Prescribing Information Newsletter Mass October 2019, Number 77



Summary of the Key Recommendations from The Bedfordshire and Luton Joint Prescribing Committee (JPC) 18th September 2019

(Incorporates Joint Formulary Amendments)

Bedfordshire Clinical Commissioning Group Luton Clinical Commissioning Group

Unless otherwise stated, the new/updated documents referred to within the Newsletter will shortly be available on GP Ref and Microguide (also available as a Microguide App).

PRIMARY CARE OR INTERFACE PRESCRIBING ISSUES

TREATMENT GUIDELINES

COPD/ACO GUIDELINE AND ICS REVIEW PROTOCOL

UPDATED

The guidelines have been reviewed and updated following the update of the NICE COPD Guideline to include triple therapy. In addition, the guidelines have been amended to reflect agreed Formulary Inhaler changes (See JPC Bulletin section, for full details).

ASTHMA GUIDELINES

UPDATED

The Asthma Guidelines have been updated to include the use of Relvar®Ellipta® (Fluticasone/vilanterol) as a 1st line option for teenage patients where compliance is a problem. (See JPC Bulletin Section – Bulletin 282)

SHARED CARE GUIDELINES AND TREATMENT PATHWAYS

GLUCAGON-LIKE PEPTIDE 1 (GLP-1) RECEPTOR AGONIST SHARED CARE GUIDELINE UPDATE

UPDATED

The shared care guidelines have been revised to incorporate the Formulary changes (addition of Semaglutide and removal of Lixisenatide and the twice daily preparation of Exenatide) agreed at the June 2019 JPC meeting and the drug fact sheets updated.

SHARED CARE/TRANSFER OF CARE GUIDELINES FOR THE TREATMENT OF DEMENTIA (BCCG/LCCG PATIENTS)

UPDATED

The shared care/transfer of guideline has been extended to include (in addition to Alzheimer's Disease Dementia) Lewy Body Dementia, Parkinson's Disease Dementia. While the majority of the information relates to the use of these drugs for both BCCG and LCCG patients, as the CCGs have

a slightly different commissioning position (with the provider ELFT), GPs are advised to consult the guideline before prescribing.

LANTHANUM AND SEVELAMER SHARED CARE GUIDELINES

UPDATED

These shared care guidelines are produced by the renal unit at East and North Herts Trust and ratified for use locally by the JPC. The updated versions of the documents were ratified by the Committee.

JPC BULLETINS/FACT SHEETS

BULLETIN 277: Safinamide for Parkinson's Disease NEW The JPC decided not to support the Formulary application for safinamide. The main concerns were the lack of head to head trials with appropriate comparators, safety issues (e.g. retinopathy) and cost/cost-effectiveness.

BULLETIN 278: Umeclidinium bromide (Incruse®Ellipta®) for COPD - (LAMA) - Formulary addition - 2nd choice option

NEW

BULLETIN 279:Umeclidinium/vilanterol (Anora®Ellipta®) for COPD - (LAMA/LABA) - Formulary addition - 2nd choice option

NEW

BULLETIN 280: Fluticasone/vilanterol (Relvar®Ellipta®) FOR COPD - (ICS/LABA) - Formulary addition - 1st choice option

NEW

BULLETIN 281: Fluticasone/umeclidinium/vilanterol (Trelegy®92 microgram/55 microgam/22 microgram)- FOR COPD - Formulary addition - ICS/LAMA/LABA (Triple therapy) - joint first-line option

NEW

BULLETIN 282: Fluticasone/vilanterol (Relvar®Ellipta®) FOR ASTHMA - Formulary addition - 1ST choice option in teenage patients where compliance is a problem.

NEW

BULLETIN 283: Doxylamine succinate and pyridoxine for nausea and vomiting in pregnancy - The Committee ratified the EoEPAC Bulletin and the following interim recommendations:-

NEW

- Prescribing of doxylamine and pyridoxine (Xonvea®) for nausea and vomiting in pregnancy is NOT recommended in primary care.
- There is insufficient information for clinical superiority or cost effectiveness for doxylamine and pyridoxine in comparison with other recognised non-pharmacological and pharmacological ways to manage nausea and vomiting in pregnancy.
- Patients presenting with nausea and vomiting in pregnancy should be managed in line with current Royal College of Obstetricians and Gynaecologists (RCOG) guidelines.
- These recommendations will be reviewed in the light of new evidence and/or publication of new national guidance (including from the RCOG and the RMOCs).

