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 8; Number 4 **February 2014**

What's new this month?

- ***Bexsero*** **is the first vaccine authorised in the UK for immunisation against invasive meningococcal disease caused by *Neisseria meningitidis* group B. Following the publication of Public Health England guidance on the management of outbreaks of invasive meningococcal disease there may be a requirement for the vaccine to be prescribed on FP10 prescription for close contacts of cases following a request from a PHE consultant or nurse. The product may also be indicated in the same high risk groups that are currently offered ACWY conjugate vaccine. At present, meningococcal group B vaccine (*Bexzero*) is designated RED-RED, although this will be subject to change once PHE guidance is published (see page 3).**
- **Colecalciferol 20,000 IU tablet (*SunVit D3*) is classified as GREEN for the treatment of severe vitamin D deficiency (<25 nmol/l 25 hydroxyvitamin D) and approved for inclusion in the *Lincolnshire Joint Formulary*. Prescribers are strongly urged to prescribe approved colecalciferol products by brand as open generic prescriptions can prove to be very costly when filled with higher cost products or specials (see page 4).**
- **Modified release venlafaxine should be prescribed as one of the three *Formulary* approved products (*Depefex XL*, *Venaxx XL* or *Venlalic XL*); to maximize cost-effectiveness prescribers should specify the brand name of the product on the prescription (see page 6).**
- ***Fencino*, *Matrifen*, *Mezolar* and *Opiodur* are currently the lowest cost fentanyl patch formulations; all of these products are matrix patches, all are currently available and all are approved for inclusion in the *Joint Formulary*. Prescriptions for fentanyl patches should always specify the low cost brand required (see page 6).**
- **Ibandronic acid is now off patent and low cost generic 150mg tablets are available. Alendronic acid 70mg and risedronate 35mg are still preferred as first line options on the grounds of efficacy, safety and cost. Monthly ibandronate 150mg tablets can be considered second line where compliance with a weekly tablet is a problem and monthly administration is thought to be a possible solution. Monthly ibandronate is not recommended first line due to weaker evidence of non-vertebral and hip fracture reduction and greater cost (it is still three times the price of generic alendronic acid or risedronate). Following this review, ibandronic acid 150mg tablets have been re-classified as GREEN (see page 7).**
- **A new study provides evidence that anastrozole reduces the incidence of breast cancer in high risk postmenopausal women. NICE Clinical Guideline 164 currently recommends that tamoxifen or raloxifene are considered for women at moderate or high risk of breast cancer; the results of this study were not available to NICE at the time that the guideline was in preparation. There have been calls for NICE to reconsider their guidance in light of this study. Until such time, anastrozole is not recommended for use to prevent breast cancer in women at high risk (see page 7).**

CONTENTS

SUMMARY OF PACEF DECISIONS: *JANUARY 2014 UPDATE*

Drug	Indication(s)	Traffic Light and Joint Formulary Status
Anastrozole 1mg tablets	For chemoprevention in post-menopausal women at high risk of breast cancer who do not have a diagnosis of breast cancer. Anastrozole does not have a marketing authorisation for this indication.	RED-RED Not currently recommended for this unlicensed indication.
Bimatoprost/timolol 300microgram/ 5mg per ml eye drops (*Ganfort UD*)	For the reduction of intraocular pressure in adult patients with open angle glaucoma who are insufficiently responsive to topical beta-blocker or prostaglandin analogues and who have a proven allergy to preservatives.	AMBER No shared care. Approved for inclusion in the *Lincolnshire Joint Formulary*. Should only be used in genuine cases of hypersensitivity to the preservative or following corneal transplant surgery.
Canakinumab 150mg injection (*Ilaris*)	For use as monotherapy or with methotrexate for active systemic juvenile idiopathic arthritis when response to NSAIDs and systemic corticosteroids is inadequate.	RED-RED Not approved for inclusion in the *Lincolnshire Joint Formulary*.
Colecalciferol 20,000 IU tablets (*SunVitD3*)	For the treatment of severe vitamin D deficiency	GREEN Approved for inclusion in the *Lincolnshire Joint Formulary*. Colecalciferol products should be prescribed as low cost brands wherever possible to avoid unintentional use of high cost alternatives or specials.
Fentanyl patches 12/25/50/75/100 microgram per hour for 72 hours (*Fencino, Matrifen*, *Mezolar* and *Opiodur*)	For severe chronic pain.	GREEN Approved for inclusion in the *Lincolnshire Joint Formulary*.
Fluocinolone acetonide 190microgram intravitreal implant (*Iluvien*)	For the treatment of visual impairment due to chronic diabetic macular oedema when response to standard therapies is insufficient	RED. Approved for inclusion in the *Lincolnshire Joint Formulary*.
Ibandronic acid 150mg tablets (generic)	Treatment of postmenopausal osteoporosis.	GREEN. Approved for inclusion in the *Joint Formulary* as a second line option after alendronate and risedronate.
Meningococcal group B vaccine (*Bexzero*)	For active immunisation against invasive disease caused by Neisseria meningitides group B.	RED-RED Subject to review following publication of Public Health England

