For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 9th August 2022

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Fentanyl Patches being cut	Remains GREEN/GREY after cons/spec initiation for cutting of a patch (only allowed under exceptional circumstances, on advice of palliative care consultant following individualised treatment plan).
Ranibizumab biosimilar (Ongavia)	RED - Ophthalmology for all licensed indications.
Morphine Sulphate orodispersible tabs	GREY For exceptional use, following a risk assessment for example: use in vulnerable patient groups, to reduce the risk of accidental or intentional overdose.
Azithromycin	AMBER For use in adult respiratory infections. See Shared care for details.
Risankizumab	RED as per NICE TA803 for treating active psoriatic arthritis after inadequate response to DMARDs.
Icosapent ethyl	RED as per NICE TA805 with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides
Roxadustat	RED as per NICE TA807 for treating symptomatic anemia in chronic kidney disease
Setmelanotide	RED as per NICE HST21 for treating obesity caused by LEPR or POMC deficiency as per NHSE
Belimumab	DNP as per NICE TA806 for treating lupus nephritis (terminated appraisal) as per NHSE
Fenfluramine	RED as per NICE TA808 for treating seizures associated with Dravet syndrome as per NHSE
Imlifidase	RED as per NICE TA809 for desensitisation treatment before kidney transplant in people with chronic kidney disease as per NHSE
Abemaciclib	RED as per NICE TA810 with endocrine therapy for adjuvant treatment of hormone receptor-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence as per NHSE
Duvelisib	DNP as per NICE TA811 - Duvelisib for treating relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments (terminated appraisal) as per NHSE
Pralsetinib (Gavreto)	RED for the treatment of adults with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer not previously treated with a RET inhibitor. NHSE commissioned

Dexamethasone + levofloxacin (Ducressa) eye drops	DNP for the prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults.
Belzutifan (Welireg)	RED for the treatment of adults with von Hippel-Lindau (VHL) disease.
Landiolol (Rapibloc)	DNP for supraventricular tachycardia and for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other circumstances where short-term control of the ventricular rate with a short acting agent is desirable

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Aquacel Ag+ ribbon (silver dressing)	Classified as GREY and added to wound care formulary
Olanzapine	Formulations further clarified GREY: Orodispersible sugar-free tablets DNP: Orodispersible tablets (unless sugar-free – GREY)
Igoro neuromuscular medical device	Classified as DNP
Macrogol	Classified as GREEN (preferred brand of Laxido removed)
Melatonin	Melatonin MR 2mg tablets (Circadin) and melatonin 3mg tablets are the preferred licensed melatonin preparations. Changes due to price reduction for Circadin
Oxycodone	Discontinuation of Shortec 1mg/ml oral solution & Shortec concentrate 10mg/ml oral solution- removed from traffic lights

Clinical Guidelines
Bisphosphonate length of treatment in osteoporosis: Guidance on treatment break,
Management of lower UTI in Chronic Kidney Disease
Vitamin supplementation in alcohol misuse
Vitamin B compound/ Vitamin B compound strong tablets position statement

Shared Care
Azithromycin – use in adult respiratory infections

PGDs
HIP and Men Group C PGD

Present:	
Derby and Derbyshire ICB	
Dr R Gooch	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)

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Mr S Hulme	Director of Medicines Management and Clinical Policies
Mrs S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Mrs L G	Assistant Director of Medicines Optimisation and Delivery
Dr H Hill	GP
Dr R Dills	GP
Derby City Council	
Derbyshire County Council	
University Hospitals of Derby and Burton NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Ms Esther Kirk	Lead Pharmacist – High Cost Drugs and Commissioning
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Dr M Broadhurst	Consultant Psychiatrist/Deputy Medical Director
Chesterfield Royal Hospital NHS Foundation Trust	
Mr A Hardy	Principal Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Mrs K Needham	Chief Pharmacist
Derby and Derbyshire Local Medical Committee	
Derbyshire Health United	
Staffordshire and Stoke-on-Trent CCG's	
In Attendance:	
Mr A Brownlee	Chief Pharmacy Technician (Interface)
Ms R Monck	Assistant Chief Finance Officer
Miss S Greenwell	Senior Administrator, DDCCG (minutes)

Item		Action
1.	**APOLOGIES**	
	Dr A Mott, M Prior, A Brailey	
2.	**DECLARATIONS OF CONFLICTS OF INTEREST**	
	Dr Gooch reminded committee members of their obligation to declare any interest they may have on any issues arising at committee meetings which might conflict with the business of JAPC. No conflicts of interest were declared in relation to this agenda, in addition to the existing register of interests.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	There were no declarations of any other business.	

