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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 14th February 2023

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Ezetimibe	GREEN as per NICE TA385 for treating primary heterozygous-familial and non-familial hypercholesterolemia
Upadacitinib	RED as per NICE TA856 for treating moderately to severely active ulcerative colitis. ICB commissioned.
Angiotensin II	DNP as per NICE TA859 for treating vasosuppressor-resistant hypotension caused by septic or distributive shock (Terminated appraisal). ICB commissioned.
Mobocertinib	RED as per NICE TA855 for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy. NHSE commissioned.
Nivolumab	RED as per NICE TA857 for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma. NHSE commissioned
Lenvatinib	RED as per NICE TA858 for untreated advanced renal cell carcinoma. NHSE commissioned
Maribavir	RED as per NICE TA860 for treating refractory cytomegalovirus infection after transplant. NHSE commissioned
Foslevodopa + foscarbidopa (Produodopa)	DNP for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. Await clinician request.
Voclosporin (Lupkynis)	DNP for the treatment of adults with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis. Await clinician request.

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Gaviscon advance	GREY, only after the formulary choice of Acidex advance, if it is thought to be inappropriate due intolerance or inadequate symptom control
Cimetidine	GREY
Nizatidine	GREY
Famotidine	GREY

Nilaqua products	DNP, nilaqua skin cleansing/ shampoo products and other personal hygiene products - Patients are advised to self-care
Testosterone	GREEN after consultant/specialist initiation, Amalgamate Nebido, Sustanon, and Tostran entries. GREEN after consultant/specialist recommendation: for male hypogonadism. Intrinsa patch has been removed, as it is discontinued and no longer used
Budesonide MR oral	GREY after consultant/specialist initiation, clarify specialist include consultant gastroenterologist and colorectal surgeon

Clinical Guidelines
Guideline on oral anticoagulation with warfarin
Nicotine replacement therapy guideline
Ulcerative colitis commissioning algorithm

PGDs:
Varicella vaccine PGD
Meningococcal Group B Vaccine PGD
Meningococcal Group B Vaccine Risk Groups PGD

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Present:	
Derby and Derbyshire CCG	
Dr H Hill	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 S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Dr R Dills	GP
Dr A Mott	GP
Mrs L G	Assistant Director of Medicines Optimisation and Delivery
Mrs R Monck	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
Chesterfield Royal Hospital NHS Foundation Trust	
Mr A Hardy	Principal Pharmacist – attended until 14:30
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:	
Ms Eve Evans	Chief Pharmacy Technician (Interface)
Ms R Ludlam	Student District Nurse
Miss S Greenwell	Senior Administrator, DDCCG (minutes)

Item		**Action**
1.	**APOLOGIES**	
	A Brailey, S Bamford, R Gooch	
2.	**DECLARATIONS OF CONFLICTS OF INTEREST**	
	Dr Hill reminded committee members of their obligation to declare any interest	

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	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.	**MATTERS ARISING FROM PREVIOUS MEETNG**	
a.	**Hepatitis B** Mr Dhadli informed the committee that this was raised due to low level prescribing across the ICB. It has been highlighted that GP's are not covered under the indemnity insurance for administering Hepatitis B vaccines for renal patients. LMC have issued communication to GPs to instruct that at risk renal patients who require Hepatitis B vaccines should not be vaccinated and referred back to the provider through inappropriate requesting. The responsibility is now with the providers to vaccinate these at-risk renal patients.	
b.	**Mycophenolate** Mr Dhadli reported there is a discrepancy between the RMOC SCA monitoring for neutrophils and lymphocytes and the JAPC SCA monitoring arrangements, which are currently under discussion with the specialists. The SCA proposal was sent to LMC and LCSF for comments regarding increased workload for primary care. LMC concerned about increased workload for primary care and lack of additional funding. Since mycophenolate is classed as a DMARD, LCSF have confirmed that additional funding is available for primary care for DMARDs (and GnRHs). **Action:** to bring back the SCA once the monitoring arrangements have been agreed and the general principles of how funding for SCA are agreed.	**SD**
c.	**Hydroxychloroquine** Mr Dhadli highlighted that University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) have recently confirmed eye checks are standard procedure for both rheumatology consultants and nurses to check during any clinical appointment for patient. After 5 years a referral is made to ophthalmology and are reviewed annually thereafter. All patients are assessed for the duration of hydroxychloroquine treatment at every clinic appointment by a nurse/consultant. All patients are also reviewed every 6 months or earlier. It is highly unlikely patients will be missed as they are seen frequently by different professionals at every appointment. Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) confirmed during the meeting that rheumatology patients are being referred for eye monitoring appropriately. **Action:** JAPC will review the Hydroxychloroquine prescribing guideline for approval via email agreement in March. **Action:** The committee will discuss eye monitoring in primary care via email	**SD** **SD**