		guidance. Not approved for inclusion in the *Lincolnshire Joint Formulary*.
Raloxifene 60mg tablets (Evista)	For chemoprevention in post-menopausal women at moderate to high risk of breast cancer who do not have a diagnosis of breast cancer. Raloxifene does not have a marketing authorisation for this indication.	GREEN Second line alternative to tamoxifen 20mg tablets
Tamoxifen 20mg tablets	For chemoprevention in pre and post-menopausal women at moderate to high risk of breast cancer who do not have a diagnosis of breast cancer. Tamoxifen does not have a marketing authorisation for this indication.	GREEN First line
Venlafaxine modified release capsules 75mg and 150mg *(Depefex XL/Venaxx XL)*	For generalised anxiety disorder. For social anxiety disorder. For the treatment and prevention of major depressive episodes	GREEN Approved for inclusion in the *Lincolnshire Joint Formulary*.
Venlafaxine sustained release tablets 37.5mg, 75mg, 150mg and 225mg (*Venlalic XL*)	For generalised anxiety disorder. For social anxiety disorder. For the treatment and prevention of major depressive episodes	GREEN Approved for inclusion in the *Lincolnshire Joint 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 NHS in Lincolnshire website (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.

The *Lincolnshire Joint Formulary* is available on line and is fully searchable; it can be accessed at www.lincolnshirejointformulary.nhs.uk

NEW DRUG ASSESSMENT: *MENINGOCOCCAL GROUP B VACCINE (BEXSERO)*

Bexsero is the first vaccine authorised in the UK for immunisation against invasive meningococcal disease caused by *Neisseria meningitidis* group B. The Joint Committee on Vaccination and Immunisation (JCVI) have assessed the product and issued an interim position statement as follows:

- **Based on the current available evidence, there is not sufficient evidence to support the introduction of a routine infant/toddler or adolescent immunisation programme using *Bexsero*.**
- The efficacy of the vaccine against meningococcal carriage is highly uncertain, but under some scenarios adolescent immunisation might be cost effective.
- Public Health England is close to publishing guidance on the use of *Bexsero* for close contacts of cases in outbreaks of invasive meningococcal disease (IMD) associated with meningococcal serogroup B.
- *Bexsero* also has a role in the same high risk groups that are currently offered ACWY conjugate vaccine. It could also be offered to laboratory workers who are at high risk of occupational exposure to meningococcal serogroup B.

Following the publication of PHE guidance on the use of *Bexzero* in the management of outbreaks of IMD there may be some requirement for the vaccine to be prescribed on FP10 prescription for close contacts of cases following a request from a PHE consultant or nurse. An alternative supply route to support the use of the vaccine during outbreaks is also being explored, but will take time to establish; in the interim period, the FP10 route will be the only viable option.

In addition, the relevant 'Green Book' chapter is also being updated and will be published early in 2014.

A full version of the JCVI interim position statement can be accessed from https://www.gov.uk/government/publications/jcvi-interim-position-statement-on-the-use-of-bexsero-meningococcal-b-vaccine-in-the-uk

PACEF Recommendation

Bexsero* is the first vaccine authorised in the UK for immunisation against invasive meningococcal disease caused by *Neisseria meningitidis* group B. Following the imminent publication of Public Health England guidance on the management of outbreaks of invasive meningococcal disease there may be a requirement for the vaccine to be prescribed on FP10 prescription for close contacts of cases following a request from a PHE consultant or nurse. The product may also be indicated in the same high risk groups that are currently offered ACWY conjugate vaccine. At present, meningococcal group B vaccine (*Bexzero*) is designated RED-RED, although this will be subject to review once PHE guidance is published. Meningococcal group B vaccine (*Bexzero*) is not currently recommended for inclusion in the *Lincolnshire Joint Formulary.