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Item		Action
4.	**JAPC ACTION SUMMARY**	
a.	**Cannabis based medicine (Sativex)** The Sativex® for moderate to severe spasticity in multiple sclerosis (MS)- prescribing guideline in primary care has been received and is on the agenda to discuss.	
b.	**Mycophenolate** RMOCs have now published these shared cares, which will be discussed later in the meeting.	
c.	**Inclisiran** Remains on workplan to review in October 2022	
d.	**Weekly GLP1** Place in therapy of weekly GLP1's being considered with diabetes guidance update.	
5.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Patiromer and Lokelma for hyperkalaemia** Mr Dhadli informed the committee that the purpose of this paper is to review two traffic light classifications for Patiromer (Veltassa®) and Sodium zirconium cyclosilicate (Lokelma®) for the management of chronic persistent hyperkalaemia in primary care in adults. Both Patiromer (Veltassa®) and Sodium zirconium cyclosilicate (Lokelma®) are licensed for the management of chronic persistent hyperkalaemia in adults only if used in emergency care for acute life-threatening hyperkalaemia alongside standard care, or for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if they have a confirmed serum potassium level of at least 6.0 mmol/litre and because of hyperkalaemia, are not taking an optimised dosage of renin angiotensin-aldosterone system (RAAS) inhibitor and are not on dialysis. University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) have requested to move prescribing of these 2 drugs to primary care, once initiated and stabilised by the specialists. . Mr Dhadli reported that the Guideline Group raised several concerns about the move of these drugs to primary care. Mr Dhadli presented these concerns to the committee along with the comments received from CRHFT and a Renal Pharmacist at UHDBFT. The UHDBFT Renal team were requesting the traffic light status of Patiromer (Veltassa®) and Sodium zirconium cyclosilicate (Lokelma®) be changed from RED to GREEN after specialist initiation following a period of stabilisation. A discussion took place, there were concerns from a GP perspective on changing the traffic light status from RED to GREEN may be too rapid of a change in responsibility and to perhaps consider a shared care instead following a period of secondary care experience of the treatments. It was also	

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	noted that with more data on the patient benefits and financial costs would help JAPC with the decision making. **Action:** The review of Patiromer and Lokelma for hyperkalaemia to be added to the JAPC action tracker with a review date of 12 months. **Agreed:** The committee agreed to keep the traffic light status for Patiromer (Veltassa®) and Sodium zirconium cyclosilicate (Lokelma®) as **RED** and to review this in 12 months.	**SD** **SD**
b.	**<u>Ranibizumab biosimilar</u>** Mr Dhadli reported that this paper was brought to JAPC to ask for a plan for the uptake of Ranibizumab biosimilar (Ongavia) by the acute trusts. NHS England and NHS Specialist Pharmacy Service (SPS) have produced various resources to support the system with Ranibizumab biosimilar (Ongavia) uptake. This resource has been developed in consultation with clinical experts and the Medicines Optimisation Delivery Group (MODG). Biosimilar use is new to ophthalmology and Mr Dhadli asked that these resources be shared with clinicians. There are currently 6 licenced and approved anti-VEGF and intravitreal corticosteroid treatments in England. Equivalent safety and efficacy for Ongavia to the original form of ranibizumab (Lucentis®) has been confirmed in phase 3 clinical trials in treatment naïve neovascular AMD. Mr Dhadli presented the document 'Operational note: Commissioning recommendations following the national procurement for medical retinal vascular medicines' published by NHSE. These Commissioning recommendations follow the national procurement for medical retinal vascular medicines and highlighted the main indications and the background surrounding the procurement strategy. It was highlighted that UHDBFT and CRHFT have confirmed that both trusts will be taking on the Ranibizumab biosimilar (Ongavia). A discussion took place regarding system finances; finance confirmed that there will be an overall system saving but the individual trusts will incur the savings. It was suggested that the Biosimilar working group be stood back up for one meeting to develop a plan with UHDBFT and CRHFT in preparation for the uptake of ranibizumab biosimilar thus securing efficiency savings for the system. **Action:** The committee agreed to step up one biosimilar working group to confirm the plan of action with UHDBFT and CRHFT for the uptake of ranibizumab biosimilar. **Agreed:** The committee agreed to discuss the provider work plans in September's JAPC.	**SD** **SD**
c.	**<u>Icosapent ethyl</u>** Mr Dhadli advised that NICE have released a new NICE TA805 for Icosapent ethyl. JAPC is to assign a traffic light classification for Icosapent ethyl, and to agree a plan of action for where this will be introduced first.	