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	agreement in March. Dr Goddard queried whether given the activity if all patients were known to the service. Trusts to validate.	
4.	**JAPC ACTION SUMMARY**	
a.	**Ranibizumab biosimilar** Waiting for the modelling to come back from the acute trusts. Very little monitoring is being reported from acute trusts. The potential cost opportunity from switching was raised and JAPC consider this a priority area	
b.	**Rabies Vaccine** UHDBFT and CRHFT both confirmed a stock of the rabies vaccine is kept on site. DHU do not stock the vaccine but will liaise with UKHSA if needed.	
5.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Dapagliflozin in CKD without Type 2 diabetes** Mr Dhadli informed the committee that a consultant nephrologist and Physician from CRHFT and an advanced pharmacist in renal services from UHDBFT proposed a review of the traffic light classification for dapagliflozin in CKD without Type 2 diabetes due to a potential gap in treatment for a group of patients. The current traffic light Derbyshire classification for dapagliflozin for adults with Type 2 diabetes **with** CKD is GREEN, with use as an addition to ACEI or ARB at optimised dose NICE TA775 recommends dapagliflozin as an option for treating CKD in adults only as an add-on to ACE or ARB, unless contraindicated, and eGFR 25-75ml/min/1.73^2 (G2-G4) and have type 2 diabetes, or urine albumin-to-creatinine ratio (uACR) 22.6mg/mmol or more (A2-A3). It has been reported to JAPC that most of the patients who meet the NICE TA755 criteria do not meet NICE criteria for referral to renal services, and the specialist services do not have capacity to see them. By restricting the prescribing to after specialist recommendation only, leaves a potentially sizeable group of patients in the community not receiving beneficial medicine that NICE has advised. Thus, the specialist recommendation is that primary care can initiate dapagliflozin as per NICE TA. A clinical pathway for the use of SGLT-2 inhibitors in CKD in Primary Care has been developed and approved by Midlands Kidney Network. There are also on-going GP trainings in Derbyshire on SGLT2 inhibitors and the Kidney Failure Risk Equation (KFRE), where the clinical pathway is being introduced to GPs. The plan is for the pathway to be uploaded to pathfinder. The recommendation for Dapagliflozin is to remove the consultant/specialist initiation requirement for patients with CKD without diabetes, in line with the NICE TA775 for patients with CKD who have an eGFR between 25 - 75ml/min and have albuminuria (uACR ≥22.6mg/mmol). A discussion took place, although GPs are now more familiar with the drug and support the change, potentially there is an unmet need and JAPC needs to understand the impact of this decision. Mrs Needham highlighted the clinical pathway for the use of SGLT-2 inhibitors in chronic kidney disease does not mention empagliflozin as a treatment option, and the clinical pathway for diabetes with chronic kidney disease does. This may course an overlap of treatment conclusions. Mrs Qureshi confirmed	

