NHS Lincolnshire

Prescribing and Clinical Effectiveness Bulletin

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What's new this month?

- **PACEF have agreed to support the development of a single Joint Formulary for the whole of Lincolnshire primary and secondary care that will be published by the end of March 2013 and will enable all Lincolnshire Trusts and Clinical Commissioning Groups to meet the national deadline for publication of April 1st 2013 (see page 2).**
- ***Epanutin* capsules (25mg, 50mg, 100mg and 300mg) were divested by Pfizer in September 2012 with an exact equivalent product now marketed by Flynn Pharma at a significantly higher price. All patients currently prescribed phenytoin sodium capsules generically in any strength can continue to receive generic scripts with no necessity to specify Flynn Pharma products. As Flynn Pharma is the only supplier to the marketplace at present, patients will automatically receive Flynn Pharma products in response to open generic scripts. The *Drug Tariff* reimbursement prices have been adjusted mid-month to reflect the Flynn Pharma list prices. Our understanding is that the Flynn Pharma product is identical to *Epanutin*, although the packaging may be different. The increased cost associated with moving from *Epanutin* to Flynn Pharma phenytoin is likely to be significant. Patients currently receiving scripts for branded *Epanutin* will need to be switched to generic phenytoin sodium capsules; as an identical product to Epanutin is the only product currently available to fill open generic scripts, this should create no problems in terms of changes in bioavailability between brand and generic (see page 3).**

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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 Lincolnshire website (www.lincolnshire.nhs.uk). Click on 'Commissioning' and follow the links to PACEF.

SUMMARY OF PACEF DECISIONS: *SEPTEMBER 2012 UPDATE*

Drug	Indication(s)	Traffic Light Status
Boceprevir capsules 200mg (*Victrelis*)	Licensed in combination with ribavirin and peginterferon alfa for chronic hepatitis C infection of genotype 1 in patients with compensated liver disease	RED
Cabazitaxel intravenous infusion (Jevtana)	Licensed in combination with prednisone or prednisolone for the treatment of hormone refractory metastatic prostate cancer in patients who have previously been treated with a docetaxol containing regimen.	RED-RED
Dasatinib tablets (Sprycel)	Licensed for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML.	RED-RED
Imatinib mesilate tablets 100mg and 400mg (Glivec)	Licensed for the treatment of chronic phase Philadelphia-chromosome-positive CML in adults	RED (standard dose only - 400 mg per day
Nilotinib capsules 150mg and 200mg (Tasigna)	Licensed for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML	RED
Telaprevir tablets 375mg (Incivo)	Licensed in combination with ribavirin and peginterferon alfa for chronic hepatitis C infection of genotype 1 in patients with compensated liver disease	RED

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.**

INNOVATION HEALTH AND WEALTH: ACCELERATING ADOPTION AND DIFFUSION IN THE NHS: IMPLICATIONS FOR JOINT FORMULARY DEVELOPMENT IN LINCOLNSHIRE

In December 2011, Sir David Nicholson, the Chief Executive of the NHS in England, published *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*. The report seeks to drive:

- Stronger NHS partnership with the pharmaceutical industry.
- More rapid adoption of new medicines, devices and technologies, specifically by ensuring more rapid and consistent implementation of NICE Technology Appraisals across the NHS.
- Reduction in variation between the best and the worst performing Trusts.
- Economic growth in the life sciences industry through accelerated adoption and diffusion of innovation across the NHS.

The report contains specific actions relating to NICE implementation including:

- Commitment to ensuring that NHS patients have access to clinically and cost-effective drugs and technologies and that NICE appraisal guidance is promptly delivered throughout the NHS.

- Emphasis on local formularies, particularly their role in supporting the timely and planned implementation of NICE Technology Appraisals (TAs).
- Emphasis on formulary processes that should proactively consider the impact of new NICE TAs and all NICE TA recommendations should. These should be automatically incorporated into local formularies where clinically appropriate. This process should take place within 90 days to support compliance with the 3 month funding direction and the NHS Constitution ensuring that these medicines are available for clinicians to prescribe, should they choose to, in a way that supports safe and clinically appropriate practice.