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	Icosapent ethyl is recommended as an option for reducing the risk of cardiovascular events in adults. The NICE TA805 recommends that Icosapent ethyl is an option for high risk of cardiovascular events and raised fasting triglycerides (1.7 mmol/litre or above) if patients are taking statins, but only if the patient has established cardiovascular disease (secondary prevention), defined as acute coronary syndrome, coronary or other arterial revascularisation procedures, coronary heart disease, ischaemic stroke, peripheral arterial disease, and low-density lipoprotein cholesterol levels above 1.04 mmol/litre and below or equal to 2.60 mmol/litre. There are currently no treatment options to reduce the risk of cardiovascular events in people taking statins who have controlled levels of LDL-C but raised levels of triglycerides. Clinical trial evidence suggests that Icosapent ethyl reduces the risk of cardiovascular events, compared with a placebo, in people with raised fasting triglycerides (1.7 mmol/litre or above) who are taking statins. The cost-effectiveness estimates for Icosapent ethyl are uncertain, but the most likely cost-effectiveness estimates for secondary prevention are within what NICE normally considers an acceptable use of NHS resources. NICE committee concluded Icosapent ethyl would likely be used mostly in a primary care setting. JAPC were advised to initially classify Icosapent ethyl as RED until the pathway position is agreed, then to reclassifying Icosapent ethyl as GREY after specialist initiation/recommendation following consultant/ specialist input. Mr Dhadli highlighted current treatment options for raised triglyceride from the current lipid guidance. A discussion took place, there were questions as to what advantage Icosapent ethyl holds as triglyceride at 1.7mmol/L may be acceptable. It was highlighted that it is unlikely for GPs to choose to initiate Icosapent ethyl unless the evidence shows substantial benefit over and above their antiplatelet full dose statin and/or ACE inhibitor betablocker. **Agreed:** JAPC provisionally classified Icosapent ethyl as **RED** with the view that the cardiologist and lipidologist to review the current lipid guidance pathway.	**SD**
d.	**Morphine orodispersible** Mr Dhadli informed the committee that Derbyshire Healthcare NHS Foundation Trust (DHcFT) have requested GPs to continue prescribing of morphine sulphate orodispersible tablets as a continuation of treatment in primary care after discharge from inpatient care. Morphine sulphate orodispersible tablets is a licensed UK product, approved by MHRA in July 2021 and has been available in the UK since April 2022 onwards, for severe pain which can be adequately managed only with opioids. Formulated as an immediate release orodispersible formulation for adults and children aged over 6 months in various strengths. Currently where oral morphine immediate release is required, morphine liquid 10mg in 5ml is supplied. The potential for accidental harm with oral morphine 10mg in 5ml is well documented and Mr Dhadli highlighted these from national documented incidents and 'near misses' to the committee. DHcFT plan to switch from morphine sulphate oral solution 10mg/5ml to	

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	morphine sulphate orodispersible tablets as part of its strategy to reduce risks of accidental/intentional overdose in its vulnerable patient group. These vulnerable patient groups include those that are at risk of self-harm or through confusion, adult patients admitted on oral morphine liquid for chronic pain and at risk of intentional overdose (depression), and older adult patients admitted on oral morphine or (rarely) started on oral morphine for pain/palliative care and at risk of unintentional overdose (dementia, Alzheimer's). JAPC were asked to consider a classification of GREEN or GREY, for exceptional use where risk assessment indicates (such as on discharge from DHcFT). Mr Jones highlighted that from a governance and patient perspective, morphine sulphate oral solution has always been a difficult product to monitor. With the morphine sulphate orodispersible tablets, patients can receive the exact dosage they need in a single product. The committee agreed to classify morphine sulphate orodispersible tablets as GREY for those high risk patients. It was further noted that morphine sulphate orodispersible tablets will reduce wastage, which may reduce the rate of prescribing and result in being cost saving. **Agreed:** JAPC agreed to the classification of **GREY** For exceptional use, following a risk assessment in vulnerable patient groups to reduce the risk of accidental or intentional overdose.	**SD**
6.	**CLINICAL GUIDELINES**	
a.	**Bisphosphonate length of treatment in osteoporosis: Guidance on treatment break** Mr Dhadli presented the updated Bisphosphonate length of treatment guidance after an extensive consultation with a consultant endocrinologist at and the Osteoporosis team at UHDBFT. The Bisphosphonate length of treatment guidance is based on the National Osteoporosis Guideline Group (NOGG) guidance and has been updated with the treatment flow chart originally taken from National Osteoporosis Guideline Group (NOGG) and with minor wording changes. No discussions took place, and the committee approved the changes. **Agreed:** JAPC ratified the Bisphosphonate length of treatment guidance for 3 years.	**SD**
b.	**Sativex** Mr Dhadli reported that the purpose of this paper was to update the committee on the proposed traffic light classification request and the new prescribing guideline for Sativex. Sativex was originally assigned a RED traffic light classification in June 2020 to allow clinicians to gain experience of using this new treatment. The NICE NG144 states that an offer of a 4 week trial of Sativex is given to treat moderate to severe spasticity in adults with Multiple Sclerosis (MS) if other pharmacological treatments for spasticity are not effective and if the company provides sativex according to its pay-for-responders scheme. After	