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	this has previously been highlighted with the Midlands Kidney Network and no response has been received. It was suggested that the JAPC chair write to the Midlands Kidney Network to include empagliflozin as a treatment option on the clinical pathway for SGLT-2 inhibitors in chronic kidney disease. A further discussion took place regarding the financial impact. There may be a cost implication for actively implementing the clinical pathway for the use of SGLT-2 inhibitors in chronic kidney disease. The cost impact of dapagliflozin for CKD as per NICE TA 775 was presented to JAPC April 2022, agreed to revisit the costing template. **Agreed:** The committee agreed to defer the review of the traffic light classification to be discussed via email in March, with the consideration of the NICE April 2022 costings template for dapagliflozin for chronic kidney disease. **Agreed:** JAPC agreed with the continuation of GREEN traffic light classification after specialist/consultant initiation for dapagliflozin for treating chronic kidney disease as per NICE TA775. Noting that this holding position does not deny treatment for eligible patients but a consideration of the pathway	**SD** **SD**
b.	**<u>Relugolix-estradiol-norethisterone acetate</u>** Mr Dhadli mentioned that JAPC have received a recommendation from a consultant Obstetrician and Gynaecologist at UHDBFT to reclassify relugolix-estradiol-norethisterone (Ryeqo) acetate for use in primary care (after 1st year of treatment in secondary care), with a prescribing guide to assist GPs. Relugolix-estradiol-norethisterone (Ryeqo) is recommended as an option for treating moderate to severe symptoms of uterine fibroids in adults of reproductive age and is currently classified as RED. The clinical evidence for relugolix-estradiol-norethisterone (Ryeqo) acetate is from 2 identical phase 3 randomised controlled trials, LIBERTY 1, and LIBERTY 2. The trials compared relugolix-estradiol-norethisterone acetate, relugolix with delayed estradiol and norethisterone acetate and placebo for heavy menstrual bleeding associated with uterine fibroids. None of the data from the relugolix with delayed estradiol and norethisterone acetate arms from the trials were considered by NICE. The primary outcome measure was a menstrual blood loss volume of less than 80 ml and at least a 50% reduction from baseline in menstrual blood loss volume over the previous 35 days of treatment. The results from the LIBERTY 1 and 2 showed that the primary outcome measure was reached by 73% and 71% respectively of people in the relugolix-estradiol-norethisterone acetate compared with 19% and 15% respectively in the placebo arms. The cost-effectiveness estimates for relugolix–estradiol–norethisterone acetate are mostly within the range normally considered by NICE to represent an acceptable use of NHS resources. There are also likely additional benefits of the treatment not captured in the economic model, including that it is an effective non-surgical treatment, it is taken orally, there is no restriction on treatment duration in the marketing authorisation and it preserves the uterus. Relugolix-estradiol-norethisterone (Ryeqo) acetate was discussed at the UHDBFT Drugs and Therapeutics Committee in December 2022 with the	

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	recommendation to update the traffic light classification to allow primary care to prescribe after specialist initiation in secondary care. It was also discussed at the CRHFT Drugs and Therapeutics Committee in January 2023 with a similar recommendation to amend the traffic light classification. A prescribing guideline for primary care has been developed to enable ongoing safe and effective prescribing of relugolix-estradiol-norethisterone (Ryeqo) acetate in primary care, which includes specialist and GP responsibilities for ongoing monitoring. A discussion took place, GPs feel uncomfortable prescribing relugolix-estradiol-norethisterone (Ryeqo) acetate as it is an unfamiliar new drug and are not aware of any patients currently being prescribed the drug. Dr Goddard highlighted that during the discussion at the UHDBFT D&T in December 2022, it was noted that GPs may be unhappy to prescribe relugolix-estradiol-norethisterone (Ryeqo) acetate and it was agreed that relugolix-estradiol-norethisterone (Ryeqo) acetate would be classified as RED for the first year and gynaecology would monitor the patients. It was also noted during the D&T meeting that relugolix-estradiol-norethisterone (Ryeqo) acetate would only be prescribed for 2-3 years until the patient either stopped treatment and/or underwent a hysterectomy. The Relugolix-Estradiol-Norethisterone (Ryeqo) acetate Prescribing guideline in primary care instructs to discontinue treatment if the patient reaches menopause and/or if jaundice develops. The SPC does not mention duration of treatment. **Action:** Modify and make clear that the Relugolix-Estradiol-Norethisterone (Ryeqo) Prescribing guideline in primary care to state the patient remains under specialist care until the 2nd DXA scan has been actioned. **Action:** To understand the patient numbers and whether the numbers proposed are prevalence and incidence and include backlog of patients already treated. Understand the financial implications and any offset costs of activity. Would use of this drug avoid clinic visits? **Agreed:** JAPC agreed to defer the review of the traffic light classification for Relugolix-Estradiol-Norethisterone (Ryeqo) pending confirmation from Gynaecologist consultants at UHDBFT and CRHFT on duration of treatment.	**SD** **RDH/ CRH** **RDH/ CRH**
c.	**<u>Ezetimibe</u>** Mr Dhadi informed the committee that a request from a Consultant Chemical Pathologist at UHDBFT has been received to re-consider the traffic light classification for ezetimibe. Ezetimibe currently has a GREY traffic light classification as per to the NICE TA385. Ezetimibe monotherapy is recommended as an option for treating primary (heterozygous-familial or non-familial) hypercholesterolaemia in adults in whom initial statin therapy is contraindicated or who cannot tolerate statin therapy. Mr Dhadli stated that there is some clinical outcome data for ezetimibe albeit limited. The NICE TA385 clinical evidence states IMPROVE-IT was a randomised, double-blind, active-controlled study in 18,144 patients with stabilised acute coronary syndrome. Patients were randomised in a 1:1 ratio	

