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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 8th December 2020

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Midazolam-Epistatus	GREY when initiated by out-of-area providers
FreeStyle Libre 2	GREY after diabetic consultant/specialist initiation within a Derbyshire Diabetes service. Available through the specialist team after February 2021
Rosuvastatin	GREY 2nd line alternative treatment option after atorvastatin. Can also be used when there is complete intolerance to atorvastatin or partial intolerance to other statins
Galcanezumab	RED NICE TA659 for prevention of migraine in adults who have ≥4 migraine days per month. CCG commissioned
Ferric carboxymaltose (Ferinject)	RED Iron deficiency when oral iron is ineffective or cannot be used, or when there is a clinical need to deliver iron rapidly. MHRA, Nov 2020 - risk of symptomatic hypophosphataemia leading to osteomalacia and fractures.
Bevacizumab biosimilar (Aybintio)	DNP await national guidance or clinician request
Siponimod	RED (NHS England as per NICE TA656)
Carfilzomib	RED (NHS England as per NICE TA657)
Isatuximab with pomalidomide and dexamethasone	RED (NHS England as per NICE TA658)
Galcanezumab	RED (as per NICE TA659)
Darolutamide with androgen deprivation therapy	RED (NHS England as per NICE TA660)
Pembrolizumab	RED (NHS England as per NICE TA661)
Durvalumab	DNP (NHS England as per NICE TA662)

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Fosfomycin	GREY 2nd line choice for UTI in non-pregnant women as per NICE/PHE antimicrobial guideline.
Macrogol	GREEN Macrogol compound oral powder. Laxido is the preferred choice. Do Not Prescribe (DNP): Macrogol 3350 (Transisoft). Macrogol compound (Laxido) is a cost-effective alternative.

Clinical Guidelines

JAPC Briefing FreeStyle Libre – partial update
Adult Lipid Modification Therapy in Non-Familial Hyperlipidaemia (non-FH)
Guidance on Prescribing of Low Molecular Weight Heparin (Enoxaparin and Tinzaparin)
Management of Undernutrition in Adults

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Patient Group Directions (PHE)
Flublok Quadrivalent
Inactivated Influenza Vaccine - extension of eligible cohorts

Present:	
Derby and Derbyshire CCG	
Dr C Emslie	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 Gooch	GP
Ms R Monck	Head of Finance
Ms A Reddish	Clinical Quality Manager – Primary Care
Derby City Council	
Derbyshire County Council	
University Hospitals of Derby and Burton NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr D Moore	Lead Pharmacist Commissioning & High Cost Medication
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Chief Pharmacist
Derby and Derbyshire Local Medical Committee	
Derbyshire Health United	
Mr D Graham	Lead Clinical Pharmacist
Staffordshire and Stoke-on-Trent CCG's	
Ms S Bamford	Medicines Optimisation Senior Lead Pharmacist
In Attendance:	
Mrs P Dhillon	Chief Pharmacy Technician – Interface (DDCCG & UHDBFT)
Mrs K Rogers	Derby and Derbyshire CCG Senior Administrator (minutes)

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Item		Action
1.	**APOLOGIES**	
	Dr K Markus	
2.	**DECLARATIONS OF CONFLICTS OF INTEREST**	
	Dr Emslie 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.	**MINUTES OF JAPC MEETING HELD ON 10 NOVEMBER 2020**	
	The minutes of the meeting held on 10th November 2020 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Buccal Midazolam** Mr Dhadli reported that Epistatus was given a Do Not Prescribe (DNP) (previously BLACK) traffic light status at the JAPC meeting in May 2018, in the presence of acute trust representatives, and after extensive consultation with specialists. This was after a long period of review and negotiation with stakeholders to ensure an appropriate training package was in place before the change. A primary care prescribing guideline was made available. For an interim period of four years (May 2014 – April 2018) Epistatus was assigned a GREY (previously BROWN) traffic light classification (use in exceptional circumstances) for transition of new patients to start Buccolam. In August 2020 JAPC further discussed Epistatus classification after concerns were raised by a consultant neurologist from Sheffield Teaching Hospital NHS Foundation Trust (STHFT). The committee agreed that the existing traffic light classification should remain, however communication would be included in the JAPC bulletin to primary care, to reinforce the message that Buccolam is the preferred choice and the importance of education and training before switching, this would also include having an up-to-date care plan in place at the next review with the specialist. Following this a request has been made from Ms L Hall, Contracts Manager (STHFT), for JAPC to discuss the risk assessments that have been produced by a STHFT Epilepsy Nurse. There are still concerns raised with the decision made, one being that STHFT may not be in a position to re-train carers for use of the different products. JAPC recognised that there are differences in formulation between Derbyshire and Sheffield. DDCCG has completed an internal risk assessment form, to be tabled at the next Clinical and Lay Commissioning Committee meeting. Following discussion JAPC members recommended revising the Derbyshire guideline to reflect out of area prescribing. It was acknowledged that patients may require switching from Epistatus in primary care and it was noted that there may be new patients who are started on this treatment out of area; there	**SD**