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	the 4-week trial, continue Sativex if the patient has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale (NRS). After the initial prescription, subsequent prescriptions of cannabis-based medicinal products may be issued by the GP as part of the prescribing in primary care guideline under the direction of the initiating specialist prescriber, if prescribing is in the best interest of the patient, the person's clinical condition is stable, and if the prescriber is confident to make a fully informed prescribing decision about cannabis-based medicinal products. The UHDBFT neurology team has established a pathway for Sativex. It is used as 5th line treatment for moderate/severe MS spasticity at dose 4-8 sprays per day. Mr Dhadli presented the Sativex for moderate to severe spasticity in multiple sclerosis prescribing guideline in primary care to the committee and highlighted the key information. A discussion took place. There were questions surrounding the benefit of Sativex and where Sativex is currently being issued. It was noted that if the specialist MS drugs are issued by the trust, would prescribing in primary care save the patient a hospital appointment and be cost effective. The committee agreed in principle to change the sativex traffic light classification from RED to GREY after consultant initiation as per to the sativex for moderate to severe spasticity in multiple sclerosis prescribing guideline in primary care, pending the confirmation of reduced patient follow up appointments. **Action:** JAPC to discuss virtually the sativex traffic light classification further in September's JAPC. **Action:** DDICB to emphasise the consideration of the NICE NG144 guideline and the consultant responsibilities within the Sativex for moderate to severe spasticity in multiple sclerosis (MS) prescribing guideline in primary care. **Agreed:** JAPC agreed to change the sativex traffic light classification from **RED** to **GREY** after consultant initiation at the next meeting pending confirmation of reduced hospital activity.	**SD** **SD** **SD**
c.	**<u>UTI CKD Guidance</u>** Mr Dhadli advised that this is an update to an expired guideline. The guideline has undergone consultation with the Renal Services and Lead Antimicrobial Pharmacists at UHDBFT and CRHFT. Mr Dhadli presented the reviewed and updated guidance to the committee. The guidance has been updated to be in line with national references. **Agreed:** The committee approved of the updated Management of Lower UTI in Chronic Kidney Disease (CKD) guidance and agreed ratification of 3 years.	**SD**