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	to either ezetimibe 10 mg plus simvastatin 40 mg once daily or simvastatin 40 mg once daily. At a median follow-up of 6 years, ezetimibe plus simvastatin produced a 6.4% relative risk (RR) reduction (ARR=2%, NNT=50 over 7 years- moderate relevance) in the primary composite efficacy end point of cardiovascular death, major coronary event, or non-fatal stroke compared with simvastatin alone (hazard ratio [HR] 0.936, 95% confidence interval [CI] 0.89 to 0.99). Ezetimibe was previously classified as GREY due to it being 2nd line to statin, limited patient orientated outcome and cost. Ezetimibe has significantly reduced in price since its patent expiry. Guideline Group also recommend updating the traffic light classification to GREEN in light of also much more expensive treatment options further in the treatment pathway. **Agreed:** The committee approved of the traffic light reclassification of Ezetimibe from GREY to GREEN.	**SD**
6.	**CLINICAL GUIDELINES**	
a.	**Anticoagulation warfarin** Mr Dhadli advised the Anticoagulation (oral) warfarin guideline has been updated as per its routine review. The guideline has undergone consultation with Consultant Haematologists at UHDBFT and CRHFT; CRHFT confirmed no new references or major amendments are required. Mr Dhadli summarised the minor changes within the guideline. Amendments include an update to page 1 on NOACs (DOAC) recommended over warfarin for non-valvular atrial fibrillation, the National Patient Safety Agency Rapid Response Report (NPSA) no longer exists and has been removed from the guidance. CRHFT no longer have an anticoagulation clinic, therefore the contact details have been removed and replaced with the Same Day Emergency Care contact number. **Agreed:** The committee approved of the updated guideline on oral anticoagulation with warfarin.	**SD**
b.	**Nicotine replacement therapy guideline** Mr Dhadli advised the nicotine replacement therapy (NRT) formulary was due for routine review. Mr Dhadli highlighted the background surrounding the nicotine replacement therapy guideline; the local Stop Smoking Services Derby city (Livewell Derby) and Derbyshire (Live Life Better Derbyshire) provide NRT through direct supply. This JAPC formulary (last updated Jan 2020) is for those exceptional circumstances where NRT is required to be prescribed by GPs who decline access to local services. NRT is commissioned by the Local Authority. The JAPC nicotine replacement therapy guideline was updated as per NICE NG209 Tobacco preventing uptake, promoting quitting, and treating dependence (Nov2021) which updates and replaces the NICE NG92 Stop smoking interventions and services, which includes ensuring behavioural interventions are accessible. It was suggested to change the wording regarding where to buy e-cigarettes on the Derbyshire Formulary for Nicotine Replacement Therapy (NRT).	

