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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 12th October 2021

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Inclisiran	RED as per NICE TA733 for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if there is a history of cardiovascular events (secondary prevention) and LDL-C ≥2.6mmol/l despite maximum tolerated lipid lowering therapy
Tretinoin + clindamycin (Treclin)	GREEN fixed combination topical products – 1st line options for the treatment of mild to moderate acne. See acne guidance
Adapalene + Benzoyl peroxide (Epiduo)	GREEN fixed combination topical products – 1st line options for the treatment of mild to moderate acne. See acne guidance
Benzoyl peroxide + clindamycin (Duac)	GREEN fixed combination topical products – 1st line options for the treatment of mild to moderate acne. See acne guidance
Clindamycin	DNP do not use clindamycin to treat acne as monotherapy (topical antibiotic) for new patients
Nefopam	DNP remains as DNP
Amitriptyline	GREEN 1st line off-label options for the treatment of chronic primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks
Duloxetine	GREEN 1st line off-label options for the treatment of chronic primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks
Citalopram	GREEN 1st line off-label options for the treatment of chronic primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks
Fluoxetine	GREEN alternative options (off-label) if 1st line options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance
Paroxetine	GREEN alternative options (off-label) if 1st line

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	options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance
Sertraline	GREEN alternative options (off-label) if 1st line options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance
Herpes Zoster vaccine (Shringrix)	DNP available only as part of the national shingles programme and obtained from centrally purchased stock
Midazolam (Miprosed)	RED use in children aged 6 months to 14 years for sedation and anxiolysis prior to diagnostic, surgical, therapeutic or endoscopic procedures, and premedication before induction of general anaesthesia
Bimekizumab	RED (as per NICE TA723) for treating moderate to severe plaque psoriasis
Nivolumab	DNP (NHS England as per NICE TA724) with ipilimumab and chemotherapy for untreated metastatic nonsmall-cell lung cancer
Abemaciclib	RED (NHS England as per NICE TA725) with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy
Daratumumab	DNP (NHS England as per NICE TA726) with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)
Isatuximab	DNP (NHS England as per NICE TA727) with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)
Midostaurin	RED (NHS England as per NICE TA728) for treating advanced systemic mastocytosis
Sapropterin	RED (NHS England as per NICE TA729) for treating hyperphenylalaninaemia in phenylketonuria
Avapritinib	DNP (NHS England as per NICE TA730) for treating unresectable or metastatic gastrointestinal stromal tumours (terminated appraisal)
Vericiguat	DNP (NHS England as per NICE TA731) for treating chronic heart failure with reduced ejection fraction (terminated appraisal)

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Beclometasone/formoterol (Luforbec)	GREEN replaces Fostair MDI 100/6 as first line MDI
Beclometasone/formoterol/glycopyrronium (Trimbow DPI)	GREY for the maintenance treatment of moderate to severe COPD. Triple therapy is reserved for exceptional use in severe disease in the presence of persistent exacerbations despite other treatments
Cariprazine	RED for licensed treatment of schizophrenia
Delafloxacin	DNP – ES37 Antimicrobial prescribing: delafloxacin

	for community-acquired pneumonia
Inclisiran	Entry temporarily removed pending NICE TA (September 2021 MMSCGG meeting)
Co-beneldopa	GREEN specialist initiation
Nicotine Replacement Therapy (NRT)	GREY usually supplied via stop smoking services, GP may prescribe in exceptional circumstances in accordance to Derbyshire formulary for NRT
Forceval	GREY for the treatment of zinc/copper deficiency following bariatric surgery, as per the bariatric surgery guideline

Clinical Guidelines

Managing Acne vulgaris – partial update
Nefopam Position Statement – partial update
Management of Non-Malignant Chronic Pain in Primary Care – updated following NICE NG193
Pharmacological Management of Osteoarthritis (OA) – new guideline
Deprescribing & Safer Prescribing of Strong Opioids in Non-malignant Pain – new guideline
Strong opioids for cancer pain – partial update

