Derbyshire JAPC Bulletin

www.derbyshiremedicinesmanagement.nhs.uk

April 2021

Due to the current COVID-19 pandemic an interim JAPC ToR has been devised to ensure that there is continuity of JAPC meetings during these extraordinary times. The increased pressures experienced by the CCG and providers necessitated the need to temporarily modify existing arrangements for the running of JAPC meetings and the work-up behind the review/production of clinical guidelines.
See http://www.derbyshiremedicinesmanagement.nhs.uk/medicines-management/joint_area_prescribing_committee

Key Messages From April's Virtual JAPC meeting

NICE TA679 - Dapagliflozin for heart failure with reduced ejection fraction - GREEN specialist/consultant initiation and stabilisation

Dapagliflozin for treating heart failure with reduced ejection fraction has been assigned a drug traffic light classification of GREEN specialist/consultant initiation and stabilisation before transfer to primary care. It is recommended for use as an add-on to optimised standard care (ACEI/ARB with BB±MRA or sacubitril valsartan with BB±MRA). Dapagliflozin has been incorporated into the JAPC heart failure guidance, with detailed prescribing notes in appendix 4, including management of patients with heart failure and type 2 diabetes. Dapagliflozin is contraindicated in type 1 diabetes and patients should be counselled on sick day rules.

Chloramphenicol eye drops 0.5%

Chloramphenicol eye drops 0.5% are now contra-indicated in children under the age of two by most manufacturers due to the presence of boron/borates in the formulation. It follows an update issued in 2017 to EMA mandatory labelling guidance on excipients.

According to the EMA guidance, any product that would result in exposure to more than 1 mg daily of boron should be labelled as not to be used in children under 2 years. Chloramphenicol eye drops contain around 3 mg boron per ml, so when used correctly they are unlikely to result in this level of exposure; however it seems that most companies have taken the precautionary route. For older patients, the limits for boron exposure are increased, and hence why this applies to less than 2 years old.

Chloramphenicol eye ointment is used in children of all ages, does not contain boron/borates, and therefore the new contraindication does not apply. However, many of the chloramphenicol eye ointment preparations are pharmacy-only ("P") medicines, and as such are licensed for use in children over the age of 2 years. This is not the same as a contraindication, and likely reflects the fact that it is advisable that antibiotic eye preparations be used in very young children only **under the supervision of a prescriber.**

The Royal College of Ophthalmologist (RCO) have produced a safety alert, and are seeking to work with MHRA on this issue to ensure appropriate advice. At the present time, the RCO believes that the benefits of chloramphenicol eye drops in paediatric ophthalmic practice for appropriate indications and with courses of appropriate duration outweigh the possible risks posed by boron ingestion.

High Cost Drugs – secondary care CCG commissioned drugs:

Brolucizumab (NICE TA672) alternative first line option for the treatment of wet age-related macular degeneration. See local commissioning algorithm for place in therapy.

Baricitinib (NICE TA681) oral treatment option for moderate to severe atopic dermatitis. See local commissioning algorithm for place in therapy.

Erenumab (NICE TA682) further treatment option for preventing migraines in adults. See local commissioning algorithm for place in therapy.

Vaccination allergy advice and guidance service FAQ

JAPC has ratified a local pathway, guidance and referral form for the appropriate management of COVID-19 vaccine allergies. These variations are based on the advice and clinical expertise of our local allergy specialist. Clinicians are reminded when referring patients into the Covid Vaccine Allergy Service to:

1. Follow the local Covid-19 vaccine allergy referral pathway, which can be found within the guideline
2. Fully complete and submit the COVID-19 Vaccination Allergy Referral form via the GP clinical system to avoid delay. See link to access the template version of the form

Patient Group Directions (PGD)

Pertussis Vaccine and Shingles vaccine – update to existing PGD which expired on 31st March 2021. Updated PGD effective from 1st April 2021. DHU PGDs have been extended to 31st October 2021.

Inhaled Budesonide for Adults (50 Years and Over) with COVID-19 – GREEN (off label)

Inhaled budesonide is not currently being recommended as standard care but can be considered (off-label) on a case-by-case basis for symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities. Prescribers should follow the principles of personalised care (including a shared decision making approach with the patient) to prescribe inhaled budesonide. Patient must meet eligibility criteria for commencement of inhaled budesonide. Pulmicort 400 Turbohaler is the recommended product, however if there is limited availability, then other forms of inhaled budesonide can be used – Easyhaler, Turbohaler 200mcg, Budelin Novolizer. See Interim Position Statement for further details.

Ingredients for COVID-19 vaccines

A table of all ingredients (including active ingredients and excipients) contained in the Pfizer-BioNTech and Astra-Zeneca COVID-19 vaccines, has been complied to use with patients to address vaccine hesitancy.

MHRA NOTICES

Bendamustine (Levact): increased risk of non-melanoma skin cancer and progressive multifocal encephalopathy (PML). COVID-19 vaccines and medicines: updates for March 2021. A summary of advice recently issued by the MHRA relating to coronavirus (COVID-19), up to 18 March 2021. COVID-19 Therapeutic Alert: Convalescent Plasma in the Management of Hospitalised Patients with COVID-19

Guideline Group key messages

NPSA- Steroid Emergency Card to support early recognition and treatment of adrenal crisis in adults

Link to alert inserted to respiratory, endocrine, and skin formulary chapter. 'Exogenous steroids, adrenal insufficiency and adrenal crisis-who is at risk and how should they be managed safely' document added to website under endocrine chapter relevant resources. This guidance is endorsed by SPS, society for endocrinology and the British Association of Dermatologist.