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	might also be a cohort of patients that need to remain on this treatment indefinitely. STHFT are proposing the use of generic templates which do not currently specify a brand of midazolam, they only state the dose to administer. JAPC recognise that not prescribing by brand carries some risk, and recommended that STHFT specify the brand when using their generic templates. Due to clinical concerns and risks, the committee agreed for Epistatus to be changed from DNP to GREY when initiated by an out of area Derbyshire provider. The change is specific to this drug and does not affect the Derbyshire out of area prescribing guidance. A statement will be included to advise primary care to transfer a patient to the recommended Buccolam preparation where appropriate and to update the patients care plan accordingly. **Agreed:** JAPC classified Epistatus as **GREY** when initiated by out-of-area providers. *The relaxation for Epistatus traffic lights is due to JAPC recognising that it may not be practical due to formulary differences to refer to a specialist outside of Derbyshire for a patient already initiated on Epistatus. Under these circumstances it will be at the discretion of the prescribing clinician to switch to Buccolam with the patient and/or carer training and updated care plans, or to continue prescribing Epistatus.	**SD** **SD**
6.	**JAPC ACTION SUMMARY**	
a.	The action summary was noted by JAPC, there were no new or current outstanding items.	
7.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Canagliflozin** Mr Dhadli advised that a new licensed indication has been added for canagliflozin for treating chronic kidney disease in people with type 2 diabetes. It has been tabled at the JAPC meeting as the renal team at STHFT are starting to recommend canagliflozin specific for this indication. A NICE TA is currently in development; however there is no confirmed publication date as yet. The final scope from the project document NICE clinical guideline 182 'chronic kidney disease in adults: assessment and management' recommends keeping systolic blood pressure below 130 mmHg and the diastolic blood pressure below 80 mmHg. It also recommends a drug that blocks or inhibits the renin-angiotensin system including angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs) and direct renin inhibitors to manage blood pressure if there is an ACR of 3 mg/mmol or more. Comparators established clinical management without canagliflozin. The outcome measures to be considered include morbidity including cardiovascular outcomes, disease progression (such as renal replacement, ESKD) and markers of disease progression (such as serum creatinine, albuminuria), HbA1c control, diabetic ketoacidosis risk, mortality, adverse effects of treatment and health-related quality of life. There has also been a CREDANCE trial: Canagliflozin and Renal Outcomes	