RAPID DRUG ASSESSMENT: *BIMATOPROST/TIMOLOL 300MICROGRAM/5MG PER ML UNIT DOSE EYE DROPS (GANFORT UD)*

Bimatoprost/timolol 300microgram/5mg per ml eye drop (*Ganfort*) was approved for use by PACEF in November 2008 and designated AMBER. *Ganfort UD* is a new preservative-free formulation of the same product available in unit dose vials. The product has a marketing authorisation for the reduction of intraocular pressure in adult patients with open angle glaucoma who are insufficiently responsive to topical beta-blocker or prostaglandin analogues and who have a proven allergy to preservatives. Prescribing bimatoprost and timolol as separate preservative-free components is more costly that the *Ganfort UD* combination product.

PACEF Recommendation:

Ganfort UD is designated AMBER and approved for inclusion in the *Joint Formulary*. It should only be used in genuine cases of hypersensitivity to the preservative or following corneal transplant surgery.

RAPID DRUG ASSESSMENT: *COLECALCIFEROL 20,000 IU TABLETS (SUNVIT D3)*

The table below summarizes PACEF guidance on the treatment of vitamin D deficiency. One of the approved doses for severe deficiency is 20,000 units three times a week necessitating the availability of colecalciferol 20,000 IU tablets on the *Joint Formulary*.

Level of deficiency	25 hydroxyvitamin D level	Recommended treatment
Severe deficiency (associated with osteomalacia including rickets in children and osteoporosis and fractures in adults)	**<25 nmol/l 25 hydroxyvitamin D**	**Prescribe 60,000 units weekly of colecalciferol for 12 weeks (either as a single weekly dose or 20,000 units three times a week).**
Deficiency associated with disease risk	25-50 nmol/l 25 hydroxyvitamin D	Prescribe 800-1600 units of colecalciferol daily for 12 weeks
Insufficiency	50-75nmol/l 25 hydroxyvitamin D	Consider lifestyle advice including: increased dietary intake and safe sun exposure. Refer to PACEF guidance on the prevention of vitamin D insufficiency
Replete	>75nmol/l 25 hydroxyvitamin D	No treatment necessary

SunVit D3 is a new colecalciferol 20,000 IU tablet. A cost comparison with already approved PACEF products reveals that *SunVit D3* is comparably priced and is free from gelatin, soya and peanut oil:

Product	Dose of colecalciferol IU	Cost (£)
SunVitD3 Free from gelatin, soya, and peanut oil. Suitable for vegetarians.	20,000	£17.99 (28)
PACEF approved brands containing 20,000 IU colecalciferol		
Aciferol D3 Free from gelatin, soya, and peanut oil. Suitable for vegetarians.	20,000	£18.99 (30)
Biovitamin D3 Contains gelatin (bovine) Free from soya and peanut oil.	20,000	£13.95 (30)
Pro-D3 Free from gelatin, soya, and peanut oil. Suitable for vegetarians.	20,000	£19.99(30)

PACEF Recommendation

Colecalciferol 20,000 IU tablets (*SunVit D3*) are classified as GREEN for the treatment of severe vitamin D deficiency (<25 nmol/l 25 hydroxyvitamin D) (see table) and approved for inclusion in the *Lincolnshire Joint Formulary*. Prescribers are strongly urged to prescribe approved colecalciferol products by brand as open generic prescriptions can prove to be very costly when filled with higher cost products or specials. An updated version of PACEF guidance on the treatment of vitamin D deficiency will be published soon.

JOINT FORMULARY UPDATE

4.3.4 *Other antidepressant drugs*

Venlafaxine Modified Release Formulations

Following a review of comparative prices and product availability, the following modified release venlafaxine formulations have been approved for inclusion in the *Lincolnshire Joint Formulary*:

- *Depefex XL* 75mg and 150mg capsules (Chiesi Ltd)
- *Venaxx XL* 75mg and 150mg capsules (Mercury Pharma)
- *Venlalic XL* 37.5mg, 75mg, 150mg and 225mg tablets (DP Ashbourne)

PACEF Recommendation:
Modified release venlafaxine should be prescribed as one of the three *Formulary* approved products (*Depefex XL*, *Venaxx XL* or *Venlalic XL*); to maximize cost-effectiveness prescribers should specify the brand name of the product on the prescription.