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	Agreed: JAPC approved of the updated Derbyshire Formulary for Nicotine Replacement Therapy (NRT).	**SD**
7.	**PATIENT GROUP DIRECTIONS**	
	The following PGDs from Public Health England were noted and agreed by JAPC: • Varicella Vaccine • Meningococcal Group B Vaccine PGD • Meningococcal Group B Vaccine Risk Groups PGD	
8.	**MISCELLANEOUS**	
a.	**<u>Upadacitinib for treating moderately to severely active ulcerative colitis</u>** Mr Dhadli mentioned Upadacitinib (NICE TA856) for treating moderately to severely active ulcerative colitis has been tabled at JAPC to incorporate upadacitinib into the Derbyshire ulcerative colitis commissioning algorithm and assign a RED traffic light classification. Upadacitinib is recommended as an option for treating moderately to severely active ulcerative colitis in adults. Standard treatments for moderately to severely active ulcerative colitis after conventional treatments are biological treatments (adalimumab, golimumab, infliximab, ustekinumab or vedolizumab) or tofacitinib. Clinical trial evidence shows that upadacitinib is more effective than placebo for treating moderately to severely active ulcerative colitis. There is no direct evidence comparing upadacitinib with treatments that are offered after conventional treatment. Indirect comparison suggests that upadacitinib is likely to be at least as effective as the treatments it was compared with. The most likely cost-effectiveness estimates for upadacitinib compared with other treatments are within the range NICE normally considers an acceptable use of NHS resources. So, upadacitinib is recommended. Upadacitinib has been placed in two positions in the ulcerative colitis commissioning algorithm, with the 30mg dose being more expensive than the 15mg dose. It was suggested that it might not be practical to start an alternative cheaper biologic if 15mg of upadacitinib is ineffective. But it was felt this was the best way to include the two different strengths. **Agreed:** JAPC approved the inclusion of upadacitinib to the ulcerative colitis algorithm.	**SD**
b.	**<u>Anticoagulation for non-valvular atrial fibrillation (NVAF)</u>** Mr Dhadli informed the committee that multiple queries had been raised by GP practices following the recent NHSE DOAC procurement and recommendation to use edoxaban as a preferred choice of anticoagulation in NVAF. Practices have asked for clarification on suitability of edoxaban (for NVAF) in patients with higher renal function. The JAPC AF guidance (based on MHRA drug safety) states >80 CrCl mL/min- should only be used in some indications after a careful evaluation of the individual thromboembolic and bleeding risk. The SPC states a trend towards decreasing efficacy with increasing CrCl was	

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	observed for edoxaban compared to well-managed warfarin, and edoxaban should be used in patients with NVAF and high CrCl only after a careful evaluation of the individual thromboembolic and bleeding risk. 2021 EHRA guidance mentions a possible decreased efficacy of edoxaban 60 mg OD compared to warfarin was observed in patients with a CrCl of >95 mL/min in a non-prespecified subgroup analysis of the ENGAGE AF trial. Interestingly, because of these findings, further post-hoc analyses revealed a similar directional signal for rivaroxaban and apixaban, but not dabigatran. Practices have also asked for clarity on the monitoring frequency in elderly patients aged 75years and above, 4 vs 6 monthly. The JAPC AF guidance recommends if the patient has additional risk factors e.g., frail, multiple co-morbidities, or age ≥75 years, check the renal function every 6 months. The CKS guidance also recommends if the person is frail or older than 75 years, repeat the full blood count and the renal and liver function tests yearly for most people, every 6 months. The SPS (2022) guidance advises elderly monitoring (FBC. LFT, U&E, CrCl) every 4 months is normally most appropriate. JAPC recommended we follow the nationally distributed guidance produced by Primary Care Cardiovascular Society (PCCS), Primary Care Pharmacist Association (PCPA), and Clinical Pharmacy Association (UKCPA) and advice from the UHDBFT Thrombosis Group, that edoxaban should not be used in patients with CrCl>95ml/min and consideration should be given to using an alternative DOAC (e.g., rivaroxaban 20ng once daily) in line with the edoxaban SmPC. Also, consensus from JAPC is keep 6 monthly monitoring of U&Es in elderly and frail patients as recommended by the Derbyshire guidance. Agreed: link on MM website to the national NVAF following NHSE DOAC commissioning recommendations. **Agreed:** The committee agreed to update the JAPC AF guidance based on the NVAF following NHSE DOAC commissioning recommendations.	**SD**
c.	**<u>Specialist Circulars</u>** Mr Dhadli advised that the specialised circulars has been tabled for information and are available upon request.	
9.	**GLOSSOP TRANSFER GMGG DECISIONS**	
a.	**<u>GMMMG Decision summaries</u>** 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 January 2023 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Gaviscon advance – classified as GREY, only after formulary choice	

