (COC) containing 20 mcg of ethinylestradiol in combination with 3mg of drospirenone. An equivalent lower cost competitor product known as *Daylette* is also now available from Consilient Health Ltd.

A number of 30mcg ethinylestradiol / drospirenone 3mg combinations have been evaluated by PACEF recently and are already included on the *Lincolnshire Joint Formulary*; these are *Acondro*, *Dretine*, *Lucette* and *Yacella*. No 20mcg ethinylestradiol / drospirenone 3mg COCs have yet been approved for use.

A pack of *Eloine* or *Daylette* contains 24 active pills and 4 inactive pills constituting a complete 28 day supply requiring no pill free days and offering the potential for fewer adherence problems. The benefit of this is to eliminate or reduce the frequency of withdrawal bleeds and any related symptoms.

Trial evidence from a number of phase 3 studies demonstrates that *Eloine* is an effective COC with comparable efficacy to ethinylestradiol 30mcg/drospirenone 3mg (*Yasmin*) and other drospirenone containing COC's. Similar evidence exists for *Daylette*. Both products are well tolerated with the most frequently reported adverse effects being headache, breast tenderness, metrorrhagia, amenorrhoea, emotional lability and nausea.

As COCs containing drospirenone, *Eloine* and *Daylette* are associated with a higher risk of venous thromboembolism (VTE) than other COCs containing levonorgestrel, norgestimate or norethisterone. This level of risk of VTE needs to be taken into account when considering which method of contraception is most appropriate for an individual. Current prescribing data shows that the most frequently prescribed COCs in county are ethinyloestradiol 30mcg/levonorgestrel 150mcg combinations. This is in line with advice to preferentially prescribe COCs containing progestones associated with a lower risk of VTE.

A cost comparison of ethinyloestradiol and drospirenone COCs reveals that *Eloine* is a premium price product directly equivalent in price to the premium price higher dose originator brand *Yasmin*; *Daylette* is significantly lower in cost, comparable to the lower cost branded versions of *Yasmin*.

	Cost
Ethinylestradiol 20mcg/drospirenone 3mg preparations	
<i>Daylette</i>	£10.50 (3x28)
<i>Eloine</i>	£14.70 (3x28)
Ethinylestradiol 30mcg/drospirenone 3mg preparations	
<i>Yasmin</i>	£14.70 (3x21)
Acondro (Mylan)	£8.35 (3x21)
<i>Cleosena</i> (Actavis)	£14.70 (3x21)
Dretine (Teva UK)	£8.34 (3x21)
Lucette (Concilient Health)	£9.35 (3x21)
Yacella (Morningside)	£9.30 (3x21)

PACEF Recommendation:

Eloine was the first lower dose ethinyloestradiol 20mcg/drospirenone 3mg COC to reach the UK market rapidly followed by *Daylette*, a lower cost equivalent. Both products are effective and well tolerated oral contraceptives with the potential for reduced heaviness of withdrawal bleeding. Due to a comparatively higher price, *Eloine* is designated RED-RED and is not approved for use through the *Lincolnshire Joint Formulary*. Where an ethinyloestradiol 20mcg/drospirenone 3mg tablet is indicated, the lower cost equivalent *Daylette* should be prescribed; it is designated GREEN and approved for use through the *Lincolnshire Joint Formulary*.

REVIEW: FENTANYL IMMEDIATE RELEASE PREPARATIONS

Fentanyl immediate release oral preparations are reviewed and three products approved for inclusion in the *Joint Formulary*: fentanyl sublingual tablets (*Abstral*), fentanyl buccal tablets (*Effentora*) and fentanyl nasal spray (*PecFent*).

The table below summarizes the range of immediate release fentanyl preparations currently available in the UK alongside their licensed indications and cost. Comparative information around immediate release oral morphine and oxycodone preparations is also included.

