Derbyshire JAPC Bulletin

www.derbyshiremedicinesmanagement.nhs.uk

February 2022

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 February JAPC meeting

Abatacept monotherapy (CCG commissioned secondary care, high cost excluded from tariff drug) accepted for use in patients with severe rheumatoid arthritis with interstitial lung disease if the request is discussed through an appropriate multidisciplinary team and drugs and therapeutics committee for agreement with commissioners.
Atrial Fibrillation (AF) guidance – updated to incorporate the latest NICE guidance-NG196. Changes to the guidance include inclusion of ORBIT as an alternative bleeding risk assessment tool to HAS-BLED, for use if available on GP clinical systems. The ORBIT tool was shown to have a higher accuracy in predicting bleeding risks when compared to other tools.
The local AF guidance places the use of novel oral anticoagulants (NOAC's), if clinically appropriate ahead of warfarin. A recent national procurement for NOACs, adopted by Derbyshire places edoxaban as first line NOAC of choice, followed by rivaroxaban, apixaban and dabigatran.

Chloral hydrate position statement/Cloral betaine

JAPC has considered advice published in a recent MHRA drug safety alert (Oct 2021) for chloral hydrate and following the Neonatal & Paediatric Pharmacist Group (NPPG) position statement, a Derbyshire position statement for the off-label use of choral hydrate has been produced with local experts to ensure patients are managed safely. The MHRA (Oct 2021) informed of new restrictions to the paediatric indication for chloral hydrate and cloral betaine due to the potential for carcinogenic effects based on animal data - short-term treatment (maximum 2 weeks) of severe insomnia only when the child or adolescent has a suspected or definite neurodevelopmental disorder and when the insomnia is interfering with normal daily life. Further chloral hydrate and cloral betaine should only be used when other therapies (behavioural and pharmacological) have failed. Following the MHRA warning, the NPPG issued a position statement reinforcing the MHRA positions, but also stating that chloral hydrate is used for other off-label indications - movement and motor disorders.
The Derbyshire position statement recommends:

1. Chloral hydrate **(RED)** - use for insomnia in patients with neurodevelopmental disorder **(licenced indication).** Used for a maximum of 2 weeks under specialist.
2. Chloral hydrate **(GREY consultant/specialist initiation)** - use in the management of intrusive movement and motor disorders in children and young people. **Off-label** use initiated by a specialist and continued in primary care if ongoing use is monitored by the initiating specialist.

See the Derbyshire position statement for further details for existing patients and an example of a chloral hydrate treatment plan. The NPPG recommend use of the standardised concentration of **500mg/5ml** for chloral hydrate. Cloral Betaine has been classified as **DNP** as it is not currently available for use.

Dementia management in primary care

The dementia in primary care guidance has been updated to be in line with NICE NG97 with a revised introduction section and streamlined to enhance clarity and ease of use. The main change to the guidance is the traffic light classification for memantine which is now **GREEN** after specialist/consultant initiation for newly diagnosed patients, **GREEN** for patients with Behavioural and Psychological Symptoms in Dementia and new additional indication of **GREEN** as an add on to an AChE inhibitor in patients with established Alzheimer's disease. Guidance for GPs about the use of memantine is available from specialists.

Dual antiplatelet for acute coronary syndrome.

Previously Derbyshire had endorsed separate guidance's for STEMI and NSTEMI for use in the North and South of the county. The separate guidance's have now been amalgamated into one document which includes STEMI and an NSTEMI/unstable angina treatment pathway. The treatment pathways recommend the following antiplatelets:

- For patients undergoing PCI (STEMI & NSTEMI) - **prasugrel** is recommended for 12 months as dual antiplatelet treatment with lifelong aspirin
- For the medical management of patients (STEMI & NSTEMI) – **ticagrelor** is recommended for 12 months as dual antiplatelet treatment with lifelong aspirin.
- For patients on existing anticoagulants (STEMI & NSTEMI) - **Clopidogrel** is recommended for 12 months ± aspirin.

The Derbyshire traffic light classification for the antiplatelets remains.

Infant feeding guideline

The Derbyshire infant feeding guideline has been updated to reflect changes made to the 2019 iMAP guideline. The main change to the iMAP is recognition the previous guidance having the effect of over diagnosis of cow's milk allergy (CMA) and increased hypoallergenic formula prescriptions, through a failure to re-challenge to milk after a brief exclusion, and negative effect on breastfeeding rates. The latter is tackled by the guidance actively encouraging users to support mothers to continue breastfeeding when possible and only to consider hypoallergenic formulas if this not possible. The non-IgE CMA management algorithm has been updated to include rechallenge at 2 weeks by primary care clinicians, to confirm diagnosis. The local guidance adopts these changes, with other minor amendments throughout the document and additional resources to assist with this.