4.7.2 *Opioid analgesics*

Fentanyl patches

Cost Comparison for 5 patches

Patches	12 microgram per hour for 72 hours	25 microgram per hour for 72 hours	50 microgram per hour for 72 hours	75 microgram per hour for 72 hours	100 microgram per hour for 72 hours
Fencino	**£8.46**	**£12.10**	**£22.62**	**£31.54**	**£38.88**
Fentalis	n/a	£26.94	£50.32	£70.15	£86.46
Matrifen	**£8.87**	**£12.68**	**£23.69**	**£33.03**	**£40.71**
Mezolar	**£8.87**	**£12.68**	**£23.69**	**£33.03**	**£40.71**
Opiodur	**£8.48**	**£12.12**	**£22.64**	**£31.56**	**£38.90**
Osmanil	£18.11	£26.94	£50.32	£70.15	£86.46
Tilofyl	n/a	£27.00	£51.00	£71.00	£88.00
Victanyl	n/a	£17.18	£32.94	£38.94	£56.94
Durogesic DTrans	£12.59	£17.99	£33.66	£46.99	£57.86

PACEF Recommendation:
***Fencino, Matrifen*, *Mezolar* and *Opiodur* are currently the lowest cost fentanyl patch formulations; all of these products are matrix patches, all are currently available and all are approved for inclusion in the *Joint Formulary*. Prescriptions for fentanyl patches should always specify the low cost brand required.**

6.6.2. *Bisphosphonates and other drugs affecting bone metabolism*

Ibandronic acid 150mg tablets

Drug	Dose	Cost (28 days)
Alendronic acid 70mg tablets (generic)	70mg once weekly	£0.90
Ibandronic acid 150mg tablets (generic)	150mg once a month	£3.02
Risedronate sodium 35mg tablets (generic)	35mg once weekly	£1.16

PACEF Recommendation:
Ibandronic acid is now off patent and low cost generic 150mg tablets are available. Alendronic acid 70mg and risedronate 35mg are still preferred as first line options on the grounds of efficacy, safety and cost. Monthly ibandronate 150mg tablets can be considered second line where compliance with a weekly tablet is a problem and

monthly administration is thought to be a possible solution. Monthly ibandronate is not recommended first line due to weaker evidence of non-vertebral and hip fracture reduction and greater cost (it is still three times the price of generic alendronic acid or risedronate). Following this review, ibandronic acid 150mg tablets are re-classified as GREEN. They are approved for inclusion in the *Joint Formulary* as a second line option after alendronate and risedronate. A review of the evidence base comparing ibandronic acid with alendronate and risedronate first appeared in *PACE Bulletin* Vol 3 No 10 (October 2009).

NEW TRIAL ASSESSMENT

ANASTROZOLE FOR THE PREVENTION OF BREAST CANCER IN HIGH RISK POST-MENOPAUSAL WOMEN

This placebo controlled, double-blind randomized controlled trial was designed to investigate the efficacy and safety of anastrozole 1mg daily in the prevention of breast cancer in 3864 postmenopausal women at high risk. After a median follow up of 5 years, 40 (2%) women in the anastrozole group and 85 (4%) in the placebo group had developed breast cancer (hazard ratio 0.47). Adverse effects were common in both groups and the overall incidence did not differ. The incidences of musculoskeletal and vasomotor side effects, hypertension and dry eyes were statistically significantly higher in the anastrozole group.

PACEF Comment:
This study provides evidence that anastrozole reduces the incidence of breast cancer in high risk postmenopausal women. The reported reduction is high; 53% reduction in relative risk or 2% reduction in absolute risk. This is higher than that reported with tamoxifen which has been shown to reduce the relative risk by 35% compared to placebo. NICE Clinical Guideline 164 currently recommends that tamoxifen or raloxifene are considered for women at moderate or high risk of breast cancer; the results of this study were not available to NICE at the time that the guideline was in preparation. There have been calls for NICE to reconsider their guidance in light of this study. Until such time, anastrozole is not recommended for use to prevent breast cancer in women at high risk.

Reference
Cuzick J, et al. Anastrozole for prevention of breast cancer in high risk postmenopausal women (IBIS-II): an international, double-blind, randomised placebo-controlled trial. *Lance*t 12 Dec 2013; doi:10.1016/S0140-6736(13062292-8).