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Present:	
Derby and Derbyshire CCG	
Dr R Gooch	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)
Mr S Hulme	Director of Medicines Management and Clinical Policies
Mrs K Needham	Assistant Director of Medicine Optimisation and Delivery
Mrs S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Dr H Hill	GP
Dr R Dills	GP
Ms J Savoury	Assistant Chief Finance Officer
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	
Ms A Brailey	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Chief Pharmacist
Derby and Derbyshire Local Medical Committee	
Dr K Markus	Chief Executive Officer
Derbyshire Health United	
Staffordshire and Stoke-on-Trent CCG's	
Ms S Bamford	Medicines Optimisation Senior Lead Pharmacist
In Attendance:	
Mr A Brownlee	Chief Pharmacy Technician (Interface)
Ms L McKean	Senior Pharmacy Technician, High-Cost Interventions, DDCCG
Mr F Rahman	Medicines Management and Clinical Policy Guidelines, Formulary and Policy Manager, DDCCG
Ms S Suri	Head of Medicines Optimisation Safety & QIPP, DDCCG
Dr S Cletus	GP Trainee, UHDBFT
Dr T Wright	GP Trainee, UHDBFT
Mrs K Rogers	Senior Administrator, DDCCG (minutes)

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Item		Action
1.	**APOLOGIES**	
	Dr A Mott, Ms A Reddish	
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.	
4.	**JAPC ACTION SUMMARY**	
a.	**Cannabis based medicine (Sativex)** Sativex was previously classified as RED for treating spasticity in adults with multiple sclerosis, at the JAPC meeting in June 2020. University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) are due to provide some audit data to JAPC which Mr Moore will table at the next meeting.	
b.	**Hydroxychloroquine** Mr Dhadli reported that the work surrounding hydroxychloroquine is still ongoing and is likely to be for some time, guidance is awaited from the Royal College of Ophthalmologists (RCO) and a local pathway will be developed following this. It was suggested that this be taken off the JAPC Action Summary and placed on the Guideline Group Action Summary for monitoring over the longer term.	
c.	**ACS** Mr Dhadli advised that no comments have been received to date for the dual antiplatelet guidelines update, in line with NICE NG185 ACS.	
d.	**Mycophenolate** Mr Dhadli reported that the Regional Medicines Optimisation Committee (RMOC) Shared Care Agreements are currently out for consultation. This will be brought to a future JAPC meeting when the Shared Care Agreements have been confirmed.	
e.	**Atrial Fibrillation** Mr Dhadli advised that the Atrial Fibrillation guidance is in the process of being updated. Consideration will be made as to the JAPC positioning of NOAC over warfarin in AF, in line with NICE NG196. A review will be carried out to look at whether Orbit is on clinical systems.	
5.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Inclisiran** Mr Dhadli informed the committee that the purpose of the paper is to agree a traffic light status for inclisiran, for treating primary hypercholesterolaemia or mixed dyslipidaemia as per NICE TA733. Inclisiran is recommended only if there is a history of any of the following	