Product	Strengths	Indication	Cost (£)	Cost per dose
Fentanyl sublingual tablets (<i>Abstral</i>) (ProStrakan)	100mcg,200mcg 300mcg,400mcg 600mcg,800mcg	Breakthrough pain in opioid therapy for chronic cancer pain	£49.99 (10 tabs) £149.70 (30) £149.70(30)	£4.99 per dose
Fentanyl lozenges (<i>Actiq</i>) (Teva UK)	200mcg,400mcg 600mcg,800mcg 1200mcg 1600mcg	Breakthrough pain in opioid therapy for chronic cancer pain	£21.05 (3 loz) £210.41 (30)	£7.02 per dose
Fentanyl buccal film sachet (<i>Breakyl</i>) (Meda)	200mcg,400mcg 800mcg	Breakthrough pain in opioid therapy for chronic cancer pain	£49.00 (10 sach) £139.72 (28)	£4.90 per dose (10's) £4.99 per dose (28's)
Fentanyl buccal tablets (<i>Effentora</i>) (Teva UK)	100mcg,200mcg 400mcg,600mcg 800mcg	Breakthrough pain in opioid therapy for chronic cancer pain	£19.96 (4 tabs) £139.72 (28)	£4.99 per dose
Fentanyl nasal spray (<i>Instanyl</i>) (Takeda)	50mcg/dose 100mcg/dose 200mcg/dose	Breakthrough pain in opioid therapy for chronic cancer pain	£59.50 (10 dose) £119.00 (20 doses) £35.70 (6 single dose units)	£5.95 per dose
Fentanyl nasal spray (<i>PecFent</i>) (Archimedes)	100mcg/dose 400mcg/dose	Breakthrough pain in opioid therapy for chronic cancer pain	£36.48 (8 doses) £145.92 (4 x 8)	£4.56 per dose
Fentanyl sublingual tablets (<i>Recivit</i>) (Grunenthal)	133mcg,267mcg 400mcg,533mcg 800mcg	Breakthrough pain in opioid therapy for chronic cancer pain	£127.20 (30 tabs)	£4.24 per dose
Morphine containing products				
Morphine sulfate immediate release tablets (<i>Sevredol</i>) (Napp)	10mg 20mg 50mg	Acute and chronic severe pain	£5.31 (56 tabs) £10.61 (56) £28.02 (56)	£0.09 (10mg) £0.19 (20mg) £0.50 (50mg)
Morphine sulfate 10mg/5ml oral solution (<i>Oramorph</i>) (Boeingerher Ingelheim)	10mg in 5ml	Severe pain	£1.89 (100ml) £5.45 (300ml) £8.50 (500ml)	£0.09 (10mg)
Morphine sulphate 20mg/ml oral solution (<i>Oramorph Conc</i>) Boeingerher Ingelheim)	20mg in 1ml	Severe pain	£4.98 (30ml) £19.50 (120ml)	£0.16 (20mg) £0.81 (100mg).
Oxycodone containing products				
Oxycodone hydrochloride immediate release capsules (<i>Lynlor</i>)	5mg 10mg 20mg	Severe pain requiring an opioid analgesic.	£6.86 (56) £13.72 (56) £27.43 (56)	£0.12 (5mg) £0.25 (10mg) £0.50 (20mg)

(Actavis)				
Oxycodone hydrochloride immediate release capsules (<i>OxyNorm</i>) (Napp)	5mg 10mg 20mg	Moderate to severe cancer pain or post-op pain. Severe pain requiring a strong opioid.	£11.43 (56) £22.86 (56) £45.71 (56)	£0.21 (5mg) £0.41 (10mg) £0.82 (20mg)
Oxycodone 5mg/5ml oral solution (<i>OxyNorm Liquid</i>) (Napp)	5mg in 5ml	Moderate to severe cancer pain or post-op pain. Severe pain requiring a strong opioid.	£9.71 (250ml)	£0.20 (5mg)
Oxycodone 10mg/1ml oral solution (<i>OxyNorm Conc</i>) (Napp)	10mg in 1ml	Moderate to severe cancer pain or post-op pain. Severe pain requiring a strong opioid.	£46.63 (120ml)	£0.39 (10mg)

Formulary products are highlighted in bold

PACEF Recommendations

- (1) Wherever on demand quick acting opioid therapy is indicated, oral immediate release morphine should be considered first line. Immediate release oxycodone should be reserved for second line use.
- (2) In comparison to immediate release morphine, fast acting fentanyl preparations are vastly more expensive and have a very limited role. Fentanyl immediate release products should only be considered when a patient is unable to take immediate release morphine for breakthrough cancer pain, or where breakthrough pain is of rapid onset and not controlled by oral morphine. Immediate release oxycodone should be considered as a second line option after morphine, before considering immediate release fentanyl. Prescribing data confirms that Lincolnshire GPs are already confining immediate release fentanyl to this very limited role.
- (3) There are currently two fentanyl immediate release formulations approved for use on the *Lincolnshire Joint Formulary* and designated GREEN. These are fentanyl sublingual tablets 100mcg, 200mcg, 300mcg, 400mcg, 600mcg and 800mcg (*Abstral*) and fentanyl buccal tablets 100mcg, 200mcg, 400mcg, 600mcg and 800mcg (*Effentora*). Treatment should only be initiated by a physician experienced in the management of opioid therapy in cancer pain (this could be a GP or a member of the palliative care team) and should be closely monitored.
- (4) At the request of the palliative care team, PACEF have also approved fentanyl nasal spray 100mcg/dose and 400mcg/dose (*PecFent Nasal Spray*) as the preferred fentanyl nasal preparation on the *Lincolnshire Joint Formulary*; designation GREEN.
PecFent Nasal Spray is significantly lower in cost per dose than fentanyl nasal spray (*Instanyl*) and should be used in preference where a nasal spray formulation is indicated.