 Drug Monitoring Fact Sheet for Aminosalicylates in IBS in Primary Care (Update) - This document has been revised as part of the general updating of JPC documents.



NICE GUIDANCE ISSUED/UPDATED

CCG Commissioned Technology Appraisals/Guidance considered by the JPC

- <u>Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uvetitis</u>, Technology appraisal guidance [TA590]
- Risankizumab for treating moderate to severe plaque psoriasis, Technology appraisal guidance [TA596]
- Dapagliflozin with insulin for treating type 1 diabetes, Technology appraisal guidance [TA597]
- Sodium zirconium cyclosilicate for treating hyperkalaemia, Technology appraisal guidance [TA599]
- Chronic obstructive pulmonary disease in over 16s: diagnosis and management, NICE guideline [NG115]
- Hypertension in adults: diagnosis and management, NICE guideline [NG136]: for NICE Visual Summary (Diagnosis and Treatment) click here

Key Messages:

- 1. Diagnosing hypertension
 - a. CV risk assessment lower risk patients now have treatment options
 - b. Clarification of blood pressure monitoring
- 2. Starting antihypertensive drug treatment
 - a. Patient decision aid to help discussions and decisions
 - b. Monotherapy as initial option for all
- 3. Monitoring treatment and blood pressure targets
 - a. Emphasis on maintaining blood pressure below target
 - b. Blood pressure targets are the same for all patients, including those with type 2 diabetes
- 4. Choosing antihypertensive drug treatment (treatment steps 1 to 4)
 - a. Minor changes in drug options
- 5. Who to refer for same-day specialist review.

SAFETY UPDATE

Drug Safety Updates (DSU) and Patient Safety Alerts

The MHRA Drug Safety Update for June, July and August 2019 and HRT paper were noted by the Committee for information and action.

June 2019 DSU

 Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome

- GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued
- Lartruvo▼ (olaratumab): withdrawal of the EU marketing authorisation due to lack of efficacy
- Oral retinoid medicines ▼: revised and simplified pregnancy prevention educational materials for healthcare professionals and women

July 2019 DSU

- Febuxostat (Adenuric): increased risk of cardiovascular death and all-cause mortality in clinical trial in patients with a history of major cardiovascular disease
- Tocilizumab (RoActemra): rare risk of serious liver injury including cases requiring transplantation
- Rivaroxaban (Xarelto ▼): reminder that 15 mg and 20 mg tablets should be taken with food

August 2019 DSU

- Daratumumab (Darzalex ▼): risk of reactivation of hepatitis B virus
- Naltrexone/bupropion (Mysimba ▼): risk of adverse reactions that could affect ability to drive
- Carfilzomib (Kyprolis ▼): reminder of risk of potentially fatal cardiac events

MHRA Drug Safety Update

Article published 30 August 2019, in advance of the next issue of Drug Safety Update <u>Hormone replacement therapy (HRT)</u>: further information on the known increased risk of breast cancer with HRT and its persistence after stopping

New data have confirmed that the risk of breast cancer is increased during use of all types of HRT, except vaginal estrogens, and have also shown that an excess risk of breast cancer persists for longer after stopping HRT than previously thought.

Prescribers of HRT should discuss the updated total risk with women using HRT at their next routine appointment.

SECONDARY CARE PRESCRIBING / COMMISSIONING ISSUES

SEVERE PSORIASIS PATHWAY

The pathway has been updated to include the use of Risankizumab (NICE TA596).

UPDATED

INFLAMMATORY BOWEL DISEASE BIOLOGIC TREATMENT PATHWAYS

NEW

The following biologic treatment pathways were supported by the JPC:-

- Crohn's Disease
- Ulcerative Collitis

OPHALMOLOGY PATHWAY UPDATE

The pathway is currently being updated to include the use of Fluocinolone acetonide intravitreal implant (NICE TA590)

Additional Papers / issues considered by the Committee REGIONAL MEDICINES OPTIMISATION COMMITTEES

The Committee was asked to note for information, the following documents that have been issued by RMOCs since the papers for the June JPC meeting were circulated:-

Regional Medicines Optimisation Committee Newsletter Issue 5 2019

Rarely Used and Urgent Medicines List

This position statement and user guide have been approved by RMOC (London).