A subsequent letter from Dr Keith Ridge, the Chief Pharmaceutical Officer, to all Trust Chief Executive Officers (dated August 16th) has emphasized the need for all local NHS formularies to be published by 1st April 2013.

PACEF Recommendation:
PACEF have agreed to support the development of a single Joint Formulary for the whole of Lincolnshire primary and secondary care that will be published by the end of March 2013 and will enable all Lincolnshire Trusts and Clinical Commissioning Groups to meet the national deadline. There are a number of formularies already in use in Lincolnshire. Of these, the most comprehensive and most frequently updated is the United Lincolnshire Hospitals Trust Formulary. Some of the Lincolnshire CCGs and their constituent localities have also developed their own formularies. PACEF have previously supported the development of a formulary for Lincolnshire Community Health Services (LCHS). It is our intention to use all existing formularies as the constituent building blocks of a wider Joint Formulary utilizing the net formulary format currently used by ULH. We will provide updates on progress through PACEF and the *PACE Bulletin*. There should be no need for any CCG currently without a formulary to prioritise the development of their formulary to meet this deadline. At the same time, formulary processes will be put in place to ensure monthly updating in accordance with PACEF, ULH Drug and Therapeutics Committee and LPFT Medicines Management Committee decisions. All medicines supported by a favourable NICE TA will be incorporated into the formulary within 90 days of publication.

GUIDANCE ON THE PRESCRIBING OF PHENYTOIN SODIUM CAPSULES

Epanutin capsules (25mg, 50mg, 100mg and 300mg) were divested by Pfizer on 21st September 2012 with an exact equivalent product now marketed by Flynn Pharma. Our understanding is that the Flynn Pharma product will be identical to *Epanutin*, although the packaging may be different. At present Flynn Pharma supply the only range of phenytoin sodium capsules available in the UK; their products are the only products that can be supplied by a community pharmacist against a generic script for phenytoin sodium capsules.

The Department of Health have announced last minute changes to the October *Drug Tariff* reimbursement prices for phenytoin capsules after the hard copy *Tariff* itself was printed and distributed. The table below details the published October *Tariff* reimbursement prices alongside the amended prices changed to correspond to the Flynn Pharma list price.

	Published October *Tariff* Price (based on *Epanutin* price)	Amended October *Tariff* Price (based on Flynn Pharma price)
Phenytoin sodium capsules 25mg	£0.66 (28)	£15.74 (28)
Phenytoin sodium capsules 50mg	£0.67 (28)	£15.98 (28)
Phenytoin sodium capsules 100mg	£2.83 (84)	£67.50 (84)
Phenytoin sodium capsules 300mg	£2.83 (28)	£67.50 (28)

This means that community pharmacies dispensing generic prescriptions for phenytoin sodium capsules will be reimbursed against the revised Flynn Pharma *Tariff* price and not against the old *Epanutin* price. Prescribers will not need to endorse the script as 'Flynn' in order for the pharmacist to be paid full reimbursement price. This should resolve any concerns felt by community pharmacists that they would be out of pocket on every generic prescription for phenytoin sodium capsules that they dispensed. These prices will be formally incorporated into the *Tariff* as from November 2012 and are likely to increase phenytoin prescribing costs significantly. Current estimates are as high as £660,000pa across the county, although appeals to the Department of Health from PCTs across the country may result in some action being taken to resolve this anomaly sooner rather than later.