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d.	**Vitamin in alcohol misuse & Vitamin B compound/Vitamin B compound strong position statements** Mr Dhadli informed the committee that the purpose of these papers was to review the Vitamin supplementation in alcohol misuse guidance and the Vitamin B position statements. Vitamin supplementation in alcohol misuse is a guidance that advises on the prescribing of thiamine/vitamins post discharge noting the differences between provider organisations in the absence of national guidance. Mr Dhadli presented the Vitamin supplementation in alcohol misuse guidance and highlighted the key changes. It was highlighted that several queries were received regarding UHDBFTs recommendation of pyridoxine 20mg OD (3-months treatment) if the patient shows signs of peripheral neuropathy, to maximise recovery. Specialists stated that self-care was not felt appropriate as this patient group is unlikely to purchase vitamin. The Primary care library and evidence service were asked to conduct a focused literacy search on the evidence for pyridoxine for alcoholic peripheral neuropathy. The systematic reviews found that associations between neuropathy and vitamin B1 and B6 deficiencies were inconclusive. Vitamin supplementation appears to exert a positive therapeutic effect in alcohol-related neuropathy and that the evidence is insufficient to determine whether vitamin B is beneficial or harmful. It was recommended to remove the prescribing note for pyridoxine from the guidance, with an action for UHDBFT to reconsider the position of pyridoxine in the vitamin supplementation in alcohol misuse guidance, based on the evidence presented. It was noted that the hepatologist at UHDBFT had previously been asked why pyridoxine is being used to treat peripheral neuropathy with the lack of evidence. Dr Goddard volunteered to ask the question again. JAPC accepted the guidance. Mr Dhadli highlighted that no clinical changes had been made to the Vitamin B position statement. **Action:** The committee agreed to add the pyridoxine issue to the JAPC action tracker. **Agreed:** The committee accepted the updated vitamin supplementation in alcohol misuse guidance and the Vit B compound/compound strong position statement with ratification of 3 years.	**SD** **SD**
7.	**PATIENT GROUP DIRECTIONS**	
	The following PGDs from Public Health England were noted and agreed by JAPC: • Haemophilus influenzae type b and meningococcal C conjugate vaccine (Hib/MenC)	
8.	**SHARED CARE GUIDELINES**	
a.	**Azithromycin**	

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	Mr Dhadli informed the committee that the purpose of the paper is to agree a traffic light status and approve a new shared care agreement (SCA) for longer term prescribing of azithromycin (off-label) for use in COPD, Bronchiectasis and Asthma. Mr Dhadli presented the information that was discussed at UHDBFT Drugs and Therapeutics committee and included reference to the BTS guideline for the use of long-term macrolides in adults with respiratory disease. A shared care agreement was produced for azithromycin based on the BTS guideline with consultant input from UHDBFT and CRHFT, as well as input from the Microbiology team and Antimicrobial Stewards at UHDBFT. Clarification on the dosage of azithromycin for asthma, COPD and bronchiectasis was requested by the guideline group. A pragmatic approach was agreed by UHDBFT specialists of a starting dose of 250mg. The baseline monitoring will be done under a consultant and for safety purposes, an ECG will be performed prior to initiation of macrolides therapy to assess the QTc intervals. Ongoing monitoring will be undertaken by a GP. Dr Dills highlighted that a number of patients are being prescribed azithromycin outside of a shared care agreement and are unsure if monitoring requirements are known. It was suggested to have communications distributed to GPs and consultants to remind them that patients need to be treated under a shared care agreement for azithromycin. **Agreed:** JAPC agreed to an **AMBER** traffic light classification for azithromycin for long-term use in COPD, bronchiectasis, and asthma	**SD**
b.	**<u>RMOC SCA</u>** Mr Dhadli advised that this paper is to update JAPC on the proposed plan to update shared care agreements based on the recent publication of the RMOC shared care agreements. This guidance defines the principles for a national system of shared care for medicines. The guidance provides a framework for the seamless shared care and decision making between the patient, specialist service and primary care prescriber in relation to medicines use. The shared care plans have been developed as a national document that can be adopted and adapted where relevant, using local governance processes for use. In most cases the need for changing the document should be minimal. DDICB reviewed and compared the JAPC local shared care agreements with the RMOC shared care agreements, and gaps were highlighted to the committee. The recommendation was to keep the JAPC style for the shared care agreements, and to update the SCA with missing sections which are included in the RMOC template. Where no JAPC SCA exists, these will be prioritised to discuss if a SCA is needed. The third step will be to compare the existing JAPC SCA with the RMOC SCA and to highlight any variations, based on the current review dates. These will be introduced on a month by month basis or when within the current time frames of when they are naturally updated. The final step will be to extend the review dates for those SCA that are due to expire this year by 6 months to allow work to take place. **Agreed:** The committee agreed to adopt the work plan and extend those SCA that are due to expire for 6 months.	**SD**