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	cardiovascular events: acute coronary syndrome, coronary or other arterial revascularisation procedures, coronary heart disease, ischaemic stroke or peripheral arterial disease, and low-density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or greater despite maximum tolerated lipid lowering therapy. Inclisiran has been identified by NHSE/I as a medicine that it wishes to adopt systematically and at scale to help address sub-optimal lipid management in high-risk patient populations, for people with ASCVD in whom lipid targets cannot be met on maximum tolerated statins alone or with ezetimibe. Inclisiran has a Black triangle status, it is first-in-class small-interfering RNA (siRNA), which inhibits PCSK9 enzyme, and reduces LDL-C levels. Inclisiran reduces production of PCSK9 through gene silencing. It is administered as a subcutaneous injection by a healthcare professional. It should be used with caution in severe hepatic impairment and severe renal impairment. Clinical effectiveness is taken from the ORION 10 trial (one of a series of 11 trials). There is no data directly comparing inclisiran with ezetimibe, alirocumab or evolocumab. There is also no long-term evidence on whether inclisiran reduces cardiovascular events. Mr Dhadli discussed the summary of patient orientated outcomes along with the costs of inclisiran. NHSE/I communicated a letter in September 2021 requesting APCs to adopt to formulary ahead of a positive NICE TA approval. A discussion took place, there were concerns with regards to inclisiran being initiated in Primary Care and the capacity implications. Ms Braithwaite also added that it brings uncertainty as to whether this could impact on the workload of staff at Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) if they were asked to administer this. There is a lack of clarity as to when inclisiran should be prescribed over other available treatment options, which have greater evidence based, long term data. If inclisiran were to be prescribed, it was felt that this would be without adequate follow up. In terms of cost, there is a NHS listed price for inclisiran and a drug tariff price accessible through FP10 prescribing. This negotiated price is time limited for 3 years. It was estimated that across Derbyshire 260 patients would receive treatment. It was noted that inclisiran is not excluded from tariff, which means that if secondary care use inclisiran, they would pay the costs associated with this. The committee agreed that due to inclisiran's Black Triangle status and it being a novel drug, along with a lack of clinical evidence without hard outcomes and uncertainty of cost effectiveness beyond 3 years, this should be classified as RED. **Action:** UHDBFT and Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) were asked to feedback on the discussions that will take place at their Drugs and Therapeutics Committee in regard to inclisiran, at the January JAPC meeting. **Agreed:** JAPC classified inclisiran as **RED** as per NICE TA733 for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if there is a history of cardiovascular events (secondary prevention) and LDL-C ≥2.6mmol/l.	**DM/AB** **SD**

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b.	**Liraglutide** Ms Braithwaite reported that The DCHSFT Tier 3 community weight management service is seeking approval to prescribe liraglutide, which has been approved for managing overweight and obesity by NICE (TA664) in December 2020. Liraglutide has already been approved for use within the UHDBFT service, based on the NICE TA. This service is separate to the DCHSFT led Tier 3 provision, but works closely with it due to shared clinical input. The bariatric unit, located at the Royal Derby Hospital site, provides bariatric services (both elective and emergency) for patients from Derbyshire, Nottinghamshire and Lincolnshire. Prior to being considered for bariatric surgery all patients need to complete a tier 3 weight management programme. Within Derbyshire this is the DCHSFT Tier 3 Weight Management service. Patients from Nottinghamshire and Lincolnshire can be referred to the hospital's tier 3 service and it is within this service that approval and usage of liraglutide has commenced. If DCHSFT wish to prescribe liraglutide, they would need either UHDBFT or CRHFT to purchase this and supply to DCHSFT, or directly dispense to the patient, as DCHSFT do not currently have an ordering pharmacy. There is a substantial cost associated with this, however patients should not be disadvantaged by the pathway in which they are choosing to receive the tier 3 community weight management service. Liraglutide is commissioned by CCGs, therefore JAPC previously assigned a traffic light classification of RED, (January 2021) for weight management. JAPC noted that this request is about the service redesign and contractual arrangements for a tier 3 weight management service. JAPC does not allocate resources for service redesign development, this is outside of the remit for JAPC. Due to this, DCHSFT have been advised to submit a business case to include all costs, and table this at the Derbyshire Prescribing Group and then the Clinical and Lay Commissioning Committee (CLCC). It has been tabled at JAPC for information and to raise awareness of this to JAPC members and pharmacy colleagues. A discussion took place, and committee members were in support of this clinically, however JAPC are not in a position to comment on how the service is implemented or how resources are allocated. **Agreed:** JAPC supports the proposal that Liraglutide is made available through the DCHSFT Tier 3 Weight Management service for patients meeting the appropriate criteria, and that funding is provided to support this provision. Pending agreement from the Derbyshire Prescribing Group and CLCC.	**AB**
6.	**CLINICAL GUIDELINES**	
a.	**Acne** Mr Dhadli advised that this is an update to an existing guidance, following publication of NICE NG198 Acne vulgaris management (25th June 2021). The guideline has been sent out for wider consultation to GPwER's dermatology, Consultant Dermatologists at both UHDBFT and CRHFT, and members of the Derbyshire Medicines Management Shared Care and Guideline Group (MMSCGG). Mr Dhadli summarised the changes within the guideline; the	