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	in Type 2 Diabetes and Nephropathy. It was designed to determine whether SGLT2-inhibitors could improve renal outcomes in a more advanced, high-risk diabetic kidney disease (DKD) population. The trial involved 4401 patients that had type 2 diabetes with albuminuric kidney disease, eGFR's between 30 to <90 mL/min/1.73 m2 (Stage II-III CKD) and urinary albumin-to-creatinine ratios of >300 to 5000 mg/g (macroalbuminuria). It included a pre-specified plan to include approximately 60% of patients with eGFR's 30 to <60 mL/min/1.73 m2 (a majority Stage III CKD population) and required all participants to already be on maximally tolerated angiotensin-converting-enzyme inhibitor. The trial was initially predicted to have a duration of 5 years. However it was stopped early at around 2.5 years after an interim analysis showed clear benefit for the primary outcome. The group receiving canagliflozin showed a significantly lower event rate for the primary composite outcome compared to the placebo group. Mr Dhadli reported that STHFT are currently using canagliflozin for this indication, it was agreed through their local Area Prescribing Committee however it has not been agreed via their funding committee as yet due to delays caused by the COVID-19 pandemic, and therefore it does not currently have a traffic light classification. Mr Moore confirmed that the University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) Drugs and Therapeutics committee are expecting an application for this to be considered in January 2021. A discussion took place and JAPC agreed that canagliflozin should remain unclassified for this indication until it has been to the UHDBFT Drugs and Therapeutics committee. It is planned to be tabled at the JAPC meeting in February 2021.	**SD**
8.	**CLINICAL GUIDELINES**	
a.	**<u>FreeStyle Libre</u>** Mr Dhadli reported that FreeStyle Libre was tabled at the previous months JAPC meeting to inform the committee that as of 1st November 2020, FreeStyle Libre 2 is available in the drug tariff. Originally, prescribing of Flash Glucose monitoring systems was restricted to selected patients with Type 1 diabetes; however NHS England has recently added a new indication for the use of FreeStyle Libre. It can now be offered to all patients with a learning disability and diabetes on the GP register, who use insulin to manage their condition. It was identified that there are approximately 200 patients across Derbyshire that may meet the criteria for this. Following this the Derbyshire FreeStyle Libre briefing document has been updated with the addition of the latest inclusion criteria. It was also confirmed that frequency of monitoring patients had previously been included in the document, it states that patients “agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.” The briefing document has been tabled at JAPC for information. During the previous months JAPC meeting the committee also considered whether other available Flash Glucose Meters should be explored and it was agreed to review this along with FreeStyle Libre 2. Mr Dhadli referred to a table in paper 8a which showed comparisons between the original FreeStyle Libre and FreeStyle Libre 2. Both monitors are the same reimbursement price, the appearance of them are slightly different i.e. colour and FreeStyle Libre 2	

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	uses bluetooth technology to enable the feature of optional alarms. FreeStyle Libre 2 Sensors are not interchangeable with FreeStyle Libre Sensors and require a different reader, or the FreeStyle Libre Link app to scan and receive the results. The Dexcom G6 real-time continuous glucose monitoring system was also mentioned; it is used with Continuous Glucose Monitoring and Insulin Pumps. The cost effectiveness, safety and affordability of Continuous Glucose Monitoring is acknowledged by a restrictive policy with eligibility criteria for both adults and children, approved by the Derbyshire Clinical Policies Advisory Group. JAPC acknowledged that the Dexcom G6 CGM system is beneficial in a different cohort of patients to that of the FreeStyle Libre 2. Concern was raised in regards to the risk of waste when moving from FreeStyle Libre 1 to 2, and prescribing errors (sensors from one not compatible with the other). The committee agreed that it must be made clear that the sensors are not interchangeable. A phased approach will be taken to switch patients from FreeStyle Libre 1 to FreeStyle Libre 2 during 2021. **Agreed:** JAPC classified FreeStyle Libre 2 as **GREY** after diabetic consultant/specialist initiation within a Derbyshire Diabetes service. Available through the specialist team after February 2021. **Agreed:** JAPC ratified the partial update to the JAPC Briefing FreeStyle Libre.	**SD** **SD**
b.	**<u>Lipid Modification in Non-Familial Hyperlipidaemia</u>** Mr Dhadli advised that the Adult Lipid Modification Therapy in Non-Familial Hyperlipidaemia (non-FH) guideline has been updated to bring it in line with the Familial Hyperlipidaemia (FH) guideline, where rosuvastatin was recently classified as GREY 2nd line to atorvastatin for FH. The guideline has been updated with information on the timing of dose, diet and lifestyle measures, and to consider increasing dose of atorvastatin if <80mg and patient at high risk. (Agree the use of higher doses with a renal specialist if eGFR<30 ml/min/1.73m2). The definition of coronary heart disease has been updated in line with the NICE FH guideline and nicotinic acid has been removed due to no longer having UK licensing. Rosuvastatin has been changed from BROWN 3rd line to GREY 2nd line alternative treatment option after atorvastatin for non-FH. **Agreed:** JAPC classified rosuvastatin as **GREY 2nd line alternative treatment option after atorvastatin**. Can also be used when there is complete intolerance to atorvastatin or partial intolerance to other statins. **Agreed:** JAPC ratified the Adult Lipid Modification Therapy in Non-Familial Hyperlipidaemia (non-FH) guideline with a review date of 3 years.	**SD** **SD**
c.	**<u>Low Molecular Weight Heparin (LMWH)</u>** Mr Dhadli advised that the Low Molecular Weight Heparin guideline has been updated following a routine review. It was sent out for consultation to Senior Clinical Pharmacists at both Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) and UHDBFT, it was also sent to a Consultant Haematologist at UHDBFT.	