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY: *DRUG SAFETY UPDATE* (NOVEMBER 2013)

MEFLOQUINE: STRENGTHENED WARNINGS ON NEUROPSYCHIATRIC SIDE EFFECTS

Although the potential for neuropsychiatric side effects with mefloquine is well-established, a recent review has led to strengthened warnings and new measures to minimise these risks. Updated information and advice for healthcare professionals is as follows:

- Psychiatric symptoms associated with the use of mefloquine such as nightmares, acute anxiety, depression, restlessness or confusion could be regarded as potentially prodromal for a more serious event.
- Cases of suicide, suicidal thoughts and self-endangering behaviour such as attempted suicide have been reported in association with mefloquine.
- Adverse reactions may occur and persist up to several months after discontinuation because of the long half-life of the drug. In a small number of patients, dizziness or

vertigo and loss of balance have been reported to continue for months after discontinuation.

- To minimise the risk of these adverse reactions, mefloquine must not be used for chemoprophylaxis in patients with active or a history of psychiatric disturbances such as depression, anxiety disorders, schizophrenia, or other psychiatric disorders.
- If neuropsychiatric reactions or changes to mental state occur during mefloquine chemoprophylaxis, the patient should be advised to stop taking mefloquine and seek medical advice as soon as possible so that it can be replaced by another medicine for malaria prevention

Roche, the marketing authorisation holder of *Lariam*, has produced copies of a prescriber checklist and patient alert card to aid compliance with these warnings. Copies are available to order from Hercules Mailing House, 0870 325 6666, malaria@hercules.uk.com

SODIUM VALPROATE: RISK OF NEURODEVELOPMENT DELAY IN CHILDREN FOLLOWING MATERNAL USE

There is new evidence on neurodevelopmental delay in children following maternal use of sodium valproate; emerging data suggest that these risks may be independent of maternal confounders. A European review is underway to evaluate all available evidence on the association between fetal valproate exposure and neurodevelopmental delay or autism spectrum disorder.
In the meantime healthcare professionals are reminded of the following advice:

- Sodium valproate should not be used during pregnancy and in women of childbearing potential unless clearly necessary.
- Women of childbearing potential should not start treatment with sodium valproate without specialist neurological or psychiatric advice, as appropriate.
- Adequate counselling should be made available to all women of childbearing potential to weigh the risk of teratogenic and neurodevelopmental effects against the benefits of treatment.
- In the management of bipolar disorders cessation of sodium valproate treatment should be considered if there is an effective alternative.
- If sodium valproate is to be used during pregnancy the lowest effective dose is recommended divided over the day or as controlled-release tablets to avoid rapid peaks in plasma levels.
- Folate supplementation should be started before pregnancy as appropriate.
- Specialist prenatal monitoring should be instigated to detect possible occurrence of neural tube defects or other malformations when valproate has been used.

RISPERIDONE AND PALIPERIDONE: RISK OF INTRAOPERATIVE FLOPPY IRIS SYNDROME IN PATIENTS UNDERGOING CATARACT SURGERY

Cases of intraoperative floppy iris syndrome (IFIS) during cataract surgery have been reported in people taking risperidone or paliperidone. IFIS occurs as a result of blockade of alpha 1 receptors in the iris dilator muscles and may increase the risk of eye complications during and after cataract surgery. Risperidone and paliperidone are antipsychotic agents with alpha 1 receptor blocking activity. IFIS has been previously described in association with alpha 1 receptor blockers, particularly tamsulosin.

Advice for health care professionals:

- GPs should document the use of alpha 1 blockers – including risperidone and paliperidone – when making a referral for cataract surgery.
- When taking a medication history before cataract surgery, patients should be questioned about current or past use of risperidone or paliperidone

- Cataract surgeons should approach surgery with caution in people with such a medication history. If IFIS is suspected, measures to prevent the iris from prolapsing during surgery may be required
- The potential benefit of stopping risperidone or paliperidone before cataract surgery on the risk of IFIS has not been established and must be weighed against the risk of stopping antipsychotic therapy

MEDICINES AND HEALTHCARE REGULATORY AGENCY: *DRUG SAFETY UPDATE* (DECEMBER 2013)

RITUXIMAB: SCREEN FOR HEPATITIS B VIRUS BEFORE TREATMENT

A recent review has shown that rituximab has been associated with reactivation of hepatitis B virus when used to treat rheumatoid arthritis or cancers. Cases included fulminant hepatitis, some of which were fatal.
Advice for healthcare professionals:

- Screening for hepatitis B virus is now recommended in all patients (not only those at risk of this infection) before starting treatment for all indications.
- Patients with active hepatitis B disease should not be treated with rituximab.
- A patient with positive serology for hepatitis B virus should be referred to a specialist in liver disease before starting treatment with rituximab.
- Please report suspected adverse reactions occurring with rituximab on a Yellow Card (www.mhra.gov.uk/yellowcard).