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	definition of acne severity has been updated to 'mild to moderate' and 'moderate to severe'. Fixed combination topical products are now recommended as 1st line treatment, Appendix B lists NICE recommended 1st line treatment options with the most cost-effective choices first. A review is recommended at 3 monthly intervals when prescribing systemic antibiotics. Traffic light classifications are to be updated to reflect the changes within the guideline. Committee members agreed with the update to the guideline noting traffic light changes that were required. **Agreed:** JAPC classified tretinoin + clindamycin (Treclin), adapalene + benzoyl peroxide (Epiduo), benzoyl peroxide + clindamycin (Duac) as **GREEN** fixed combination topical products – 1st line options for the treatment of mild to moderate acne. **Agreed:** JAPC classified clindamycin as **DNP** do not use clindamycin to treat acne as monotherapy (topical antibiotic) for new patients. **Agreed:** JAPC ratified the Managing Acne vulgaris guideline, with a review date of 3 years.	**SD** **SD** **SD**
b.	**<u>Nefopam</u>** Mr Dhadli reported that this is a routine review to the existing Nefopam position statement. Historically nefopam was GREEN 3rd line at STEP 2 of WHO pain ladder after codeine/tramadol, as a treatment option if paracetamol, NSAID and opioids could not be tolerated or patients were unresponsive to non-opioid analgesics. Its use in Derbyshire was restricted in January 2016 for use only in patients with contraindications or intolerance to NSAIDs or opiates. Nefopam was then further restricted in November 2016 to DNP (previously knowns as Black) following a review of its cost effectiveness. Currently SPS evidence summary on nefopam for chronic pain remains unchanged from the previous position, but there has been a cost reduction, however still more expensive than other formulary analgesics. Significant work has been carried out by NHS Derby and Derbyshire CCG (DDCCG) Medicines Management team, practices, providers and UHDBFT to reduce nefopam prescribing since 2016. However there are some patients where prescribing of nefopam cannot be stopped due to medical reasons (mainly renal or liver complications), where patients are unable to use paracetamol or NSAIDS. It was noted that some areas e.g. Nottingham, Sheffield allow restricted use of nefopam. This has been tabled at JAPC to either agree the position statement update as nothing has changed, or recognise that a review of its use has been carried out and it has been restricted, therefore consider the option to 'relax' its use to allow current prescribing and clinical reasons by exception. The latter would include a strict criterion for appropriate prescribing and a review period to monitor effectiveness in each patient. Mr Dhadli discussed costs associated with nefopam. A discussion took place, it was suggested that if it is reclassified, where prescribing of nefopam is appropriate in a small number of patients, initiation should be carried out within secondary care. It was highlighted that significant	

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	work has been done over the past few years to reduce prescribing and since then, there have been very few requests from clinicians/pain clinics for the use of nefopam. Adequate pain services are also not yet in place. After consideration of these points, members felt that nefopam should remain classified as DNP. **Agreed:** JAPC recommended that nefopam remain classified as **DNP.** **Agreed:** JAPC ratified the Nefopam Position Statement with a review date of 3 years.	**SD** **SD**
c.	**<u>Non-malignant chronic pain</u>** Mr Dhadli advised that the Management of Non-malignant Chronic Pain in Primary Care guideline has been re-drafted following NICE NG193 – Chronic pain (primary and secondary) in over 16s, which represents significant change to current practice, particularly with regards to the (pharmacological) management of chronic primary pain. NICE NG193 includes the definition for chronic primary pain, management for primary chronic pain utilising non-pharmacological interventions, use of off-label antidepressants and a list of 'DO NOT initiate' drugs which include NSAID, opioids, paracetamol, antiepileptics including gabapentinoids, antipsychotics, benzodiazepines, corticosteroids injections, ketamine and local anaesthetics. At the time of publication the Faculty of Pain Medicine (FPM) and British Pain Society (BPS) have both expressed concerns over NICE recommendations around the new concept of chronic primary pain in terms of both diagnosis and management. In May 2021 JAPC recommended a local chronic pain guideline be produced, which will acknowledge that there are gaps in capacity and service provision across Derbyshire for non-pharmacological therapies as well as specialist pain management and other associated services (e.g. CBT) and the concerns raised by FPS/BPS. A separate local guideline for low back pain & sciatica was approved by JAPC in July 2021. The non-malignant chronic pain guideline has been re-drafted in line with principles agreed at a previous JAPC meeting. Key changes were highlighted to JAPC members. NICE recommends six antidepressants, Mr Dhadli presented a table which listed dose, cost and considerations for each classified antidepressant. Amitriptyline (TCA) is recommended as 1st line, as the most cost-effective choice and others listed from each drug class. Mr Jones highlighted that hyponatraemia may be associated with all antidepressants, he asked that signposting to the antidepressant guideline be added, for further advice in regard to switching more commonly used antidepressants. Mr Dhadli went on to say that the referral criteria for chronic pain has been updated in line with NICE Clinical Knowledge Summaries (CKS) and neuropathic pain referral criteria has been moved into the neuropathic pain guideline. Pharmacological management of osteoarthritis is now a new stand-alone document, based on NICE CG177. Tramadol has been removed and added into the neuropathic pain guideline. A new stand-alone document has been produced relating to opioid prescribing	**SQ**