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	It was recognised that UHDBFT use enoxaparin (Inhixa) and they advise the use of eGFR, however creatinine clearance level (CrCl) is calculated if BMI <18.5 or >30. CRHFT use tinzaparin and calculated creatinine clearance for therapeutic anticoagulation. Doses were also updated as per the Royal College of Obstetrics and Gynaecology (RCOG) Reducing the Risk of Venous Thromboembolism during Pregnancy and the Puerperium guideline. **Agreed:** JAPC ratified the Guidance on Prescribing of Low Molecular Weight Heparin (Enoxaparin and Tinzaparin) with a review date of 3 years.	**SD**
d.	**<u>Undernutrition in adults</u>** Mr Dhadli advised that the Management of Undernutrition in Adults guideline has been updated following a routine review. It went out for consultation to the Dietetic Manager and Team Leader at UHDBFT and Head of Nutrition & Dietetics, Dietetic Manager at CRHFT who have jointly reviewed and updated this guideline. The Nutritional Support Flowchart has been updated to present as a stepped wise approach, as per PrescQIPP and a Subjective Assessment has been added as per bapen.org.uk. A new table has been added to the guideline to recognise that some products contain high levels of vitamin K which may interact with warfarin and vitamin A which should be avoided during pregnancy. There is a new table added to the guideline named 'factors to consider to maximise ONS compliance', and under Appendix 2 'Big Nutrition for Small Appetites' patient information leaflet, a new section has been added to include information for lactose and dairy free (vegan) diets. In Appendix 3 'Standard ONS Products For Adults', product information has been updated with currently available preparations and cost. Under Appendix 4 'Specialist Nutritional Products' specialist/dysphagia products has also been updated. **Agreed:** JAPC ratified the Management of Undernutrition in Adults guideline with a review date of 3 years.	**SD**
9.	**PATIENT GROUP DIRECTIONS**	
	The following Public Health England (PHE) PGD's were noted at JAPC: • Flublok Quadrivalent This PGD is for the administration of Flublok Quadrivalent (recombinant quadrivalent influenza vaccine, QIVr) to individuals in accordance with the national influenza immunisation programme. This is a new PHE PGD template for Flublok product, based on PHE IM Influenza PGD v08.00, which will take effect from 23rd November 2020. • Inactivated Influenza Vaccine - extension of eligible cohorts This document provides confirmation that the use of the Inactivated Influenza Vaccine PGD V08.00, PHE publications gateway number: GW-1533, valid from 1 September 2020 to 31 March 2021, may be extended to the following eligible individuals: o from mid-November, once Fluarix® Tetra is available to be ordered from ImmForm, children eligible for the Routine Childhood Seasonal Influenza Vaccination Programme who do not accept live attenuated influenza vaccine (LAIV) due to porcine gelatine content	