The position statement includes a list of Rarely Used and Urgent Medicines. The list indicates which medicines should be stocked locally, and which could be obtained via other methods when the need arises.

There is a "How To" guide to support pharmacy staff to access Rx-info's Define system in order to identify which local Trusts have recently issued medicines included in this list.

RMOC briefing on adalimumab - July 2019

Biosimilar versions of the original biological medicine adalimumab (brand name Humira®) have been introduced in the NHS as part of a formal framework agreement dated 1 December 2018, after the patent for Humira® expired in October 2018. This briefing provides important details for ongoing implementation of best value adalimumab products.

Regional Medicines Optimisation Committee Newsletter Issue 6 2019

Forthcoming 2019 JPC Meetings

Wednesday 4th December

For information on agenda items scheduled for the prospective meetings above and/or if you would like to be included in the consultation for these and/or future agenda items please contact the JPC medicines management team: jacqueline.clayton@nhs.net or sandra.mcgroarty@nhs.net

OTHER NEWS

Use of Scriptswitch/Optimise Rx

To further enhance the communication of JPC advice to GPs, BCCG and LCCG medicine management Teams are actively reviewing the messages to NetFormulary/Scriptswitch and Optimise Rx to highlight when JPC guidance is available and including a hyperlink to the GP Ref website.

Contact Us:- iacqueline.clayton@nhs.net and sandra.mcgroarty@nhs.net

FORMULARY UPDATE

The Bedfordshire and Luton Joint Formulary (a combined medicines formulary for use by BCCG, LCCG, Bedford Hospital and the Luton and Dunstable University Hospital) is now 'live'. It can currently be accessed <u>here</u>

FORMULARY ADDITIONS:- In addition to the inhalers outlined in the JPC Bulletins and other items outlined in CCG Commissioned NICE Guidance Sections (see above), the following additions to the Formulary were noted or ratified by the JPC:

NICE Technology Appraisal Guidance - New Drugs added

- Ocrelizumab for treating primary progressive multiple sclerosis [TA585]
- Blinatumomab for treating acute lymphoblastic leukaemia in remission with minimal residual disease activity [TA589]
- Letermovir for preventing cytomegalovirus disease after a stem cell transplant [TA591]
- Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma [TA592]
- Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer [TA593]
- Dacomitinib for untreated EGFR mutation-positive non-small-cell lung cancer [TA595]
- Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy [TA598]

DTC decisions

- **Letrozole:** approved for off label use in polycystic ovary syndrome at L and D hospital DTC in July 2019 **Hospital only**
- Trometamol (THAM): retrospective addition at L and D hospital DTC in July 2019, kept in emergency drug room for metabolic acidosis in paediatrics under the advice of a tertiary centre – Hospital only
- Cetraxel Plus ® (ciprofloxacin and fluocinolone acetonide): for treatment of otitis externa and otitis media approved by Bedford Hospital DTC Hospital only

Items agreed virtually by the Joint Formulary Group

- Biktarvy® (Bictegravir-emtricitabine-tenofovir alafenamide (B/F/TAF)) for treating Human immunodeficiency virus-1 (HIV-1) in adults. Commissioned by NHSE
- Testosterone products have been added to the formulary in line with gender dysphoria SCG and status changed to amber
- Lanreotide RAG status amended to amber
- Sun creams updated prescribing criteria added
- **Degaralix** changed to amber
- Menopur multidose formulation added

FORMULARY (RESTRICTED USE)

Safety Needles to be made available by GP prescription **only** for patients who cannot self-inject and require a carer (not a healthcare professional) to administer the insulin.

FORMULARY DELETIONS:-

Bath and shower preparations for dry and pruritic skin conditions – all products to be removed. "Leave-on" emollients to be used instead in line with national guidance.

Insulin pen needles that cost > £5 per 100 needles (all <£5 per 100 needles to be made available).

Insulin pen needles of 8mm and 12 mm.

Olaratumab – Marketing Authorisation withdrawn. To be made non formulary with a note to cover historic prescribing