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Item		Action
9.	**MISCELLANEOUS**	
a.	**Cutting fentanyl patches** Mr Dhadli notified the committee that Derbyshire Community Healthcare Services NHS Foundation Trust (DCHSFT) informed JAPC of the recent MHRA warnings that have been released regarding not cutting fentanyl patches and have requested that JAPC review the current advice to allow 'cutting fentanyl matrix patches if required'. Currently in Derbyshire the traffic light classification for fentanyl patches is GREEN, for 2nd line use only as per strong opioid for cancer pain. The current CNS formulary chapter states that If required, fentanyl matrix patches may be cut in half. For accuracy the matrix patch should be cut diagonally; the other half should be disposed of, in the correct manner as for a controlled drug. N.B. cutting a fentanyl matrix patch renders the use of the drug as "off licence." The senior pharmacist for quality and safety at DDICB reviewed the recorded safety incidents locally and there has been no error recorded with fentanyl patches in relation to cutting locally. Comments from UHDBFT, DHcFT and CRHFT were received. It was noted that a Palliative care consultant at CRHFT is going to correspond with MHRA and NICE on this issue and is reassured that there are no cutting fentanyl reservoir patches available in the UK. No reservoir patches are used in Derbyshire. The recommendation is to update the CNS formulary chapter and the strong opioid for cancer pain guidance with an insert from the MHRA warning & wording and to clarify the exceptional circumstances for cutting fentanyl patches, on advice of a palliative care consultant only following individualised treatment plan. e.g., for a starting dose where dose required is smaller than available whole patch. The committee agreed to keep the traffic light classification for fentanyl patches as GREEN, for 2nd line use only as per strong opioid for cancer pain and add advice from the palliative care consultant. **Action:** DDICB to update the CNS formulary chapter and the strong opioid for cancer pain guidance with the advice from the palliative care consultant for the clarification on cutting fentanyl patches. **Agreed:** The committee agreed to keep the traffic light classification for fentanyl patches as **GREEN**, for 2nd line use only as per strong opioid for cancer pain and add cutting advice from the palliative care consultant.	**SD** **SD**
b.	**Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs** Mr Dhadli presented the updated Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs based on NICE TA803 published in July 2022. Risankizumab alone or with methotrexate is recommended as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is	

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	recommended only if they have peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10) and/or had 2 conventional DMARDs and at least 1 biological DMARD. This has been incorporated into the commissioning algorithm. Mr Dhadli presented the Derbyshire commissioning guidance for the treatment of psoriatic arthritis and highlighted the updates. **Agreed:** JAPC approved the updated Risankizumab PsA algorithm.	**SD**
c.	**<u>Revised TORs delegation</u>** Mr Dhadli informed the committee that changes have been made to the JAPC and Guideline Group terms of references. Mr Dhadli presented the updated JAPC terms of references and highlighted the key changes. These primarily included the request to the ICB for delegated financial authority Where areas of significant resource are identified these will need to be escalated. JAPC will be taking on these delegation responsibilities from the Derby and Derbyshire Population Health and Strategic Commissioning Committee (PHSCC) a subgroup of the ICB. Mr Dhadli also presented the Guideline Group terms of reference which referenced escalation to JAPC in areas of significant resource requirements. It was noted that where areas of significant financial or clinical risk by exception will need be escalated to PHSCC by the chair, the Director of Medicines Management and Clinical Policies or DDICB Finance. **Action:** DDICB to include the Director of Medicines Management and Clinical Policies under the objectives in the JAPC and Guideline Group terms of reference.	**SD**
d.	**<u>Innovative medicines fund</u>** Mr Dhadli advised that the Innovative Medicines Fund has been tabled for information. The department of health has produced the Innovative Medicines Fund (IMF) which launched in June 2022, and this gives patients in England early access to promising drugs. The IMF will support patients with any condition to get early access to the most clinically promising treatments. Up to £340 million has been made available through the IMF to purchase the most promising medicines and fast-track them to patients to give adults and children the best chances of survival, recovery, or a healthier, longer life. It builds on the success of the reformed Cancer Drugs Fund which, in the past 5 years, has provided more than 80,000 people access to life-extending or potentially life-saving drugs which might otherwise not have been available for years. Questions were raised as to the drug introduction dates.	
e.	**<u>Specialist Circulars</u>** Mr Dhadli advised that the specialised circulars has been tabled for	