NICE UPDATE

NICE Technology Appraisal	Guidance	PACEF Recommendation
TA 368: <i>Apremilast for treating moderate to severe plaque psoriasis</i> (November 2015)	Apremilast is not recommended for treating adults with moderate to severe chronic plaque	Apremilast 10mg, 20mg and 30mg tablets (<i>Otezla</i>) are designated RED-RED for this

	psoriasis that has not responded to systemic therapy, or where systemic therapy is contraindicated or not tolerated.	indication and have not been approved for use through the <i>Lincolnshire Joint Formulary</i>.
TA 369: <i>Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears</i> (December 2015)	Ciclosporin is recommended as an option for treating severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes.	Ciclosporin 0.1% single use eye drops (<i>Ikervis</i>) are designated RED for this indication and have been approved for use through the <i>Lincolnshire Joint Formulary</i>. Local treatment guidance is in development.
TA 370: <i>Bortezomib for previously untreated mantle cell lymphoma</i> (December 2015)	Bortezomib is recommended as an option for the treatment of previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable.	Bortezomib 3.5mg injection (<i>Velcade</i>) is designated RED and approved for inclusion in the <i>Lincolnshire Joint Formulary</i> for this indication. Also approved for use: <ul style="list-style-type: none"> • as monotherapy for relapsed progressive multiple myeloma (NICE TA129) • in combination with thalidomide for the first line treatment of multiple myeloma (NICE TA228). • in combination with other agents for the induction therapy of previously untreated multiple myeloma (NICE TA311).
TA 371: <i>Trastuzumab emtansine for treating HER2-positive, unresectable, locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane</i> (December 2015)	Trastuzumab emtansine is not recommended for treating adults with human epidermal growth factor 2 (HER2) positive, unresectable locally advanced or metastatic breast cancer previously treated with trastuzumab and a taxane.	Trastuzumab emtansine 100mg and 160mg for solution for infusion (<i>Kadcyla</i>) is designated RED-RED for this indication and is not approved for use through the <i>Lincolnshire Joint Formulary</i>.
TA 372: <i>Apremilast for treating active psoriatic arthritis</i> (December 2015)	Apremilast alone or in combination with disease-modifying antirheumatic drug (DMARD) therapy is not recommended for treating adults with active psoriatic arthritis that has not responded to prior DMARD therapy, or where such therapy is not tolerated.	Apremilast 10mg, 20mg and 30mg tablets (<i>Otezla</i>) are designated RED-RED for this indication and have not been approved for use through the <i>Lincolnshire Joint Formulary</i>.
TA 373: <i>Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis</i> (December 2015)	Abatacept, adalimumab, etanercept and tocilizumab are recommended as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA.	Abatacept injection and infusion (<i>Orencia</i>), adalimumab injection (<i>Humira</i>), etanercept injection (<i>Enbrel</i>) and tocilizumab injection and infusion (<i>RoActemra</i>) are already approved for use through the <i>Lincolnshire Joint Formulary</i>

		<p>for the management of a range of musculoskeletal conditions covered by NICE guidance. Both etanercept and tocilizumab already have NICE approval for the treatment of juvenile idiopathic arthritis under NICE TAs 35 and 238 (respectively). Abatacept and adalimumab are also included on the <i>Joint Formulary</i> for the treatment of juvenile idiopathic arthritis, their use in this instance covered by an NHS England interim policy. All four agents are designated RED for this indication.</p>
<p>TA 374 <i>Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy</i> (December 2015)</p>	<p>Erlotinib is recommended as an option for treating locally advanced or metastatic non-small-cell lung cancer that has progressed in people who have had non-targeted chemotherapy because of delayed confirmation that their tumour is epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive, only if the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE technology appraisal guidance 258.</p> <p>Erlotinib is recommended as an option for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours of unknown EGFR-TK mutation status, only if: the result of an EGFR-TK mutation diagnostic test is unobtainable because of an inadequate tissue sample or poor-quality DNA and the treating clinician considers that the tumour is very likely to be EGFR-TK mutation-positive and the person's disease responds to the first 2 cycles of treatment with erlotinib and the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE technology</p>	<p>Erlotinib 25mg, 100mg and 150mg tablets (Tarceva) are designated RED for this indication and approved for use through the <i>Lincolnshire Joint Formulary</i>.</p> <p>Erlotinib 25mg, 100mg and 150mg tablets (Tarceva) are designated RED for this indication and approved for use through the <i>Lincolnshire Joint Formulary</i>.</p>

	<p>appraisal guidance 258.</p> <p>Erlotinib is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-negative.</p> <p>Gefitinib is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-positive.</p>	<p>Erlotinib 25mg, 100mg and 150mg tablets (<i>Tarceva</i>) are designated RED-RED for this indication and not approved for use through the <i>Lincolnshire Joint Formulary</i>.</p> <p>Gefitinib 250mg tablets (<i>Iressa</i>) are designated RED-RED and not approved for use through the <i>Lincolnshire Joint Formulary</i> for this indication.</p>
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