CLOPIDOGREL: RISK OF ACQUIRED HAEMOPHILIA

Twelve cases of acquired haemophilia have been reported in association with clopidogrel. Six cases resolved after stopping clopidogrel and corrective treatment; 2 cases were considered life threatening. This very rare but serious condition may be missed due to the established risk of bleeding associated with clopidogrel treatment.

Advice for healthcare professionals:

- Be aware of the risk of acquired haemophilia in association with clopidogrel
- Prompt diagnosis is required to minimise the time the patient is at risk of bleeding and to avoid major bleeding
- Acquired haemophilia should be considered in the event of isolated prolonged aPTT (activated partial thromplastin time)
- Patients with confirmed acquired haemophilia should be managed by specialists, and clopidogrel should be discontinued. Invasive procedures should be avoided.

DORZOLAMIDE HYDROCHLORIDE / TIMOLOL (COSOPT) PRESERVATIVE FREE SINGLE DOSE EYE DROPS: REPORTS OF EYE INJURY

There have been 69 complaints in the UK related to this product after the introduction of a new design of dropper in July 2013. These complaints include scratches to the cornea and difficulty in administration of the drops onto the eye. After opening the single dose unit, a wing of plastic extends from the administration tip and any tiny pieces of plastic attached to this wing may increase the risk of eye injury. Patients using these drops may be experiencing problems administering the drops and may benefit from additional education in the safe self-administration of eye drops. A new dropper will be introduced early in 2014.

NICE TECHNOLOGY APPRAISAL TA301: *FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT FOR TREATING CHRONIC DIABETIC MACULAR OEDEMA AFTER AN INADEQUATE RESPONSE TO PRIOR THERAPY* (NOVEMBER 2013)

Fluocinolone acetonide intravitreal implant is recommended as an option for treating chronic diabetic macular oedema that is insufficiently responsive to available therapies only if:

- the implant is to be used in an eye with an intraocular (pseudophakic) lens **and**
- the manufacturer provides fluocinolone acetonide intravitreal implant with the discount agreed in the patient access scheme.

PACEF Recommendation:
Fluocinolone acetonide 190microgram intravitreal implant (*Iluvien*) was originally designated RED-RED for this indication in response to Technology Appraisal 271. Following this re-appraisal, *Iluvien* is designated RED for the treatment of visual impairment due to chronic diabetic macular oedema when response to standard therapies is insufficient. It is approved for inclusion in the Joint Formulary for this indication.

NICE TECHNOLOGY APPRAISAL TA302: *CANAKINUMAB FOR TREATING SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS* (TERMINATED APPRAISAL) (NOVEMBER 2013)

NICE is unable to make a recommendation about the use in the NHS of canakinumab for systemic juvenile idiopathic arthritis because no evidence submission was received from the manufacturer of the technology.

PACEF Recommendation: Canakinumab 150mg injection (*Ilaris*) is not recommended as monotherapy or with methotrexate for active systemic juvenile idiopathic arthritis when response to NSAIDs and systemic corticosteroids is inadequate. It is designated RED-RED for this indication and not approved for inclusion in the *Joint Formulary*.

Acknowledgements

Many thanks to Cathy Johnson, Interface Lead Pharmacist, GEM CSU, Gill Kaylor, Prescribing Adviser, GEM CSU, Robyn Thompson, Senior Pharmacist, ULH, Shiraz Haider, Chief Pharmacist, LPFT, Richard Glet, Prescribing Adviser, GEM CSU, Kerryn Marriott, Delivery and Project Manager, GEM CSU for their help in the compilation of this *Bulletin*.

Stephen Gibson
Head of Prescribing and Medicines Optimisation (Clinical Services and Strategy)
GEM CSU

February 2014