Atopic eczema in children. New JUCD resource document added to website under skin chapter relevant resources. This useful document covers diagnosis, management and referral for atopic eczema in children, and includes a patient information leaflet. Formulary align

Formulary alignment:

Cilodex brand (dexamethasone 0.1%/ciprofloxacin 0.3% ear drops) discontinued- brand removed from TLC/ ENT chapter

Hydrocortisone 10% foam enema discontinued- removed from TLC/ GI chapter

Dulaglutide new strength 3mg/ 4.5mg- added to T2DM guideline
PhosLo brand (calcium acetate) discontinued- removed from TLC

Updated advice added to Obs & Gynae chapter and Emergency Contraception guideline as per FSRH statement. If EC is considered to be required in the specific situation in which an established CHC user restarts CHC after a hormone-free interval and then misses 2-7 pills in the first week of pill-taking (or makes an equivalent error with combined patch or ring use):

- LNG-EC may be offered, with immediate restart of CHC and use of condoms for 7 days
- if UPA-EC is preferred, it may be offered, now with immediate restart of CHC and use of condoms for 7 days.

Note added to Freestyle Libre statement. Alcohol wipes are no longer supplied with Freestyle Libre – please advise patients that these can be purchased at minimal cost from pharmacies and other retailers. See https://freestylediabetes.co.uk/freestyle-libre/faqs

Traffic light changes

Drug	Date considered	Decision	Details
Budesonide	April 2021	**GREEN**	Inhaled budesonide (off-label) can be considered on a case-by-case basis for symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities in line with published interim postion statement.The recommended product is Pulmicort Turbohaler 400mcg, but other inhaled budesonide preparations such as Easyhaler, 200mcg turbohaler and Budelin Novolizer may be considered when supplies are limited.
Lenalidomide	April 2021	**RED**	NICE TA680: Lenalidomide maintenance treatment after an autologous stem cell transplant for newly diagnosed multiple myeloma. NHSE commissioned
Baricitinib	April 2021	**RED**	NICE TA681: Barcitinib for treating moderate to severe atopic dermatitis. CCG commissioned
Erenumab	April 2021	**RED**	NICE TA682: Erenumab for preventing migraine. CCG commissioned
Pembrolizumab	April 2021	**RED**	NICE TA683: Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer. NHSE commissioned
Nivolumab	April 2021	**RED**	NICE TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease. NHSE commissioned.
Anakinra	April 2021		NICE TA685 Anakinra for treating Still's disease. NHSE commissioned.
Blinatumomab	April 2021	**DNP**	NICE TA686 Blinatumomab for previously treated Philadelphia chromosome-positive acute lymphoblastic leukaemia (terminated appraisal)
Ribociclib (with fulvestrant)	April 2021	**RED**	NICE TA687 Ribociclib with fulvestrant for treating hormone receptorpositive, HER2-negative advanced breast cancer after endocrine therapy
Upadacitinib	April 2021	**DNP**	Treatment of active psoriatic arthritis in adults who have responded inadequately to, or who are intolerant to ≥1 DMARDs. Upadacitinib may be used as monotherapy or in combination with methotrexate. Awaiting NICE TA. Treatment of active ankylosing spondylitis in adults who have responded inadequately. Awaiting NICE TA.
Delafloxacin	March 2021	**RED**	Change from DNP to RED as per NICE ES32 - Antimicrobial prescribing: delafloxacin for acute bacterial skin and skin structure infections. IV administration.

Definitions:

RED: drugs are those where prescribing responsibility lies with a hospital consultant or a specialist.
AMBER: drugs are those that although usually initiated within a hospital setting, could appropriately become the responsibility of the GP, under a shared care agreement.
GREEN*: drugs are regarded as suitable for primary care prescribing.
GREY*: drugs are those that JAPC does not recommend for use, except in exceptional circumstances, due to lack of data on safety, effectiveness, and/or cost-effectiveness.
Do Not Prescribe (DNP)*: drugs, treatments or medical devices are **not** recommended or commissioned* (*unless agreed through the individual funding request route)

CONSULTANT/SPECIALIST INITIATION: consultant/specialist issues the first prescription usually following a consultation because:

a. The patient requires specialist assessment before starting treatment and/ or
b. Specialist short term assessment of the response to the drug is necessary.

GPs will be asked to continue prescribing when the patient is stable or predictably stable
CONSULTANT/SPECIALIST RECOMMENDATION: consultant/specialist requests GPs prescribe initial and on-going prescriptions, but ensures:

a. There is no immediate need for the treatment and is line with discharge policies and
b. The patient response to the treatment is predictable and safe

DERBYSHIRE MEDICINES MANAGEMENT, PRESCRIBING AND GUIDELINES WEBSITE

This website is the first port of call for information on local NHS decisions and guidance on medicines use. It includes: local prescribing formularies, JAPC decisions, traffic lights, shared care guidelines, medicines guidelines, newsletters, controlled drug resources, and other medicines management resources. The site improves upon previous sites in several ways. It is faster, more reliable, has its own search engine, and it is easier to find information. Content is constantly being updated and you can sign up for e-mail alerts to keep you up to date.