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	Acidex advance is thought to be inappropriate due intolerance or inadequate symptom control. • Cimetidine – classified as GREY • Nizatidine - classified as GREY • Famotidine - classified as GREY JAPC advises the types of patients who may require an H2RA include: 1. Those needing acid suppression who are genuinely allergic or intolerant or contraindicated to all PPIs, which is rare 2. those needing acid suppression where low magnesium occurs, which is felt as very rare 3. those who have needed upward titration for reflux symptoms despite high dose PPIs, where addition of H2RA, generally at night-time, helps. 4. occasionally there seems to be a small number who claim not to do well on PPI yet symptomatically get better on H2RA. • Nilaqua products – classified as DNP, nilaqua skin cleansing/ shampoo products and other personal hygiene products- Patient are advised to self-care. Nilaqua is not listed in DT. • Testosterone – classified as GREEN after consultant/specialist initiation, Amalgamate Neobio, Sustanon, and Tostran entries. GREEN after consultant/specialist recommendation: for male hypogonadism. Remove patch (Intrinsa) as discontinued and no longer used. • Budesonide MR oral – classified as GREY after consultant/specialist initiation, clarify specialist include consultant gastroenterologist and colorectal surgeon. Formulary Update: • GI ○ H2RA section updated to clarify criteria for using and to include dosing advice. ○ Insert link to SPS 'difference in oral mesalazine preparations and considerations when switching'. ○ Mesalazine monitoring updated to reflect SPS recommendation, however, individual SPC should also be considered ○ Methotrexate injection in North Derbyshire- prescribing the purple-lidded cytotoxic waste bins (FP10) and accepting the full bins back will be the responsibility of the practice from 1st April 2023. Clinical Guidelines (minor updates): ○ Blood glucose monitoring meter formulary review date extended to June 23. PrescQIPP publication expected in April/May 2023. ○ Nebuliser for COPD patient's guideline removed. Originally produced in 2009, this guideline mainly explains referral process which is now imbedded into practice and GP clinical system. Clinical advice incorporated into COPD guideline. ○ Osteoarthritis guideline replaced with NICE visual summary following NICE update to NG226. Paracetamol or weak opioids no longer routinely recommended, unless they are used infrequently for short-term pain relief,	

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	and all other treatments are ineffective or unsuitable. Local formulary advice can be found in formulary chapter and TLC pages. o PSA algorithm clarification for secukinumab for patients with concomitant moderate to severe plaque psoriasis or patients whose disease has responded inadequately to TNF alpha inhibitors o Formulary skin chapter/acne guideline – replaces brand Duac with generic benzoyl peroxide/ Clindamycin gel as more cost-effective o Formulary endocrine chapter/ Type 2 diabetes guideline - Insuman insulin range (basal, rapid, mix) discontinued - minimal prescribing across Derbyshire. Alternatives available see formulary. Website Changes: o Other useful guidelines UKMi Medicines compliance aid database link replaced with SPS- Medicine Compliance Aid Stability/ Usage of Medicines in Compliance Aids o COPD detailing aid and ICS stepdown guideline reviewed and updated with no major change. MHRA Drug Safety: o Xaqua (metolazone) 5mg tablets: exercise caution when switching patients between metolazone preparations- link added to formulary chapter 2 and heart failure guideline. o Topical testosterone (Testogel): risk of harm to children following accidental exposure- link added to formulary chapter 6 and menopause guideline. Guideline Timetable: o The guideline table action summary and progress was noted by JAPC. **Cumulative figures biosimilar** Mr Dhadli highlighted acute trusts have been asked to report data through their D&T meetings. Data on ranibizumab biosimilars is particularly important. UHDBFT and CRHFT have been asked to report data on ranibizumab as a matter of urgency. The committee discussed once a biosimilar has reach target of 80% switch and this is stale for 6 months, further monitoring should be by exception only. The committee discussed the previous high-cost drugs meeting, and the benefits of having this meeting reinstated. **Action:** UHDBFT and CRHFT biosimilar reporting to be added to the JAPC action tracker.	**SD**
11.	**BIOSIMILAR REPORT**	
	Mr Dhadli advised that the biosimilar report has been tabled for information.	**SD**
12.	**JAPC BULLETIN**	
	The January 2023 bulletin was ratified.	**SD**
13.	**MHRA DRUG SAFETY UPDATE**	

