Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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

Summary of PACEF decisions from August 2017

PACE Short (Vol 11 No 11)

Device, Dressing or Drug	Indication(s)	Traffic Light and *Joint Formulary* Status
Rituximab (Truxima®) 500mg vial concentrate for solution for infusion.	Truxima® is licensed for intravenous use in adults with: • rheumatoid arthritis • granulomatosis with polyangiitis and microscopic polyangiitis • non-Hodgkin's lymphoma (NHL) • chronic lymphocytic leukaemia (CLL)	Red Approved for use within ULHT initially for treatment of rheumatoid arthritis as an alternative to MabThera®.

Other news

Prescribing specialist Infant Formulae – quick reference guide

Revised guideline for the diagnosis and treatment of cow's milk protein allergy and lactose intolerance.

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

Denosumab (Prolia, Xgeva) Reports of osteonecrosis of the external auditory canal

Brimonidine gel (Mirvaso) risk of systemic cardiovascular effects, not to be applied to broken or damaged skin.

E cigarettes and refill containers. Report suspected side effects and safety concerns

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Rapid Drug Assessment Rituximab (Truxima®) 500mg vial concentrate for solution for infusion.

Following the expiry of rituximab patent the first biosimilar version of rituximab, Truxima®, was approved for use in Europe in February 2017 and was launched in the UK in April 2017. Truxima® holds the same licensed indication as MabThera®, which is the originator molecule and is listed in the Lincolnshire Joint Formulary as 'for restricted use' for rheumatoid arthritis.

- Truxima has been classed as a RED hospital only drug and all prescribing, supply and monitoring of patients will remain the responsibility of hospital based specialists.
- The rheumatology department will be responsible for all initiations of new treatments and the review of patients receiving therapy with MabThera.

Quick reference guide - Prescribing Specialist Infant Formulae

The Optum Medicine Management and Optimisation service in partnership with ULHT dieticians have produced a quick reference guide which incorporates the advice originally published in PACE Bulletin Vol 11 No 3.

- The guide provides information on what the presenting symptoms are for suspected cow's milk protein allergy (CMPA), Gastro-oesophageal reflux disease (GORD), and lactose intolerance.
- Advice is given on initial management of the condition and which formulae to prescribe.
- The guide also provides information on the "red flag "symptoms which require immediate referral to secondary care.
- A copy of the guideline will be displayed on the PACEF website http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-pacef

Revised Guideline for the Diagnosis and Treatment of Cows Milk Protein Allergy and Lactose Intolerance.

United Lincolnshire Hospital Trust Paediatric Service has published a revised edition of the above guidance. Changes include more details regarding the different mediation of cow's milk protein allergy, prescribing of specialist formulae and further information as to when it is appropriate to refer to secondary care hosted services.

The document is intended to provide guidance on the following:

- Diagnosis of cow's milk allergy and lactose intolerance
- Guidance on the choice of the correct formulae to prescribe or recommend
- Details on the length of time formulae should be prescribed.
- When to refer for specialist dietary advice or secondary care advice
- Guidance on management of breast feeding babies/infants who present with symptoms of cow's milk protein allergy.
- Cost comparison tables are also provided to guide choice of product.

A copy of the guideline will be displayed on the PACEF website http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-pacef

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

Denosumab (Prolia, Xgeva) Reports of osteonecrosis of the external auditory canal

The MHRA have updated their advice on the risk of osteonecrosis of the external auditory canal associated with Denosumab (Prolia, Xgeva) therapy.

Denosumab is currently classed as RED (hospital only drug) in Lincolnshire although there may be some prescribing within Lincolnshire supported with shared care protocols from other NHS Trusts.

The MHRA has updated it advice to health care professionals:

Advice for healthcare professionals:

- The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving denosumab who present with ear symptoms including chronic ear infections or in those with suspected cholesteatoma.

- Possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma.
- Advise patients to report any ear pain, discharge from the ear, or an ear infection during denosumab treatment.
- Report any cases of osteonecrosis of any bone suspected to be associated with denosumab or any other medicine on a yellow card.

Brimonidine gel (Mirvaso) risk of systemic cardiovascular effects, not to be applied to broken or damaged skin.

Systemic cardiovascular effects including bradycardia, hypotension and dizziness have been reported after application.

Brimonidine gel is classed as Amber 2 on the Lincolnshire formulary.

The MHRA has issued the following advice to health care professionals:

- Cases of bradycardia, hypotension (including orthostatic hypotension) and dizziness after application of brimonidine gel have been reported, some of which require hospitalisation.
- Some cases were associated with application of brimonidine gel after laser procedures to the skin caused increased absorption of the gel
- Warn patients not to apply brimonidine gel to irritated or damaged skin, including after laser therapy to the skin.

e-cigarettes and refill containers: report suspected side effects and safety concerns

MHRA have issued a reminder that healthcare professionals and members of the general public should report any suspected side effects or safety concerns associated with e-cigarettes and the e-liquids used for vaping.

NICE Update

NICE Technology Appraisal	Guidance	PACEF recommendation
TA 446 Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma	Brentuximab vedotin is recommended as an option for treating CD30‑positive Hodgkin lymphoma in adults if certain criteria are met. Brentuximab vedotin is recommended for use within the Cancer Drugs Fund as an option for treating CD30‑positive Hodgkin lymphoma in adults, only if certain criteria are met.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.
NICE TA 447 Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer	Pembrolizumab is recommended for use within the Cancer Drugs Fund as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer in adults, if certain criteria met.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.
NICE TA 448 Etelcalcetide for treating secondary hyperparathyroidism Technology appraisal guidance	Etelcalcetide is recommended as an option for treating secondary hyperparathyroidism in adults with chronic kidney disease on haemodialysis, only if: •treatment with a calcimimetic is indicated but cinacalcet is not suitable and •the company provides etelcalcetide with	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication.

	the discount agreed in the patient access scheme	
NICE TA 449 Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease	Everolimus and sunitinib are recommended, within their marketing authorisations, as options for treating well- or moderately differentiated unresectable or metastatic neuroendocrine tumours (NETs) of pancreatic origin in adults with progressive disease. 1.2 Everolimus is recommended, within its marketing authorisation, as an option for treating well-differentiated (grade 1 or grade 2) non-functional unresectable or metastatic NETs of gastrointestinal or lung origin in adults with progressive disease. 1.3 Everolimus is recommended only when the company provides it with the discount agreed in the patient access scheme.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication
NICE TA 450 Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia	Blinatumomab is recommended within its marketing authorisation as an option for treating Philadelphia-chromosome-negative relapsed or refractory precursor B-cell acute lymphoblastic leukaemia in adults, only if the company provides it with the discount agreed in the patient access scheme.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication
NICE TA 451 Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia June 2017	Ponatinib is recommended, within its marketing authorisation, as an option for treating chronic-, accelerated- or blast-phase chronic myeloid leukaemia in adults when certain criteria are met. Ponatinib is recommended, within its marketing authorisation, as an option for treating Philadelphia-chromosome-positive acute lymphoblastic leukaemia in adults when certain criteria are met.	Designated RED and approved for use through the Lincolnshire Joint Formulary for this indication

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