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	'Deprescribing & safer prescribing of strong opioids in non-malignant pain'. Mr Dhadli informed the committee of financial implications associated with implementing the Non-Malignant Chronic Pain guideline, which would require a move from drug treatments to implementing pain management services. A discussion took place, it was agreed to clarify in the traffic light classification that amitriptyline is for off licence use, as per pain guidance. Mr Dhadli discussed in more detail the Pharmacological Management of Osteoarthritis guideline and the Deprescribing & Safer Prescribing of Strong Opioids in Non-malignant Pain guideline. Mr Jones requested that gabapentinoids and beta-blockers be added to 'considerations for patients at high risk of opioid harm' on page 3. **Agreed:** JAPC classified amitriptyline, duloxetine and citalopram as **GREEN 1st line off-label options** for the treatment of chronic primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks. **Agreed:** JAPC classified fluoxetine, paroxetine and sertraline as **GREEN alternative options (off-label)** if 1st line options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance. **Agreed:** JAPC ratified the Management of Non-Malignant Chronic Pain in Primary Care guideline, with a review date of 3 years. **Agreed:** JAPC ratified the Pharmacological Management of Osteoarthritis (OA) guideline, with a review date of 3 years. **Agreed:** JAPC ratified the Deprescribing & Safer Prescribing of Strong Opioids in Non-malignant Pain guideline, with a review date of 3 years.	**SQ** **SQ** **SD** **SD** **SD** **SD** **SD**
d.	**<u>Strong opioids for cancer pain</u>** Mr Dhadli reported that this is an update to the existing Choice of Strong Oral/Topical Opioid for Cancer Pain guideline. It went out for consultation to Ms A Braithwaite Head of Medicines Management DCHSFT, Mr C Ward Divisional Lead Pharmacist for Cancer UHDBFT and the MMSCGG. There is a minor update to Zomorph administration direction as per SPC, and clarity in unstable patients & those whose opioid needs remain unclear, when consideration should be given to the use of a syringe driver ahead of transdermal fentanyl. DDCCG QIPP group is reviewing preferred brands of strong opioids in the coming months, preferred brands will be updated if recommended. **Agreed:** JAPC ratified the Choice of Strong Oral/Topical Opioid for Cancer Pain guideline, with a review date of 3 years.	**SD**
7.	**MISCELLANEOUS**	
a.	**<u>Prescribing Specification 2022-23</u>** Mr Dhadli advised that the Prescribing Specification is part of the healthcare	

