Derbyshire JAPC Bulletin

www.derbyshiremedicinesmanagement.nhs.uk

November 2022

This is a countywide group covering NHS Derby & Derbyshire Integrated Care Board, Derbyshire Community Health Service Foundation Trust, Derbyshire Healthcare Foundation Trust, University Hospital of Derby and Burton and Chesterfield Royal Hospital foundation trusts. It provides recommendations on the prescribing and commissioning of drugs See http://www.derbyshiremedicinesmanagement.nhs.uk/home

Key Messages from November's JAPC meeting

Hyperprolactinaemia guidance – update of an existing guidance. Minor amendment for the update includes consideration and documentation of a baseline ECHO undertaken by the specialist.

Liothyronine shared care agreement (SCA) and **position statement** **–** update of existing SCA and position statement. Amendments to the SCA include removal of acute conditions as outside of the scope of the SCA and the adverse effects section brought in line with the BNF. The position statement now includes links to the RMOC liothyronine prescribing advice and SPS advice on Amour thyroid.

Ozanimod indicated for treating moderate to severe ulcerative colitis - High-Cost Drug for secondary care ICB commissioned. Commissioning algorithm for ulcerative colitis updated to include ozanimod NICE TA828 as an additional treatment option.

Vitamin D deficiency guidance and **position statement** **–** update of an existing guidance and position statement. The guidance continues with the advice of treatment with a high dose short course for confirmed vitamin D deficiency and to self-care for prevention, maintenance and insufficiency of vitamin D. The guidance includes a more rapid dosing schedule (over 15 days) for symptomatic patients that require a rapid replacement to aid compliance. Clinicians are advised that prescriptions for the rapid dosing schedule, are not to be added to the repeat section of the patient's electronic health record. A section has been added to include advice in pregnancy with the lower dose of 3200IU/day for 90 days for vitamin D deficiency as recommended by specialists, this is in line with the SPS safe upper limit of 4000IU/day.

Vitamin B12 and Metformin

The MHRA June 2022, issued a drug safety update (DSU) regarding metformin and reduced vitamin B12 levels. The advice explains that decreased vitamin B12 levels, or vitamin B12 deficiency, is now considered to be a common side effect in patients on metformin treatment, especially in those receiving a higher dose or longer treatment duration and in those with existing risk factors. JAPC has ratified the following recommendations for practices regarding patients currently taking metformin and reduced vitamin B12 levels, on the advice of local diabetes specialists:

1. The **maximum recommended dose of metformin is now 2g/day** as higher doses give a high risk of B12 deficiency for minimal benefit. We would therefore **advise that the dose is reduced to 2g a day and you may want to check a B12 level at the same time**. Practices could search for these patients and add an alert to test B12 and review metformin dose at the patient's next appt or deal with now if able to do so.
2. **Every person presenting with symptoms of B12 deficiency needs a B12 test.** This could be neuropathy symptoms (pins and needles/tingling especially of the feet), glossitis (painful swollen tongue) or a macrocytic anaemia (low Hb with raised MCV). Many people with neuropathy due to low B12 do not have anaemia so a normal FBC does not rule out a low B12.
3. A low B12 in a patient on metformin is likely to be multifactorial hence the **advice is to replace B12 rather than stop the metformin.**

Shared care pathology guideline for vitamin B12 have amended their guidance to include the message of maximum dose for metformin 2g/day and when to check for vitamin B12.

PGDs

The following UKHSA PGDs have been uploaded to our Medicines Management website:

Hep A/B vaccine PGD - Examples added to chronic liver disease in criteria for inclusion; addition of individuals under one year of age to exclusion criteria; removal of reference to hepatitis vaccine shortages in additional information; minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates and updated UKHSA PGD Policy.

Hep A vaccine PGD - Phenylalanine content in Avaxim® vaccine and action to be taken; booster dosing delays still provide protection; minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates.

BCG vaccine AJV PGD - includes information in the inclusion and exclusion criteria, actions if excluded and additional information in relation to SCID screening; includes minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates.

Smallpox vaccine PGD **- a**llows use of US licensed Batch FDP00072 of Jynneos® vaccine; deleted references to the vaccine being used off-label. The vaccine has been authorised for active immunisation against monkeypox in adults in the UK by the Medicines and Healthcare Products Regulatory Agency (MHRA); added the use of the intradermal fractional dose route (ID) in the relevant sections: off-label use, route of administration, dose and frequency, adverse reactions; added observation following vaccination in cautions and patient advice sections; added individuals with history of developing keloid scarring in cautions and patient advice sections; reworded paragraph relating to co-administration with other vaccines in the off-label section; minor wording changes and additions to text for consistency; updated references.

MHRA NOTICES

MHRA promoting Medicines Safety Week, 7-13 November 2022, focusing upon the importance of reporting suspected adverse reactions to medicines and vaccines.

Guideline Group key messages – traffic light amendments

Ciprofloxacin+ dexamethasone ear drops **– GREY.** For use in children with acute otitis media with tympanostomy tubes(grommets) or tympanic perforation in adults & children over 6months of age.

Ipratropium bromide nasal spray – **GREEN.** For symptomatic relief of rhinorrhoea in non-allergic rhinitis

Acetylcysteine 5% eye drops (Ilube) - **GREY cons/spec initiation**. For filamentary keratitis.