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	○ from 1 December 2020, people aged 50 to 65 years[1]	
10.	**MISCELLANEOUS**	
a.	**Derbyshire Recovery Partnership position statement** Mr Dhadli reported that this is a request to extend the review date of the Derbyshire Recovery Partnership Over the counter, Opiate based medication and Benzodiazepine position statement. It was produced in 2018 however; a full review of this document has been delayed due to the COVID-19 pandemic. Clinical leads for services in Derbyshire Healthcare NHS Foundation Trust (DHcFT) Substance Misuse services have been consulted, and there are no significant change/safety concerns identified. **Agreed:** JAPC agreed to extend the review date of the Derbyshire Recovery Partnership Over the counter, Opiate based medication and Benzodiazepine position statement, for a further 3 years.	**SD**
b.	**Requests from JUCD – assurance of formulary/system approach** Mr Dhadli stated that there have been a number of requests to approve/add prescribing formularies/recommendations to the Derbyshire Medicines Management website from Joined Up Care Derbyshire (JUCD) work streams, who are working with different providers. Examples include Common side effects from glaucoma drops, Headache/migraine pathway, Atopic eczema, and Gender dysphoria. Whilst JAPC has an established decision making process, other work streams within DDCCG are responsible for their own governance, to ensure guidance produced are robust and align with existing JAPC formulary/guidelines when pharmacological therapies are involved. To facilitate this process, a template for drug inclusion has been developed. Each time this template is completed, it will be checked either via the Derbyshire Medicines Management Shared Care and Guideline Group (MMSCGG) or by JAPC, to confirm that the information does align with JAPC formulary/guidelines. If there are any variations then recommendations will be made. It was also advised that where guidelines are developed through a work stream with secondary care involvement, that these be taken through the secondary care Drugs and Therapeutics committee for approval. Mr Dhadli referred to paper 11bi as an example, where the gender dysphoria treatment pathway has been added to the template and reviewed. A discussion took place and the committee agreed to trial this process. It was highlighted that the template does not ask the indication in which a drug might be used; Mr Dhadli confirmed that this is one of the areas that will be monitored and looked at as the process evolves.	**SD**
c.	**Horizon scan 21/22** Mrs Qureshi reported that this is the annual horizon scan for new drugs which will impact on primary and secondary care prescribing budgets for 2021/22. At the time of the paper being submitted to JAPC, the prescribing outlook cost calculator had not been released; therefore local cost implications for DDCCG could not be included. This is now available and it will be brought back to the JAPC meeting in January 2021. Two papers were presented, the first being drugs which will impact on primary	**SQ**

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	care prescribing and the second being CCG commissioned high cost drugs. The following potential high risk drugs were highlighted for primary care: ticagrelor (licence extension), lasmiditan oral and dapagliflozin oral (licence extension). Potential cost saving drugs for primary care includes bempedoic acid oral, beclometasone/formoterol/glycopyrronium inhaler (licence extension), fluticasone/umeclidinium/vilanterol inhaler (licence extension) and glycopyrronium/indacaterol/mometasone inhaler. Potential CCG commissioned high risk drugs includes aducanumab injection, solriamfetol oral, tanezumab injection, ibrutinib oral (licence extension), ruxolitinib oral (licence extension), BMS-986165 oral. JAPC noted this for information.	
d.	**<u>Migraine High Cost Drug pathway</u>** Mrs Qureshi advised that NICE TA659 has been published for galcanezumab, used to prevent migraine. This is a CCG commissioned drug. Previously fremanzeumab has been used for preventing migraines, Mrs Qureshi referred to a table in paper 11d which noted comparisons between the two drugs. The full costing for galcanezumab is not yet known, further details are awaited. The recommendation for galcanezumab differs from that of fremanzeumab. Galcanezumab should be initiated for preventing migraine in adults, only if they have 4 or more migraine days a month, whereas fremanzeumab should be initiated for preventing migraine in adults, only if the migraine is chronic, that is, 15 or more headache days a month for more than 3 months with at least 8 of those having features of migraine. Galcanezumab should be stopped after 12 weeks of treatment if in episodic migraine the frequency does not reduce by at least 50%, or in chronic migraine the frequency does not reduce by at least 30%. Fremanzeumab should be stopped if the migraine frequency does not reduce by at least 30% after 12 weeks of treatment. NICE TA631 concluded that treatment with another anti-CGRP drug, after failure of a previous anti-CGRP drug, is not supported by evidence and is not recommended. There have been no head to head studies with fremanezumab. Galcanezumab can be used as a separate indication for episodic migraines. It is predicted that the total drug cost within Derbyshire would be more with treatment of episodic migraines, as the number of patients would increase. Mrs Qureshi referred to paper 11di 'Derbyshire commissioning guidance for preventing migraines'. It was proposed that this will be updated along with Blueteq forms, to include galcanezumab once costings have been received. The committee were in agreement. **Agreed:** JAPC classified galcanezumab as **RED** NICE TA659 for prevention of migraine in adults who have ≥4 migraine days per month.	**SQ** **SQ**
e.	**<u>Green book update for COVID</u>** Mr Dhadli reported that the Green book has been updated to include the COVID-19 vaccines. JAPC noted this for information.	