Item		Action
	services contract that commissioners have with provider organisations. This document outlines the role and responsibilities of our provider trusts in ensuring a transparent and collaborative approach to the safe and effective management of medicines, seamless care of patients between NHS organisations and ensuring high quality prescribing. The Prescribing Specification has been updated to remove references to the CCG, and it has been replaced with Joined Up Care Derbyshire Integrated Care System (JUCD ICS) throughout the document. There have been two publications released which include Combination use of Biologics for Different Co-morbidities, produced by RMOC South, and RMOC advice on Free of Charge (FOC) Medicines Schemes. RMOC South published an advisory statement stating that evidence on the co-administration of two or more biologics for co-morbidities is lacking and limited to case reports and case series. Although the efficacy of combination biologic therapy may be inferred due to their targets, evidence to support this is lacking; and there may be risk of interactions and additive adverse effects. Some RMOC members considered that the assessment of patients via the Individual Funding Request (IFR) route was currently the most appropriate option in this scenario. Following a discussion with UHDBFT and CRHFT, it has been agreed that the Prescribing Specification should state that requests for use of combination biologics should be approved through an MDT meeting, and then presented at a D&T meeting with a CCG representative present (and NHSE view if applicable). The RMOC FOC scheme template has been recirculated, this has been added to the Prescribing Specification as an appendix. The aim of this advice is to highlight considerations that locally systems should take into account, to address potential financial, administrative, and clinical risks, to ensure there is a consistent and equitable approach through providing guidance for Trusts and commissioners when considering the use of FOC medicines schemes. **Agreed:** JAPC accepted the proposed changes to the Prescribing Specification. **Action:** The consultation period for this has been extended to allow reasonable time for further changes and comments. If minor changes are received then this will be tabled at the December JAPC meeting, however if several comments are received then it will be tabled at the January JAPC meeting for further discussion.	**SD** **SD/SQ**
8.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in September 2021 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Beclometasone/formoterol (Luforbec) – classified as GREEN, replaces Fostair MDI 100/6 as first line MDI.	

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	• Beclometasone/formoterol/glycopyrronium (Trimbow DPI) – classified as GREY, for the maintenance treatment of moderate to severe COPD. Triple therapy is reserved for exceptional use in severe disease in the presence of persistent exacerbations despite other treatments.
	• Daptomycin – to remain classified as RED, clarify daptomycin (IV) red for both adult and children.
	• Cariprazine – reclassified as RED from DNP for licensed treatment of schizophrenia.
	• Delafloxacin – reclassified as DNP from GREY. ES37 Antimicrobial prescribing: delafloxacin for community-acquired pneumonia.
	• Inclisiran – entry temporarily removed pending NICE TA (September 2021 MMSCGG meeting).
	• Co-beneldopa – classified as GREEN specialist initiation.
	• Co-careldopa – to remain classified as GREEN specialist initiation. Comment added 'Sinemet is currently a cost-effective brand'.
	• Nicotine Replacement Therapy (NRT) – reclassified as GREY from GREEN. Usually supplied via stop smoking services, GP may prescribe in exceptional circumstances in accordance to Derbyshire formulary for NRT.
	• Forceval – classified as GREY for the treatment of zinc/copper deficiency following bariatric surgery, as per the bariatric surgery guideline.
	
	Formulary / Clinical Guidelines Update:
	• CNS chapter – inserted key message and link to NICE NG201 antenatal care – advice on nausea and vomiting in pregnancy
	  ○ mild to moderate nausea & vomiting likely to resolve before 16-20 weeks
	  ○ non-pharmacological option including ginger
	  ○ for women who choose pharmacological option offer an antiemetic after discussion advantages and disadvantages. Refer to table detailing advantages and disadvantages of each option.
	• Respiratory formulary chapter, asthma guideline, COPD guideline, common inhalers document to be updated to include Luforbec as cost effective alternative to Fostair (Fostair removed/remains Green) and Trimbow DPI.
	• JUCD adult headache pathway added under other resources to CNS chapter. Relevant messages added to CNS formulary chapter.
	• Skin chapter – inserted MHRA drug safety update on topical corticosteroids – risk of topical steroid withdrawal reactions.
	
	Minor formulary update following clinical system formulary alignment:
	• Note added to endocrine chapter to state "Dextrogel 40% gel is currently a cost-effective brand of glucose 40%".
	• GTN 300microgram S/L tablet discontinued – removed from TLC and CV chapter.
	• Aluminium hydroxide (Alu-caps) discontinued – removed from TLC and phosphate binder guideline.
	• Methylprednisolone with lidocaine – TLC and MSK chapter updated to list generically.
	• Dexamethasone 500 microgram tablets added to endocrine chapter.
	• Hydrocortisone 2.5% cream removed from TLC and skin chapter.	