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	The MHRA Drug Safety Alert for January 2023 was noted. Mr Dhadli highlighted the following MHRA advice: • Xaqua (metolazone) 5mg tablets: exercise caution when switching patients between metolazone preparations. Prescribers and dispensers should use caution if switching patients between different metolazone preparations as the rate and extent of absorption of metolazone are formulation dependent. This can impact the bioavailability of the product. Follow good practice in prescribing medicines by considering the licensed formulation (Xaqua) in preference to unlicensed imported metolazone preparations in new patients. The product information for Xaqua has been updated to clarify that references to comparative bioavailability with other metolazone products relate specifically to Metenix and not to any other metolazone preparations. • Topical testosterone (Testogel): risk of harm to children following accidental exposure. Premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone and who were repeatedly accidentally exposed to this medicine. To reduce these risks, advise patients to wash their hands after application of topical testosterone, cover the application site with clothing once the product has dried, and wash the application site before physical contact with another adult or child. • COVID-19 vaccines and medicines: updates for January 2023 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 will be published regularly to include other safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy. o The MHRA has revised the format of the Summary of Yellow Card reporting to focus on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Any new assessments or safety issues regarding vaccines used in the primary and initial booster campaigns will also be included in this record, however previous and known information on these vaccines will remain available as a record only and can be viewed in an archived form on our website. Yellow Card reports received via the scheme across all vaccines will be updated and reflected in the COVID-19 vaccine reports.	
14.	**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: • Bulevirtide (*Hepcludex*) – classified as **RED** (as per NHS England commissioning intentions) • Eltrombopag (*Revolade*) – classified as **RED** • Hydrocortisone (Hisone) – classified as **GREEN, GREY, DNP** • Insulin degludec (*Tresiba*) – classified as **GREY** consultant/specialist	

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	initiation • Smallpox vaccine (*Imvanex*) – no **TLC** New indications in the UK: • Axicabtagene ciloleucel (Yescarta) – classified as **RED** (as per NHS England commissioning intentions) New formulation launches in the UK: • Sofosbuvir + velpatasvir (*Epclusa*) - classified as **RED** (as per NHS England commissioning intentions) • Treprostinil sodium (*Trepulmix*) - classified as **RED** (as per NHS England commissioning intentions) Approved in the UK: • COVID-19 vaccine (COVID-19 Vaccine Janssen) – no **TLC** • Foslevodopa + foscarbidopa (Produodopa) – **DNP, await for clinician request** • Risankizumab (Skyrizi) – classified as **RED** • Tozinameran (Comirnaty 3micrograms/dose) – no **TLC** • Voclosporin (Lupkynis) – **DNP, await for clinician request**	
15.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in January 2023: ICS commissioned drugs: TA856 Upadacitinib for treating moderately to severely active ulcerative colitis - classified as **RED** (as per NICE TA856) TA859 Angiotensin II for treating vasosuppressor-resistant hypotension caused by septic or distributive shock (Terminated appraisal) – classified as **DNP** (as per NICE TA859) NHSE commissioned drugs: TA855 Mobocertinib for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy – classified as **RED** (as per NICE TA855) TA857 Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma – classified as **RED** (as per NICE TA857) TA858 Lenvatinib with pembrolizumab for untreated advanced renal cell carcinoma - classified as **RED** (as per NICE TA858) TA860 Maribavir for treating refractory cytomegalovirus infection after transplant - classified as **RED** (as per NICE TA860)	
16.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
a.	• MOST minutes 01/12/2022	

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Item		Action
	• APG Minutes 17/11/2022 • Staffordshire and Stoke on Trent APC&G 23/09/2022	
17.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Ezetimibe - GREEN as per NICE TA385 for treating primary heterozygous-familial and non-familial hypercholesterolemia Upadacitinib – RED as per NICE TA856 for treating moderately to severely active ulcerative colitis. Angiotensin II – DNP as per NICE TA859 for treating vasosuppressor-resistant hypotension caused by septic or distributive shock (Terminated appraisal). Mobocertinib – RED as per NICE TA855 for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy. Nivolumab – RED as per NICE TA857 for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma. Lenvatinib – RED as per NICE TA858 for untreated advanced renal cell carcinoma. Maribavir – RED as per NICE TA860 for treating refractory cytomegalovirus infection after transplant. Foslevodopa + foscarbidopa (Produodopa) – DNP for treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. Await clinician request. Voclosporin (Lupkynis) – DNP for the treatment of adults with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis. Await clinician request.	
18.	**ANY OTHER BUSINESS**	
a.	There were no items of any other business.	
19.	**DATE OF NEXT MEETING**	
	Tuesday, 14th March 2023, papers are to be circulated and agreed via email as per JAPC interim Terms of Reference, which is effective during the COVID-19 pandemic.	