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	information and are available upon request.	
9.	**GLOSSOP TRANSFER GMGG DECISIONS**	
a.	**GMMMG Decision summaries** Mr Dhadli reported that this will be tabled in JAPC for the next 12 months to review.	
10.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in July 2022 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Silver dressing – classified as **GREY**, addition of Aquacel Ag+ ribbon to the silver dressing TL and wound care formulary • Olanzapine – classified as **GREY & DNP**, updated to clarify **GREY -** Orodispersible sugar-free tablets. **DNP -** Orodispersible tablets (unless sugar-free – GREY) • Igoro – classified as DNP, Iqoro device (Neuromuscular training device – used to relieve symptoms from stroke-related dysphagia or hiatus hernia) – **DNP** and await clinician request. Based on lack of high-quality evidence for both conditions • Macrogol – classified as **GREEN**, reference to Laxido removed from TL. • Melatonin – classified as **GREY** con/spec initiation, TL changed to state –" Melatonin MR 2mg tablets (Circadin) and melatonin 3mg tablets are the preferred licensed melatonin preparations." changed due to price reduction for Circadin. • Oxycodone – classified as **GREEN**, discontinuation of Shortec 1mg/ml oral solution & shortec concentrate 10mg/ml oral solution – reference from TL removed Formulary Update: • Nutrition and blood o Sodium bicarbonate caps - GREEN cons/spec recommendation o Sodium bicarbonate gastro-resistant capsules (Nephrotrans) is RED o Powered products list updated to Energie shake, Foodlink Complete, Complan shake and Ensure shake. o Ready-made products list updated to include Altraplen Energy, Energy Shake Complete 1.5kcal, Aymes Complete, Fortisip bottle. Clinical Guidelines (minor updates): o Management of undernutrition in adults – updated with cost effective formulary choices for powered and ready-made products (see above). Website Changes/Miscellaneous: o NICE NG219 Gout: diagnosis and management - link to NG and visual summaries added to Chapter 10 and relevant resources on website o MHRA - Chapter 4 updated with DSU for topiramate - new safety	

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	review into topiramate, triggered by a recently published observational study reporting an increased risk of neurodevelopmental disabilities in children with prenatal exposure Guideline Timetable: o The guideline table action summary and progress was noted by JAPC.	
10.	**BIOSIMILAR REPORT**	
	Mr Dhadli advised that the biosimilar report has been tabled for information. **Action:** DDICB to ask CRHFT and UHDB to provide data for the biosimilar figures.	**SD**
11.	**JAPC BULLETIN**	
	The July 2022 bulletin was ratified.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for July 2022 was noted. Mr Dhadli highlighted the following MHRA advice: • Topiramate (Topamax): start of safety review triggered by a study reporting an increased risk of neurodevelopmental disabilities in children with prenatal exposure. The MHRA have initiated a new safety review into topiramate as a result of an observational study reporting an increased risk of neurodevelopmental disabilities in children whose mothers took topiramate during pregnancy. Topiramate is known to be associated with an increased risk of congenital malformations and effects on foetal growth if used during pregnancy. Continue to counsel patients who can become pregnant on the known and emerging risks of topiramate for an unborn baby and on the need to use effective contraception throughout use. • Covid-19 vaccines and medicines: updates for July 2022 o The MHRA have recently updated the product information for Vaxzevria (COVID-19 Vaccine AstraZeneca). These changes included updating preclinical data for breastfeeding and updating the efficacy, safety and immunogenicity data. Wording has also been updated to state that in clinical trials, transient mild thrombocytopenia was commonly reported. o The MHRA continue to publish the summaries of the Yellow Card reporting for the COVID-19 vaccines being used in the UK. The report summarises information received via the Yellow Card scheme and includes other data such as usage of COVID-19 vaccines and relevant epidemiological data. The report is updated regularly to include other safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy. o Report suspected side effects to medicines, vaccines, medical device and test kit incidents used in coronavirus (COVID-19) testing and treatment using the dedicated Coronavirus Yellow Card reporting site or via the Yellow Card app.	
13.	**HORIZON SCAN**	
a.	**Monthly Horizon Scan**	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Item		Action
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New drug launches in the UK: • Brivaracetam *(Briviact)*- classified as **GREY** after consultant/specialist initiation • Dimethyl fumarate (*Tecfidera*) – classified as **RED** • Doravirine (*Pifeltro*) – classified as **RED** • Empagliflozin (*Jardiance*) – classified as **GREEN** after consultant specialist initiation • Enfortumab vedotin (*Padcev*) – classified as **RED** • Migalastat (*Galafold*) – classified as **RED** • Pralsetinib *(Gavreto) – classified as **RED** as per NHSE commissioning* • Sofosbuvir + velpatasvir (*Epclusa*) – classified as **RED** • Tafasitamab (*Minjuvi*) – classified as **RED** • Tixagevimab + cilgavimab (*Evusheld*) – classified as **RED** New indications in the UK: • Botulinum A toxin (Botox) – classified as **RED** • Doravirine + lamivudine + tenofovir disoproxil fumarate (*Delstrigo*) – classified as **RED** New formulation launches in the UK: • Buprenorphine + naloxone (*Zubsolv*) – classified as **DNP** await clinician request • Dexamethasone + levofloxacin (*Ducressa*) – classified as **DNP** await clinician request • Pyridostigmine – classified as **GREEN** after consultant/specialist initiation and dose titration Approved in the UK: • Asciminib (scemblix) – classified as **RED** • Belzutifan (*Welireg*) – classified as **RED** • Landiolol (*Rapibloc*) – classified as **DNP** await clinician request • Levodopa + carbidopa + entacapone (*Lecigon*) – classified as **GREEN** • Menotrophin (*Menopur*) – classified as **DNP** await clinician request • Sofosbuvir + velpatasvir (*Epclusa*) – classified as **RED** • Tebentafusp (*Kimmtrak*) – classified as **RED** NHSE commissioned	
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the ICB which had been made for the following NICE guidance in July 2022: ICS commissioned drugs: TA803 Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs – classified as **RED (**as per NICE TA803) TA805 Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides – classified as **RED**	