Item		Action
	Website Changes/Miscellaneous: • Lithium (Priadel) switch document removed as no longer applicable. • New link to the Rightbreathe website under respiratory chapter other resources. Guideline Timetable: • The guideline table action summary and progress was noted by JAPC.	
9.	**BIOSIMILAR REPORT**	
	Mr Dhadli advised that the biosimilar report has been tabled for information.	
10.	**JAPC BULLETIN**	
	The September 2021 bulletin was ratified.	**SD**
11.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for September 2021 was noted. Mr Dhadli highlighted the following MHRA advice: • Topical corticosteroids: information on the risk of topical steroid withdrawal reactions. Rarely, severe adverse effects can occur on stopping treatment with topical corticosteroids, often after long-term continuous or inappropriate use of moderate to high potency products. To reduce the risks of these events, prescribe the topical corticosteroid of lowest potency needed and ensure patients know how to use it safely and effectively. • COVID-19 vaccines and medicines: updates for August 2021 ○ statement published on booster doses of Pfizer/BioNTech and AstraZeneca COVID-19 vaccines ○ approval given to Ronapreve▼ (casirivimab/imdevimab), a monoclonal antibody treatment for the prevention and treatment of COVID-19 ○ shelf life, special precautions for storage and special precautions for disposal updated in the Summary of Product Characteristics and Patient Information Leaflet for Spikevax (formerly COVID-19 Vaccine Moderna) ○ precautionary warning added about Guillain-Barré Syndrome to the Summary of Product Characteristics and Patient Information Leaflet for Vaxzevria (formerly COVID-19 Vaccine AstraZeneca) following a review of the available data ○ extension authorised to the current UK approval of the Spikevax vaccine (formerly COVID-19 Vaccine Moderna) that allows its use in 12 to 17 year olds.	
12.	**HORIZON SCAN**	
a.	**<u>Monthly Horizon Scan</u>** Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New drug launches in the UK: • Adalimumab biosimilar (Yuflyma) – to remain classified as **RED** (as per NHS England commissioning intentions) • Baloxavir marboxil (Xofluza) – classified as **DNP** await national guidance or	

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	clinician request • Botulinum A toxin (Botox) – to remain classified as **RED** (as per NHS England commissioning intentions) • Cannabidiol (Epidyolex) – to remain classified as **RED** (as per NHS England commissioning intentions) • Dapagliflozin (Forxiga) for treatment pf CKD – await national guidance • Empagliflozin (Jardiance) use in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction – await national guidance • Daratumumab (Darzalex) – classified as **RED** (as per NHS England commissioning intentions) • Herpes zoster vaccine (Shingrix) – classified as **DNP** available only as part of the national shingles programme and obtained from centrally purchased stock • Ipilimumab (Yervoy) – classified as **RED** (as per NHS England commissioning intentions) • Midazolam (Miprosed) – classified as **RED** for use in children aged 6 months to 14 years for sedation and anxiolysis prior to diagnostic, surgical, therapeutic or endoscopic procedures, and premedication before induction of general anaesthesia New formulation launches in the UK: • Nivolumab (Opdivo) – classified as **RED** (as per NHS England commissioning intentions) • Pembrolizumab (Keytruda) – classified as **RED** (as per NHS England commissioning intentions) • Tralokinumab (Adtralza) – classified as **RED** (as per NHS England commissioning intentions) • Vericiguat (Verquvo) – classified as **DNP** (terminated appraisal) • Ropeginterferon alfa-2b (Besremi) – to remain classified as **RED** (as per NHS England commissioning intentions) • Secukinumab (Cosentyx) – to remain classified as **RED** (as per NHS England commissioning intentions) Licence extensions: • Sucroferric oxyhydroxide (Velphoro) – previously classified as **RED** • Sodium oxybate (Xyrem) – previously classified as **RED** • Beclometasone + formoterol (Luforbec) – previously classified as **GREEN** • Tiotropium (Tiogiva) – previously classified as **GREEN** • Treprostinil sodium (Treprostinil Tillomed) – previously classified as **RED**	
13.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in September 2021: TA723 Bimekizumab for treating moderate to severe plaque psoriasis – classified as **RED** (as per NICE TA723) TA724 Nivolumab with ipilimumab and chemotherapy for untreated metastatic nonsmall-cell lung cancer – classified as **DNP** (NHS England as per NICE	