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11.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in November 2020 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Fosfomycin – classified as GREY 2nd line choice for UTI in non-pregnant women as per NICE/PHE antimicrobial guideline. • Macrogol – classified as GREEN: Macrogol compound oral powder. Laxido is the preferred choice. Do Not Prescribe (DNP): Macrogol 3350 (Transisoft). Not as cost effective. Macrogol compound (Laxido) is a cost-effective alternative. Formulary Update (Chapter 13 – Skin): • CKS advice on management of localised infected eczema added – topical antibiotic ± steroid not for routine use but may be trialled on individual basis for maximum of 2 weeks. • Cocois replaces Sebco scalp ointment for treatment of psoriasis. • Clairette is the preferred brand for co-cyprindiol 2000/35 microgram tablets. • NICE/PHE advice for dermatophyte infection added – topical terbinafine first-line; use topical imidazole e.g. clotrimazole if candida possible. • Lamisil removed as preferred brand for terbinafine 1% cream – prescribe generically. • Lyclear is the preferred brand for permethrin 5% dermal cream. Clinical Guidelines: • Management of pregnant women & neonates in contact with measles; chickenpox & shingles – reviewed with no major change. The two information sheets give clear advice on immediate steps to be taken by GP/Midwife in primary care; details include contact numbers, advice on obtaining immunoglobulin treatments, and links to further resources. • AF guideline – following update from SPS Suggestions for Drug Monitoring in Adults in Primary Care document, apixaban and rivaroxaban monitoring have been re-aligned to 6 monthly if patient has additional risk factors such as age >75 years or frail. • Emollient guideline minor update as per Epimax emollient range name change ○ Epimax cream – Epimax original cream ○ ExCetra cream – Epimax ExCetra cream ○ Isomol Gel – Epimax Isomol Gel Website Changes/Miscellaneous: • Interim Clinical Commissioning Policy: Remdesivir for patients hospitalised with COVID-19 (adults and children 12 years and older) Version 2 – uploaded to Covid section of Derbyshire Medicines Management website and RED TLC. • Link to Sheffield Shared Care Guidelines added to Out of Area SCG section on Derbyshire Medicines Management website.	

Item		Action
	• Fenticonazole vaginal cream discontinued – removed from formulary chapter/TLC • Haloperidol 500 microgram capsules discontinued – removed from formulary chapter. Note 500 microgram tablets not cost effective – use 5mg/5ml oral solution SF. Guideline Timetable: • The guideline table action summary and progress was noted by JAPC.	
12.	**BIOSIMILAR REPORT**	
	Mr Dhadli advised that the biosimilar report has been tabled for information.	
13.	**JAPC BULLETIN**	
	The November 2020 bulletin was ratified.	**SD**
14.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for November 2020 was noted. Mr Dhadli highlighted the following MHRA advice: • Modafinil (Provigil): increased risk of congenital malformations if used during pregnancy – modafinil potentially increases the risk of congenital malformations when used in pregnancy. It should not be used during pregnancy and alternative treatment options for narcolepsy should be considered. Women of childbearing potential must use effective contraception during treatment and for 2 months after stopping modafinil. • Pirfenidone (Esbriet): risk of serious liver injury and updated advice on liver function testing – serious liver injury has been reported during treatment with pirfenidone in the first year after initiation, including 2 cases with a fatal outcome. Measure alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin levels before starting pirfenidone treatment, monthly for the first 6 months of treatment, and then every 3 months thereafter. Follow new guidance on testing liver function promptly in patients who report symptoms or have clinical signs that might indicate they have liver injury and adjust the dose or discontinue treatment according to new recommendations. • Ferric carboxymaltose (Ferinject▼): risk of symptomatic hypophosphataemia leading to osteomalacia and fractures – monitor serum phosphate levels in patients treated with multiple high-dose administrations, or those on long-term treatment, and in those with pre-existing risk factors for hypophosphataemia. Re-evaluate ferric carboxymaltose treatment in patients with persistent hypophosphataemia. • Bupropion (Zyban): risk of serotonin syndrome with use with other serotonergic drugs – cases of serotonin syndrome have been identified in associated with bupropion, especially in overdose or when bupropion is administered with other drugs with a serotonergic effect. If serotonin syndrome is suspected, either decrease the dose of bupropion or withdraw therapy depending on the severity of the symptoms. • Isotretinoin (Roaccutane▼): contribute to expert review – a review is being undertaken by the Medicines and Healthcare products Regulatory Agency with advice from the Commission on Human Medicines and the Isotretinoin	