PACEF Recommendation:
***Epanutin* capsules (25mg, 50mg, 100mg and 300mg) were divested by Pfizer in September 2012 with an exact equivalent product now marketed by Flynn Pharma at a significantly higher price. All patients currently prescribed phenytoin sodium capsules generically in any strength can continue to receive generic scripts with no necessity to specify Flynn Pharma products. As Flynn Pharma is the only supplier to the marketplace at present, patients will automatically receive Flynn Pharma products in response to open generic scripts. The *Drug Tariff* reimbursement prices have been adjusted mid-month to reflect the Flynn Pharma list prices. Our understanding is that the Flynn Pharma product is identical to *Epanutin*, although the packaging may be different. The increased cost associated with moving from *Epanutin* to Flynn Pharma phenytoin is likely to be significant. Patients currently receiving scripts for branded *Epanutin* will need to be switched to generic phenytoin sodium capsules; as an identical product to Epanutin is the only product currently available to fill open generic scripts, this should create no problems in terms of changes in bioavailability between brand and generic**

NICE UPDATE

NICE TECHNOLOGY APPRAISAL 251: *DASATINIB, NILOTINIB AND STANDARD-DOSE IMATINIB FOR THE FIRST-LINE TREATMENT OF CHRONIC MYELOID LEUKAEMIA* (APRIL 2012)

Key Recommendations

Standard-dose imatinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML).

Nilotinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML if the manufacturer

makes nilotinib available with the discount agreed as part of the patient access scheme.

Dasatinib is not recommended for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML.

PACEF Recommendations: Imatinib mesilate tablets 100mg and 400mg (*Glivec*) are already designated RED at *standard dose* for the treatment of chronic phase Philadelphia-chromosome-positive CML in adults (see NICE TA241 and PACE Bulletin Vol 6 No 7 (May 2012)). *High-dose imatinib* is not recommended for the treatment of chronic, accelerated or blast-crisis phase Philadelphia-chromosome-positive CML that is resistant to standard-dose imatinib (see NICE TA241 and PACE Bulletin Vol 6 No 7 (May 2012)). Nilotinib capsules 150mg and 200mg (*Tasigna*) are designated RED for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML. Dasatinib tablets (*Sprycel*) are designated RED-RED for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML.

NICE TECHNOLOGY APPRAISAL 252: *TELAPREVIR FOR THE TREATMENT OF GENOTYPE 1 CHRONIC HEPATITIS C* (APRIL 2012)

Telaprevir in combination with peginterferon alfa and ribavirin is recommended as an option for the treatment of genotype 1 chronic hepatitis C in adults with compensated liver disease: (1) who are previously untreated or (2) in whom previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin has failed, including people whose condition has relapsed, has partially responded or did not respond.

PACEF Recommendation: Telaprevir tablets 375mg (*Incivo*) have already been approved and funded for this indication in anticipation of the NICE TA by the East Midlands Specialised Commissioning Group. Telaprevir tablets 375mg (*Incivo*) are designated RED for this indication.

NICE TECHNOLOGY APPRAISAL 253: *BOCEPREVIR FOR THE TREATMENT OF GENOTYPE 1 CHRONIC HEPATITIS C* (APRIL 2012)

Boceprevir in combination with peginterferon alfa and ribavirin is recommended as an option for the treatment of genotype 1 chronic hepatitis C in adults with compensated liver disease: (1) who are previously untreated or: (2) in whom previous treatment has failed.

PACEF Recommendation: Boceprevir capsules (*Victrelis*) have already been approved and funded for this indication in anticipation of the NICE TA by the East Midlands Specialised Commissioning Group. Boceprevir capsules 200mg (*Victrelis*) are designated RED for this indication.

NICE TECHNOLOGY APPRAISAL 255: *CABAZITAXEL FOR HORMONE-REFRACTORY METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A DOCETAXEL-CONTAINING REGIMEN* (MAY 2012)

Cabazitaxel in combination with prednisone or prednisolone is *not recommended* for the treatment of hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.

PACEF Recommendation: Cabazitaxel intravenous infusion (*Jevtana*) is designated RED-RED for this indication.

Acknowledgements

Many thanks to colleagues in the Prescribing and Medicines Optimisation Team who helped with the item on prescribing of phenytoin sodium capsules.

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