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	TA724) TA725 Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy – classified as **RED** (NHS England as per NICE TA725). This guidance updates and replaces NICE TA579 TA726 Daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA726) TA727 Isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA727) TA728 Midostaurin for treating advanced systemic mastocytosis – classified as **RED** (NHS England as per NICE TA728) TA729 Sapropterin for treating hyperphenylalaninaemia in phenylketonuria – classified as **RED** (NHS England as per NICE TA729) TA730 Avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA730) TA731 Vericiguat for treating chronic heart failure with reduced ejection fraction (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA731)	
14.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
a.	• UHDBFT Drugs and Therapeutics Group 17/08/2021 • Medication Optimisation Safety Team 01/07/2021	
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	<u>Classifications</u> Inclisiran – RED as per NICE TA733 for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if there is a history of cardiovascular events (secondary prevention) and LDL-C ≥2.6mmol/lLariglutide approving. Tretinoin + clindamycin (Treclin) – GREEN fixed combination topical products – 1st line options for the treatment of mild to moderate acne. Adapalene + benzoyl peroxide (Epiduo) – GREEN fixed combination topical products – 1st line options for the treatment of mild to moderate acne. Benzoyl peroxide + clindamycin (Duac) – GREEN fixed combination topical products – 1st line options for the treatment of mild to moderate acne. Clindamycin – DNP do not use clindamycin to treat acne as monotherapy (topical antibiotic) for new patients. Nefopam – DNP remains as DNP Amitriptyline – GREEN 1st line off-label options for the treatment of chronic	

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	primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks. Duloxetine – GREEN 1st line off-label options for the treatment of chronic primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks. Citalopram – GREEN 1st line off-label options for the treatment of chronic primary pain. Antidepressants can help with quality of life, pain, sleep and psychological distress, even in the absence of a diagnosis of depression. Review the efficacy and side-effects after 4-6 weeks. Fluoxetine – GREEN alternative options (off-label) if 1st line options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance. Paroxetine – GREEN alternative options (off-label) if 1st line options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance. Sertraline – GREEN alternative options (off-label) if 1st line options are not suitable for the treatment of chronic primary pain. See non-malignant chronic pain in primary care guidance. Herpes Zoster vaccine (Shringrix) – DNP available only as part of the national shingles programme and obtained from centrally purchased stock. Midazolam (Miprosed) – RED use in children aged 6 months to 14 years for sedation and anxiolysis prior to diagnostic, surgical, therapeutic or endoscopic procedures, and premedication before induction of general anaesthesia. Bimekizumab – RED (as per NICE TA723) for treating moderate to severe plaque psoriasis. Nivolumab – DNP (NHS England as per NICE TA724) with ipilimumab and chemotherapy for untreated metastatic nonsmall-cell lung cancer. Abemaciclib – RED (NHS England as per NICE TA725) with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy. Daratumumab – DNP (NHS England as per NICE TA726) with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal). Isatuximab – DNP (NHS England as per NICE TA727) with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal). Midostaurin – RED (NHS England as per NICE TA728) for treating advanced systemic mastocytosis. Sapropterin – RED (NHS England as per NICE TA729) for treating hyperphenylalaninaemia in phenylketonuria. Avapritinib – DNP (NHS England as per NICE TA730) for treating unresectable or metastatic gastrointestinal stromal tumours (terminated appraisal). Vericiguat – DNP (NHS England as per NICE TA731) for treating chronic heart failure with reduced ejection fraction (terminated appraisal).	
16.	**ANY OTHER BUSINESS**	
a.	There were no items of any other business.	

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17.	**DATE OF NEXT MEETING**	
	Tuesday, 9th November 2021, papers are to be circulated and agreed virtually as per JAPC interim Terms of Reference, which is effective during the COVID-19 pandemic.	