Item		Action
	Expert Working Group due to concerns about the possible association between isotretinoin and suspected psychiatric and sexual disorders. An Expert Working Group is reviewing the available evidence relating to isotretinoin, and will advise whether the MHRA should take additional regulatory action, for example, improving the information for patients to help minimise the risks of psychiatric and sexual side effects, suspected to be associated with isotretinoin.	
15.	**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: • Bevacizumab biosimilar (Aybintio) – classified as **DNP** await national guidance or clinician request • Glasdegib (Daurismo) – to remain classified as **DNP** (as per NICE TA646) New formulation launches in the UK: • Bilastine (Ilaxten) – to remain classified as **DNP** • Dasatinib (Sprycel) – to remain classified as **RED** (as per NHS England commissioning intentions) • Letermovir (Prevymis) – to remain classified as **RED** (as per NHS England commissioning intentions) Licence extensions: • Burosumab (Crysvita) – previously classified as **RED** Drug discontinuations: • Acumor XL (Galantamine) • IUB Ballerine MIDI • Celevac (Methylcellulose) • Clarityn Rapide Allergy (Loratadine) • Ciproxin Tablets (Ciprofloxacin) • DDAVP Nasal Solution (Desmopressin) • Dioderm (Hydrocortisone) • ErectEase • EyeGel (Carbomer) • Galantamine tabs • Galfer FA (Ferrous fumarate/ folic acid) • Hulio (Adalimumab) • Mepradec (Omeprazole) • Nemdatine (Memantine) • Phlexy-10 Capsules • SoftDrops (Hypromellose) • Tramquel SR (Tramadol) • Zyomet (Metronidazole)	

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Item		Action
16.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in November 2020: TA656 Siponimod for treating secondary progressive multiple sclerosis – classified as **RED** (NHS England as per NICE TA656) TA657 Carfilzomib for previously treated multiple myeloma – classified as **RED** (NHS England as per NICE TA657) TA658 Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma – classified as **RED** (NHS England as per NICE TA658) TA659 Galcanezumab for preventing migraine – classified as **RED** (as per NICE TA659) TA660 Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer – classified as **RED** (NHS England as per NICE TA660) TA661 Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma – classified as **RED** (NHS England as per NICE TA661) TA662 Durvalumab in combination for untreated extensive-stage small-cell lung cancer (terminated appraisal) – classified as **DNP** (NHS England as per NICE TA662) NG184 Human and animal bites: antimicrobial prescribing includes management with antibiotics. (Updated through the summary of antimicrobial prescribing guidance on MM website) NG185 Acute coronary syndromes. This guideline covers the early and longer-term (rehabilitation) management of acute coronary syndromes. These include STEMI, NSTEMI and unstable angina. The guideline aims to improve survival and quality of life for people who have a heart attack or unstable angina.	
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
a.	• UHDBFT Drugs and Therapeutics Group 22/09/2020 • Sheffield Area Prescribing Group 17/09/2020 • Medication Optimisation Safety Team 07/10/2020 The following items were highlighted in the UHDBFT Drugs and Therapeutics Group: • Insulin Lispro (Lyumjev) – new product application • Insulin glargine + lixisenatide (Suliqua) – new product application • Formulary harmonisation – work is being done to harmonise the UHDBFT formulary with DDCCG & South Staffordshire CCG. The second chapter reviewed was the cardiovascular chapter.	

