

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 July's JAPC meeting

Low back pain and sciatica – this is a new JAPC guidance based on recently updated NICE guidance, utilising a pragmatic approach for the management of low back pain and sciatica. Drug management is a small element of the guidance and there is an emphasis on self-care and non-pharmacological management including group exercise programme, manual therapy and/or psychological therapies. JAPC acknowledge there is a gap in current commissioned services, and this will be taken through the appropriate commissioning route.

### Bempedoic acid with ezetimibe - GREY as per NICE TA694

Bempedoic acid is a new drug which received a positive Technology Appraisal from NICE for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if: statins are contraindicated or not tolerated, and ezetimibe alone does not control low-density lipoprotein cholesterol well enough. Bempedoic acid is a novel oral lipid-lowering medicine. It is a prodrug that is activated in the liver and works upstream to 3-hydroxyl-3-methylglutaryl Coenzyme A (HMG-CoA) reductase in the cholesterol synthesis pathway. Monitoring of bempedoic acid includes LFTs at baseline, 3 months & annually thereafter. Bempedoic acid is an additional treatment option for patients ahead of PCSK9 inhibitors (specialist treatment options) with high cholesterol levels. See the following treatment pathways for place in therapy - lipid modification for FH and non-FH.

## Ondansetron for IBS-Diarrhoea - GREY specialist initiation

JAPC has approved the use of ondansetron for IBS associated diarrhoea. The current treatment options include loperamide alongside mebeverine (or hyoscine) and TCAs. Recent guidance from the BSG recommends 5HT3 receptor antagonist are efficacious 2<sup>nd</sup> line drugs for IBS-diarrhoea. Ondansetron has shown significantly higher improvement rates for urgency, bloating and stool formation when compared to placebo. Recommended doses include 4 mg once a day to a maximum of 8 mg three times a day, however the lower starting dose has been shown to effective at managing symptoms. Ondansetron has been placed in the primary care IBS pathway with the following warnings: Female patients will be advised to stop ondansetron if planning a pregnancy or during their first trimester and QTc interval check in appropriate patients will be carried out by secondary care prior to handing over prescribing to primary care after demonstrating a net benefit.

## **Patient Group Directions**

<u>Rotavirus vaccine Patient Group Direction v5.00</u> – inclusion of Rotarix® oral suspension (1.5ml) in multi-monodose (5 single dose) squeezable tube presentation connected by a bar, minor rewording, layout and formatting changes. <u>Meningococcal group A, C, W and Y (MenACWY) conjugate vaccine v4.00</u> - minor rewording, layout and formatting.

## MHRA NOTICES

<u>Chloramphenicol eye drops</u> containing borax or boric acid buffers: use in children younger than 2 years. Following a review of the available toxicological data and a calculation of daily exposure to boron from a typical dosing regimen, the MHRA have concluded that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 to 2 years. **Chloramphenicol eye drops can be safely administered to children aged 0 to 2 years where antibiotic eye drop treatment is indicated.** 

<u>CDK4/6 inhibitors</u> (abemaciclib  $\mathbf{\nabla}$ , palbociclib  $\mathbf{\nabla}$ , ribociclib  $\mathbf{\nabla}$ ): reports of interstitial lung disease and pneumonitis, including severe cases. Advice from MHRA includes during clinic appointments, to ask patients about pulmonary symptoms indicative of interstitial lung disease and pneumonitis, such as cough or dyspnoea, and advise them to seek advice right away if they occur.

<u>Atezolizumab</u> (Tecentriq ▼) and other immune-stimulatory anti-cancer drugs: risk of severe cutaneous adverse reactions. Advice from MHRA includes the need to seek urgent medical assistance if severe skin reactions occur including itching, skin blistering, peeling or sores, or ulcers in the mouth or in lining of nose, throat or genital area.

# Guideline Group key messages – traffic light amendments

**Budesonide/Formoterol/glycopyrronium (Trixeo aerosphere)** – Grey (Combination inhaler is cost effective to use in COPD). **Glycopyrronium/formoterol (Bevespi Aerosphere)** – Green. (Combination inhaler is cost effective to use in COPD) **Potassium dihydrogen phosphate** – RED as per UHDB/CRH formularies. **Thuasne Action Reliever osteoarthritis knee brace** – DNP Medical device (appliance). Awaiting national review. **Delafloxacin** – DNP (secondary care clinician's preference). **Pizotifen** – Grey. Review existing patients when appropriate. Not for new patients. **Rifampicin** – RED for all indications including TB. **Clomipramine MR (Anafranil SR)** – Removed because discontinued. **Sodium chloride 5% eye drops (Aeon)** - Removed entry for specific brand.

### Traffic light changes

Drug	Date considered	Decision	Details
Bempedoic acid & bempedoic acid/ezetimibe	Jul 21	GREY	For primary hypercholesterolaemia or mixed dyslipidaemia: when a statin is contraindicated or not tolerated, and ezetimibe alone does not control low-density lipoprotein cholesterol well enough. (For primary prevention)
Ondansetron	Jul 21	GREY specialist initiation	For IBS associated diarrhoea. Female patients will be advised to stop ondansetron during their first trimester; QTc interval check in appropriate patients will be carried out by secondary care prior to handing over to primary care. See primary care management of IBS guidance. (hyperlink)
Onasemnogene abeparvovec (Zolgensma)	Jul 21	RED	Treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1, or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene. NHSE commissioned
Ibrutinib	Jul 21	DNP	NICE TA702 - Ibrutinib with obinutuzumab for untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (terminated appraisal)
Ibrutinib	Jul 21	DNP	NICE TA703 - Ibrutinib with rituximab for untreated chronic lymphocytic leukaemia (terminated appraisal)
Trastuzumab deruxtecan	Jul 21	RED	NICE TA704 - Trastuzumab deruxtecan for treating HER2- positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies
Atezolimumab	Jul 21	RED	NICE TA705 - Atezolizumab monotherapy for untreated advanced non-small-cell lung cancer
Ozanimod	Jul 21	DNP	NICE TA706 - Ozanimod for treating relapsing–remitting multiple sclerosis
Nivolumab	Jul 21	RED	NICE TA707 - Nivolumab for previously treated unresectable advanced or recurrent oesophageal cancer
Budesonide orodispersible tabs	Jul 21	RED	NICE TA708 - Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis
Pembrolizumab	Jul 21	RED	NICE TA709 - Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency
Ravulizumab	Jul 21	RED	NICE TA710 - Ravulizumab for treating atypical haemolytic uraemic syndrome
Guselkumab	Jul 21	RED	NICE TA711 - Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs

#### **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 <u>not</u> 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** <u>**RECOMMENDATION**</u>: 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.