Item		Action
	or **GREY** specialist initiation (as per NICE TA805) TA807 Roxadustat for treating symptomatic anaemia in chronic kidney disease – classified as **RED (**as per NICE TA807) NHSE Commissioned drugs: HST21 Setmelanotide for treating obesity caused by LEPR or POMC deficiency – classified as **RED** (NHS England as per NICE HST21) TA806 Belimumab for treating lupus nephritis (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA806) TA808 Fenfluramine for treating seizures associated with Dravet syndrome – classified as **RED** (NHS England as per NICE TA808) TA809 Imlifidase for desensitisation treatment before kidney transplant in people with chronic kidney disease – classified as **RED** (NHS England as per NICE TA809) TA810 Abemaciclib with endocrine therapy for adjuvant treatment of hormone receptor-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence - classified as **RED** (NHS England as per NICE TA810) TA811 Duvelisib for treating relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA811)	
15.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
a.	• Medication Optimisation Safety Team 09/06/2022 • Sheffield Area Prescribing Group 16/06/2022	
16.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	<u>Classifications</u> Fentanyl Patches – **GREEN/GREY** after palliative care specialist initiation - Cutting of a patch is only allowed under exceptional circumstances, on advice of palliative care consultant following individualised treatment plan. Ranibizumab biosimilar (Ongavia) – **RED** - Ophthalmology indications. Morphine Sulphate orodispersible tabs – **GREY** for exceptional use following a risk assessment e.g.in vulnerable patient groups, to reduce the risk of accidental or intentional overdose. Azithromycin – **AMBER** for the use in adult respiratory infections. See Shared care for details. Risankizumab – **RED** as per NICE TA803 for treating active psoriatic arthritis after inadequate response to DMARDs. Icosapent ethyl – **RED** as per NICE TA805 with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides Roxadustat – **RED** as per NICE TA807 for treating symptomatic anemia in chronic kidney disease Setmelanotide – **RED** as per NICE HST21 for treating obesity caused by LEPR or POMC deficiency	

Item		Action
	Belimumab – **DNP** as per NICE TA806 for treating lupus nephritis (terminated appraisal) Fenfluramine – **RED** as per NICE TA808 for treating seizures associated with Dravet syndrome Imlifidase – **RED** as per NICE TA809 for desensitisation treatment before kidney transplant in people with chronic kidney disease Abemaciclib – **RED** as per NICE TA810 with endocrine therapy for adjuvant treatment of hormone receptor-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence Duvelisib – **DNP** as per NICE TA811 - Duvelisib for treating relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments (terminated appraisal) Pralsetinib (Gavreto) – **RED** for the treatment of adults with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer not previously treated with a RET inhibitor. NHSE commissioned Dexamethasone + levofloxacin (Ducressa) eye drops – DNP for the prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults. Belzutifan (Welireg) – **RED** for the treatment of adults with von Hippel-Lindau (VHL) disease. Landiolol (Rapibloc) – **DNP** for supraventricular tachycardia and for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other circumstances where short-term control of the ventricular rate with a short acting agent is desirable.	
16.	**ANY OTHER BUSINESS**	
a.	There were no items of any other business.	
17.	**DATE OF NEXT MEETING**	
	Tuesday 11th October 2022, papers are to be circulated and agreed virtually as per JAPC interim Terms of Reference, which is effective during the COVID-19 pandemic.	