Morphine orodispersible tab (Actimorph). Additional exceptional criteria added to the **GREY** classification - additional patient factors e.g., poor manual dexterity.

Melatonin - Dual classification:

GREY consultant/specialist initiation for use in children with neurodevelopment disorders and CAMHS patients (including off-label use).

- Melatonin MR 2mg tablets (Circadin) and Adaflex tablets are the preferred licensed melatonin preparations.
- For other preparations including liquids when it is not possible to use crushed tablets see specials guidance.

DNP melatonin 1mg/ml oral SF solution

- For short-term treatment of jet-lag disorder in adults
- Melatonin 1mg/ml oral SF solution -not suitable for children under 6 years of age due to safety concerns regarding propylene glycol content
- Slenyto

Traffic light changes

Drug	Date considered	Decision	Details
Ozanimod	Nov 2022	**RED**	**NICE TA828** - Ozanimod for treating moderately to severely active ulcerative colitis. ICB commissioned
Upadacitinib	Nov 2022	**RED**	**NICE TA829** - Upadacitinib for treating active ankylosing spondylitis. ICB commissioned
Relugolix–estradiol–norethisterone	Nov 2022	**RED**	**NICE TA832** - Relugolix–estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids.
SQ HDM SLIT (Acarizax)	Nov 2022	**RED**	**NICE TA834** - SQ HDM SLIT (Acarizax) for treating allergic rhinitis and allergic asthma caused by house dust mites (terminated appraisal), pending DTC review for continued use as per JAPC SLIT guidance
Fostamatinib	Nov 2022	**RED**	**NICE TA835** - Fostamatinib for treating refractory chronic immune thrombocytopenia. ICB commissioned
Azacitidine	Nov 2022	**RED**	**NICE TA827** - Oral azacitidine for maintenance treatment of acute myeloid leukaemia after induction therapy
Pembrolizumab	Nov 2022	**RED**	**NICE TA830** - Pembrolizumab for adjuvant treatment of renal cell carcinoma
Olaparib	Nov 2022	**DNP**	**NICE TA831** - Olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer. (Not recommended)
Zanubrutinib	Nov 2022	**RED**	**NICE TA833** - Zanubrutinib for treating Waldenstrom's macroglobulinaemia. NHSE commissioned
Palbociclib with fulvestrant	Nov 2022	**RED**	**NICE TA836** - Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy. NHSE commissioned
Pembrolizumab	Nov 2022	**RED**	**NICE TA837** - Pembrolizumab for adjuvant treatment of resected stage 2B or 2C melanoma. NHSE commissioned
Nivolumab with fluoropyrimidine	Nov 2022	**RED**	SSC2431 - nivolumab with fluoropyrimidine- and platinum-based chemotherapy for untreated unresectable advanced recurrent or metastatic oesophageal squamous cell carcinoma. NHSE commissioned
Rituximab	Nov 2022	**RED**	SSC2433 – NHSE Clinical Commissioning policy for Rituximab in the management of Thrombotic Thrombocytopenic Purpura
Canakinumab	Nov 2022	**DNP**	SSC2437 - NHSE Clinical Commissioning Policy: Canakinumab for patients with Still's disease refractory to anakinra and tocilizumab (adults and children 2 years and over)- The policy confirms that canakinumab is not routinely commissioned for these patients
Dabrafenib and trametinib	Nov 2022	**RED**	SSC2444 - Clinical commissioning policy: Dabrafenib and trametinib in the treatment of patients with BRAF-mutated anaplastic thyroid cancer. NHSE commissioned
Gozetotide (Locametz)	Nov 2022	**DNP**	Identification of prostate-specific membrane antigen-positive lesions by positron emission tomography in adults with prostate cancer, after radiolabelling with gallium-68. Await clinician request or national guidance
Potassium bicarbonate + potassium citrate (Sibnayal)	Nov 2022	**DNP**	Treatment of distal renal tubular acidosis in adults, adolescents and children aged ≥1 year. Await clinician request or national guidance
Daridorexant (Quviviq)	Nov 2022	**DNP**	Treatment of adults with insomnia characterised by symptoms present for ≥3 months and considerable impact on daytime functioning. Await clinician request
Eptacog beta (activated) (Cevenfacta)	Nov 2022	**DNP**	Use in adults and adolescents aged ≥12 years for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures. Await clinician request
Evinacumab (Evkeeza)	Nov 2022	**DNP**	Use as an adjunct to diet and other low-density lipoprotein cholesterol lowering therapies for the treatment of adult and adolescent patients aged ≥12 years with homozygous familial hypercholesterolaemia. Await clinician request
Lenacapavir (Sunlenca)	Nov 2022	**DNP**	Use in combination with other antiretroviral(s) for the treatment of adults with multidrug-resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen
Lonafarnib (Zokinvy)	Nov 2022	**DNP**	Treatment of patients aged ≥12 months with a genetically confirmed diagnosis of Hutchinson-Gilford progeria syndrome or a processing-deficient progeroid laminopathy associated with either a heterozygous LMNA mutation with progerin-like protein accumulation or a homozygous or compound heterozygous ZMPSTE24 mutation
Tezepelumab (Tezspire)	Nov 2022	**DNP**	Use as an add-on maintenance treatment in adults and adolescents aged ≥12 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment. Await clinician request
Tirzepatide (Mounjaro)	Nov 2022	**DNP**	Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. Await clinician request

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

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