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	The following items were highlighted in the Sheffield Area Prescribing Group minutes: • Development of a Shared Care Protocol for cinacalcet • Melatonin – a further section is to be added to the melatonin shared care protocol to cover patients with swallowing difficulties and to allow for the prescribing of melatonin liquid in a small cohort of patients who have autistic spectrum disorder (ASD) or phobias to textures. o JAPC noted that Sheffield APC have included Slenyto® 1mg and 5mg prolonged release tablets in the Melatonin shared care protocol. Its licenced indicated is for treatment of insomnia in 2-18 year olds with ASD and/or Smith-Magenis Syndrome and is recommended to be offered first line for 2-18 year olds with ASD or SMS.	
18.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Midazolam-Epistatus – GREY when initiated by out-of-area providers Rosuvastatin – GREY 2nd line alternative treatment option after atorvastatin. Can also be used when there is complete intolerance to atorvastatin or partial intolerance to other statins. FreeStyle Libre 2 – GREY after diabetic consultant/specialist initiation within a Derbyshire Diabetes service. Available through the specialist team after February 2021. Galcanezumab – RED NICE TA659 for prevention of migraine in adults who have ≥4 migraine days per month. CCG commissioned. Ferric carboxymaltose (Ferinject) – RED Iron deficiency when oral iron is ineffective or cannot be used, or when there is a clinical need to deliver iron rapidly. MHRA, Nov 2020 - risk of symptomatic hypophosphataemia leading to osteomalacia and fractures. Bevacizumab biosimilar (Aybintio) – DNP await national guidance or clinician request Siponimod – RED (NHS England as per NICE TA656) Carfilzomib – RED (NHS England as per NICE TA657) Isatuximab with pomalidomide and dexamethasone – RED (NHS England as per NICE TA658) Galcanezumab – RED (as per NICE TA659) Darolutamide with androgen deprivation therapy – RED (NHS England as per NICE TA660) Pembrolizumab – RED (NHS England as per NICE TA661) Durvalumab – DNP (NHS England as per NICE TA662)	
19.	**ANY OTHER BUSINESS**	
a.	**At risk groups to receive free winter supply of vitamin D** Mr Dhadli advised that due to the COVID-19 pandemic, the Government is offering a free 4-month supply of daily supplements of vitamin D for all adults who are clinically extremely vulnerable, to support general health and in particular for bone and muscle health. People within these criteria who wish to receive their free supply of vitamin D are asked to opt-in and register their details between 30 November 2020 and 4 January 2021 via the NHS website. GP's should not need to prescribe vitamin D to eligible patients during the 4	

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	month period and should not continue to prescribe this once the 4 month period has ended. Mr Dhadli advised that this has been tabled at the JAPC meeting for information and it will be communicated out via the December JAPC bulletin.	**SD**
b.	**JAPC Terms of Reference (ToR)** Mr Dhadli advised that the JAPC ToR has received a minor update. During the COVID-19 pandemic and the Brexit transition it is recognised that there will be an acute need for time critical decisions, which include for example a guideline, policy or PGD. It will be at the discretion of the Professional Secretary, APC Chair or Director of Medicines Management (two of the three in case of absences) that these will be disseminated virtually for approval, adoption and circulation, to allow actions to be completed in a timely way. JAPC members were in agreement with this.	**SD**
c.	**COVID-19 Vaccination** Ms Braithwaite reported that a COVID-19 vaccination Standard Operating Procedure (SOP) for vaccination centres and services has been produced. This is a live document; therefore it is subject to change on a regular basis. There are also appendices embedded within the document that may require frequent updates. A national protocol and PGD are expected in the near future, these will be added once available. Many NHS organisations across Derbyshire will be involved in the COVID-19 vaccination process, including DDCCG, Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) and Derbyshire Health United (DHU). The SOP/appendices have been tabled at the JAPC meeting for information and agreement, they give an overview of how the COVID-19 vaccination centres and services will operate outside of UHDBFT and CRHFT hospitals. It was noted the importance of ensuring that everyone has access to and is using the latest version of the document. Consideration is being made to add this to the DDCCG Intranet and appoint a chief pharmacist at each Primary Care Network (PCN), who will always have access to the latest SOP. It was noted that some national COVID-19 vaccination guidance is available through the Specialist Pharmacy Service (SPS) website; however the local SOP contains further detail that many users will find useful. A discussion took place and a query was raised as to whether the vaccine contained latex, egg or gelatine. Ms Braithwaite confirmed that there is no latex used in the rubber bung however each patient should be assessed on an individual basis and asked about allergies via the screening questions. The Green book confirms that there is also no egg or gelatine contained within the vaccine. Transportation of the vaccine in a frozen state and how it would be handled upon arrival at its destination were discussed. National guidance is awaited for this. It was also advised that staff start to review the E-learning training provided for the COVID-19 vaccine. JAPC members were in agreement with the COVID-19 vaccination SOP.	
20.	**DATE OF NEXT MEETING**	
	Tuesday, 12th January 2021 at 1.30pm to be held virtually via Microsoft Teams.	