MHRA Notices

Haloperidol (Haldol): reminder of risks when used in elderly patients for the acute treatment of delirium. The lowest possible dose should be used for the shortest possible time, and cardiac and extrapyramidal adverse effects should be closely monitored.
Venetoclax (Venclyxto▼): fatal cases of tumour lysis syndrome have been reported, even in patients receiving the lowest ventoclax dose used in the dose-titration schedule.
Dapagliflozin (Forxiga): The authorisation holder for dapagliflozin has withdrawn the indication for type 1 diabetes mellitus. The removal of the type 1 diabetes indication is not due to any new safety concerns and the other indications of dapagliflozin are unchanged. JAPC classification for dapagliflozin for type 1 diabetes remains RED.
Approval of Xevudy (sotrovimab), a monoclonal antibody treatment for COVID-19.
Brolucizumab (Beovu▼): risk of intraocular inflammation and retinal vascular occlusion increased with short dosing intervals
Paclitaxel formulations (conventional & nab-paclitaxel): caution advised when prescribing, dispensing, preparing, and administering any

paclitaxel formulations to prevent medication errors, which have the potential to cause harm.
Approval of Paxlovid - oral COVID-19 antiviral treatment.

Guideline Group key messages – traffic light amendments

Dapagliflozin, empagliflozin, canagliflozin - GREEN consultant/ specialist initiation**.** Type 2 Diabetes with CKD- as per NICE NG28, for adults with CKD and type 2 diabetes, in additions to an ACEI or ARB at an optimised dose.
Leuprorelin & Triptorelin - GREEN Consultant/ Specialist initiation. Patients with metastatic prostate cancer will be seen in clinic and will be initiated on bicalutamide. A 3- monthly LHRH injection will be issued to the patient to take to the GP for administration between 7-14 days after initiation of bicalutamide.
Withdrawal of the Recommendation for Consideration of Inhaled Budesonide as a Treatment Option for COVID-19 Inhaled.
Aqueous cream – Grey. Aqueous cream is no longer recommended as an emollient but may be considered as a soap substitute. However, adverse effects are possible with any use.
Mintec, Fybogel, Rectogesic removed as preferred brand- prescribe generically. **Salamol** as preferred choice of salbutamol MDI due to lower carbon footprint. **Ipratropium MDI** deleted. **Luforbec MDI replaces** Fostair MDI as cost effective choice.
Lipid (non-FH) guideline- statin interaction table updated to include advice on oral miconazole. See SPS- Using miconazole oral gel to treat oral thrush in adults taking a statin. **Ventolin nebuliser solution discontinued**. Removed from TLC and respiratory formulary chapter as preferred brand. Prescribe generically.
PHE statin intolerance pathway added as other relevant resources under CV formulary chapter.

