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

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 13th October 2020

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Insulin lispro (Lyumjev)	GREEN: 100units/ml BROWN: 200units/ml* *See MHRA April 2015, High strength, fixed combination and biosimilar insulin products to minimise the risk of medication error
Insulin glargine + lixisenatide (Suliqua)	BROWN specialist initiation and stabilisation of dosage: restricted for those patients struggling to manage multiple injections. Ongoing specialist support should be maintained for patients on this treatment.
Micronised Progesterone (Utrogestan)	GREEN (oral capsules): Progesterone only component of combined HRT. Oral alternative to Mirena IUS. 2nd line option for women requiring combined HRT but unsuitable for or intolerant of standard combination preparations. Patient group includes women at high risk of VTE (e.g. migraines, BMI >30 kg/m2, PMH of VTE) in whom transdermal oestrogen is recommended, but in whom Evorel Conti is not tolerated or unsuitable because of the need for variable oestrogen dose.
Givosiran (Givlaari)	RED (as per NHS England commissioning intentions)
Isatuximab (Sarclisa)	RED (as per NHS England commissioning intentions)
Mogamulizumab (Poteligeo)	RED (as per NHS England commissioning intentions)
Relebactam + cilastatin + imipenem (Recarbrio)	BLACK await national guidance or clinician request
Elexacaftor+ ivacaftor + tezacaftor (Kaftrio)	RED (as per NHS England commissioning intentions)
Avelumab	RED (NHS England as per NICE TA645)
Glasdegib	BLACK (as per NICE TA646)
Eculizumab	BLACK (as per NICE TA647)
Dupliumab	BLACK (as per NICE TA648)
Polatuzumab vedotin with rituximab and bendamustine	RED (NHS England as per NICE TA649)
Pembrolizumab with axitinib	BLACK (NHS England as per NICE TA650)
Naldemedine	BROWN consultant/specialist initiation and stabilisation for 3 months (as per NICE TA651)

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Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Dorzolamide	GREEN specialist initiation, first line carbonic anhydrase inhibitor (CAI) for glaucoma treatment
Brinzolamide	BROWN specialist initiation, alternative CAI for glaucoma treatment.
Alfentanil	RED 5mg/1ml injection BROWN 5mg/10ml injection palliative care specialist recommendation only, for use in patients with severe renal impairment.
Venlafaxine	GREEN

Clinical Guidelines

Advisory guidance on when to initiate a PPI with a NSAID (or antiplatelet) for gastro-protection – partial update

Patient Group Directions

Typhoid Vi Polysaccharide Vaccine (PHE PGD)
Vitamin K (local Derbyshire PGD)

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Present:	
Derby and Derbyshire CCG	
Dr C Emslie	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)
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
Ms J Savoury	Assistant Chief Finance Officer
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 J Shaw	Principal Pharmacist
Derby and Derbyshire Local Medical Committee	
Derbyshire Health United	
Staffordshire and Stoke-on-Trent CCG's	
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, Ms S Bamford, Ms A Braithwaite, Ms A Brailey, Dr R Gooch, Mr S Hulme, Mr D Graham	
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 8 SEPTEMBER 2020**	
	The minutes of the meeting held on 8th September 2020 were agreed as a correct record after minor amendments to the following agenda items: • New Drug Assessment/Traffic Light Addition 7a added: '*in line with* NICE TA345 for treating opioid induced constipation'. • Miscellaneous 9c post meeting note added: following notification from the Competition and Markets Authority, current plans to switch patients from Priadel® to an alternative brand of lithium carbonate tablets are PAUSED, until further notice.	
5.	**MATTERS ARISING**	
a.	**Luteinizing hormone-releasing hormone agonists (LHRH)** Mr Dhadli advised that he has seen the final version of the Gonadarelins and Degarelix service specification, the Primary Care Enhanced Services Steering Review Group have confirmed that they are happy for the first LHRH injection to be administered in Primary Care. This is a change in service delivery however the traffic light classification will remain the same. It has been requested that this change take effect from 1st January 2021 to allow for communication and for practices to prepare. During a previous JAPC meeting it had been noted that clarity was needed as to where the responsibility lies for contacting the patient if they do not book, or fail to attend an appointment. This has been clarified within the service specification. The change in service and effective date will be communicated via the JAPC bulletin.	**SD**
b.	**PGD's – Hepatitis A Vaccine and Combined Hepatitis A Virus (Inactivated) and Typhoid Polysaccharide Vaccine** Mr Dhadli reported that at the previous months JAPC meeting Derbyshire CCG's local PGD's for Hepatitis A Vaccine adult, Hepatitis A Vaccine child and Hepatitis A and Typhoid Vaccine were nearing their expiry. The recommendation was to adopt the national templates, to which the committee were in agreement. They have now been formally signed off by Dr S Lloyd Medical Director, Derby and Derbyshire CCG and are available on the Derbyshire Medicines Management website.	