Traffic light changes

Drug	Date considered	Decision	Details
Memantine	Feb 2022	**GREEN**	• after specialist/consultant initiation for newly diagnosed dementia patients • for patients with BPSD (see separate guideline) • as add on to an AChE inhibitor in patients with established Alzheimer's disease. This can be started on specialist recommendation or by GP. Advice about the appropriateness of adding in memantine is available from the specialist if needed through advice & guidance request.
Abatacept	Feb 2022	**RED**	Use as monotherapy for patients with RA+ILD (local agreement)
Chloral Hydrate	Feb 2022	**RED**	use for insomnia in patients with neurodevelopmental disorder
	Feb 2022	**GREY**	GREY after consultant/specialist initiation- use in the management of intrusive movement and motor disorders in children and young people. Use 500mg/5ml oral solution
Chloral Betaine	Feb 2022	**DNP**	Not currently available.
Mexiletine	Feb 2022	**RED**	NICE TA748 - Mexiletine for treating the symptoms of myotonia in non-dystrophic myotonic disorders
Liraglutide (Saxenda)	Feb 2022	**DNP**	NICE TA749 – Liraglutide for managing obesity in people aged 12 to 17 years (terminated appraisal)
Olaparib	Feb 2022	**DNP**	NICE TA750 - Olaparib for maintenance treatment of BRCA mutation-positive metastatic pancreatic cancer after platinum-based chemotherapy (terminated appraisal)
Dupilumab	Feb 2022	**RED**	NICE TA751 - Dupilumab for treating severe asthma with type 2 inflammation. (NHSE commissioned)
Belimumab	Feb 2022	**RED**	NICE TA752 - Belimumab for treating active autoantibody-positive systemic lupus erythematosus
Cenobamate	Feb 2022	**RED**	NICE TA753 - Cenobamate for treating focal onset seizures in epilepsy (NHSE and CCG commissioned)
Mogamulizumab	Feb 2022	**RED**	NICE TA754 - Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome
Risdiplam	Feb 2022	**RED**	NICE TA755 - Risdiplam for treating spinal muscular atrophy
Fedratinib	Feb 2022	**RED**	NICE TA756 - Fedratinib for treating disease-related splenomegaly or symptoms in myelofibrosis
Cabotegravir	Feb 2022	**RED**	NICE TA757 - Cabotegravir with rilpivirine for treating HIV-1
Solriamfetol	Feb 2022	**RED**	NICE TA758 - Solriamfetol for treating excessive daytime sleepiness caused by narcolepsy. (CCG commissioned)
Fostamatinib	Feb 2022	**DNP**	NICE TA759 - Fostamatinib for treating refractory chronic immune thrombocytopenia
Selpercatinib	Feb 2022	**RED**	NICE TA760 - Selpercatinib for previously treated RET fusion-positive advanced non-small-cell lung cancer
osimertinib	Feb 2022	**RED**	NICE TA761 - Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection
Risankizumab	Feb 2022	**DNP**	Use alone or in combination with methotrexate for treatment of active **psoriatic arthritis** in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs. CCG commissioned

Eptinezumab	Feb 2022	**DNP**	Treatment of **migraine** in adults who have at least four attacks per month. CCG commissioned
Deucravacitinib	Feb 2022	**DNP**	Moderate to severe **plaque psoriasis**. CCG commissioned
Spesolimab	Feb 2022	**DNP**	Generalised **pustular psoriasis**. CCG commissioned
Linzagolix	Feb 2022	**DNP**	Treatment of moderate to severe symptoms of **uterine fibroids** in adult women of reproductive age. CCG commissioned
Vedolizumab	Feb 2022	**DNP**	Treatment of adults with moderately to **severely active chronic pouchitis**, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis and have had an inadequate response with or lost response to antibiotic therapy. CCG commissioned.
Ravulizumab	Feb 2022	**DNP**	Generalised **myasthenia gravis** in adults. CCG commissioned.
Risankizumab	Feb 2022	**DNP**	Moderate-to-severe **Crohn's disease**. CCG commissioned
Upadacitinib	Feb 2022	**DNP**	Treatment of adults with moderately to severely active **ulcerative colitis**, who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. CCG commissioned
Somapacitan	Feb 2022	**DNP**	Replacement of endogenous growth hormone in adults with growth hormone deficiency. CCG commissioned
Abatacept	Feb 2022	**RED**	Abatacept for refractory idiopathic inflammatory myopathies (adults and children aged 2 and over). NHSE commissioned
Rituximab	Feb 2022	**RED**	Rituximab for the treatment of IgM paraproteinaemic demyelinating peripheral neuropathy in adults. NHSE commissioned
Venetoclax (with Azacitidine)	Feb 2022	**RED**	Venetoclax with azacitidine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable, but venetoclax will be available through the CDF. NHSE commissioned
Pembrolizumab	Feb 2022	**RED**	Pembrolizumab for adjuvant treatment of completely resected stage 3 melanoma. NHSE commissioned
Pembrolizumab	Feb 2022	**RED**	Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies. NHSE commissioned
Asciminib	Feb 2022	**RED**	Asciminib indicated for the treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) without T315I mutation previously treated with two or more tyrosine kinase inhibitors. NHSE commissioned
Tucatinib	Feb 2022	**RED**	Use in combination with trastuzumab and capecitabine for the treatment of adults with HER2-positive locally advanced or metastatic breast cancer who have received ≥2 prior anti-HER2 treatment regimens. NHSE commissioned
Amivantamab	Feb 2022	**RED**	Monotherapy for treatment of adults with locally advanced or metastatic non-small cell lung cancer with activating epidermal growth factor receptor Exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy. NHSE commissioned
Tagraxofusp	Feb 2022	**RED**	Monotherapy for the first-line treatment of adults with blastic plasmacytoid dendritic cell neoplasm. NHSE commissioned
Avacopan	Feb 2022	**RED**	Use in combination with a rituximab or cyclophosphamide regimen, for the treatment of adults with severe, active granulomatosis with polyangiitis or microscopic polyangiitis
Casirivimab + imdevimab (Ronapreve)	Feb 2022	**RED**	Treatment of COVID-19 in adults and adolescents aged ≥12 years and weighing ≥40kg who do not require supplemental oxygen and who are at increased risk of their disease becoming severe and for preventing COVID-19 in people aged ≥12 years and weighing ≥40kg
Glucarpidase	Feb 2022	**RED**	Use to reduce toxic plasma methotrexate concentration in adults and children aged ≥28 days with delayed methotrexate elimination or at risk of methotrexate toxicity. NHSE commissioned
Inebilizumab	Feb 2022	**RED**	Monotherapy for the treatment of adults with neuromyelitis optica spectrum disorders who are anti-aquaporin 4 immunoglobulin G seropositive. NHSE commissioned
Lonapegsomatropin	Feb 2022	**RED**	Growth failure in children and adolescents aged from 3 years up to 18 years due to insufficient endogenous growth hormone secretion (growth hormone deficiency). NHSE commissioned
Regdanvimab	Feb 2022	**RED**	Treatment of adults with COVID-19 who do not require supplemental oxygen and who are also at increased risk of their disease becoming severe. NHSE commissioned.
Tecovirimat	Feb 2022	**RED**	Treatment of smallpox, monkeypox and cowpox in adults and children with body weight ≥13kg, and to treat complications due to replication of vaccinia virus following vaccination against smallpox, in adults and children with body weight ≥13kg. NHSE commissioned. NHSE commissioned.
Ganaxolone	Feb 2022	**RED**	Treatment of seizures associated with CDKL5 deficiency disorder. NHSE commissioned.

Loncastuximab tesirine	Feb 2022	**RED**	Relapsed or refractory diffuse large B-cell lymphoma. NHSE commissioned.
Mosunetuzumab	Feb 2022	**RED**	Relapsed or refractory B-cell non-Hodgkin lymphoma. NHSE commissioned.
Olipudase alfa	Feb 2022	**RED**	Acid sphingomyelinase deficiency in adults and children. NHSE commissioned.
Sutimlimab	Feb 2022	**RED**	Primary cold agglutinin disease. NHSE commissioned.
Tabelecleucel	Feb 2022	**RED**	Epstein-Barr virus-associated post-transplant lymphoproliferative disorder. NHSE commissioned.
Vadadustat	Feb 2022	**RED**	Anaemia in chronic kidney disease in patients on dialysis and not on dialysis. CCG commissioned (Non-dialysed patients)
Tucatinib	Feb 2022	**RED**	Use in combination with trastuzumab and capecitabine for the treatment of adults with HER2-positive locally advanced or metastatic breast cancer who have received ≥2 prior anti-HER2 treatment regimens. NHSE commissioned
Nirmatrelvir + ritonavir (Paxlovid)	Feb 2022	**RED**	Coronavirus disease 2019 (COVID-19) treatment in non-hospitalised adults at high risk of progression.
Anifrolumab	Feb 2022	**RED**	Use as an add-on therapy for the treatment of adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus, despite standard therapy. NHSE commissioned
Enfortumab vedotin	Feb 2022	**RED**	Treatment of adults with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor 1 or programmed death ligand 1 inhibitor. NHSE commissioned
Somatrogon	Feb 2022	**RED**	Treatment of children and adolescents aged ≥3 years with growth disturbance due to insufficient secretion of growth hormone. NHSE commissioned
Tegafur + gimeracil + oteracil (Teysuno)	Feb 2022	**RED**	Use as monotherapy or in combination with oxaliplatin or irinotecan, with or without bevacizumab, for the treatment of patients with metastatic colorectal cancer for whom it is not possible to continue treatment with another fluoropyrimidine due to hand-foot syndrome or cardiovascular toxicity that developed in the adjuvant or metastatic setting. NHSE commissioned
Voxelotor	Feb 2022	**RED**	Treatment of haemolytic anaemia due to sickle cell disease in adults and paediatric patients aged ≥12 years as monotherapy or in combination with hydroxycarbamide. NHSE commissioned
Fosdenopterin	Feb 2022	**RED**	Molybdenum cofactor deficiency Type A. NHSE commissioned
Lumasiran	Feb 2022	**RED**	Reduction of plasma oxalate in the treatment of patients with advanced primary hyperoxaluria type 1. NHSE commissioned
Luspatercep	Feb 2022	**RED**	Thalassaemia beta, treatment of anaemia in non-transfusion-dependent adults. NHSE commissioned

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.