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Item		Action
c.	**BLACK/BROWN drug classifications** Mr Dhadli reported that in light of Black Lives Matter and the issues to address equality and diversity, a concern had been raised by a GP in regards to utilising the category 'BLACK' for drugs that are not recommended for prescribing, within the Derbyshire traffic light classification list. This debate extended to the BROWN classification. It had been tabled at previous months' JAPC meetings where a discussion took place to consider alternative options and what further action should be taken. At the September JAPC meeting, 3 options were considered; the committee were in agreement with option 1 which included traffic light classifications of GREEN/AMBER/RED with the addition of GREY to replace BROWN and DNP (Do Not Prescribe) to replace BLACK categories. This option was considered to be the most consistent with other CCG's by JAPC members and the committee agreed that this would be the simplest way of maintaining current systems with limited changes. Mr Dhadli advised that Ms C Haynes Involvement Manager DDCCG, presented the discussion to the Derbyshire County Council BME forum, to comment on the preferred option of the three put forward and to collate any additional comments the forum might have. There has not been any formal feedback as yet, however Mr J Lee facilitator of the BME forum, agrees that the current arrangements can have negative connotations. He suggested making a change and is also in support of option 1. Following on from this, JAPC agreed that a work plan should be produced to look at the most effective way to implement these changes. Mr Dhadli will work with the Derbyshire Medicines Management Shared Care and Guideline Group (MMSCGG) and Medicines Management, Clinical Policies and Decisions team to look at how this might be carried out.	**SD**
d.	**Priadel** Mr Jones reported that the Competition and Markets Authority (CMA) have begun a formal investigation into the activities of Essential Pharma and their earlier decision to withdraw Priadel® tablets from the UK market. Due to this, the discontinuation of Priadel has been paused. This means that Priadel® tablets will continue to be available and Essential Pharma would need to give DHSC at least 6 months' notice of their intention, if they subsequently decide to withdraw any of their products from the UK market. In light of this, the switching of patients from Priadel should be halted. It is a local decision as to what should happen if patients have already been taken off Priadel and changed to a different medication. Mr Jones advised that Derbyshire Healthcare NHS Foundation Trust (DHcFT) would recommend switching patients back to Priadel if they were previously stable on this. Mrs Needham confirmed that a small number of GP practices have started to switch patients from Priadel. JAPC agreed that if patients have been switched and are not stable, consideration should be made to revert back to Priadel. If patients are stable following a switch they should remain on the medication they have been changed to. The Priadel switching guidance will remain available to JAPC members in case this is required in the future. Mr Jones confirmed that DHcFT would continue to host the virtual education sessions on lithium for GP's/practices and these had been well received so far.	

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6.	**JAPC ACTION SUMMARY**	
a.	**Continence guidance** Mr Dhadli suggested that this be removed from the JAPC action summary and added to the MMSCGG action tracker, to monitor and review once it has been completed.	
b.	**BLACK/BROWN drug classifications** This was discussed as an agenda item earlier in the meeting. It is to remain on the JAPC action summary. Work will continue as to how the new changes will be implemented.	
7.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Insulin Lispro (Lyumjev)** Mr Moore advised that there had been a request from one of the diabetologist's at the University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) for JAPC to consider Lyumjev. Lyumjev is a formulation of insulin lispro that contains citrate and treprostinil to provide a faster glucose-lowering effect that mimics more closely the physiological carbohydrate absorption profile and mealtime insulin response than the currently available insulin lispro products. Lyumjev is indicated for the treatment of diabetes mellitus in adults only. It is a mealtime insulin for subcutaneous (SC) injection and should be administered 0-2 minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal. The current mealtime insulins that UHDBFT use cannot be taken after starting a meal. Lyumjev would benefit patients who struggle with their mealtime insulin or do not remember to take it before eating. There would be no cost increase for using Lyumjev over the similar alternatives. Three main studies have been carried out regarding the use of Lyumjev, non-inferiority of Lyumjev vs. Humalog in overall glycaemia (HbA1c) was demonstrated in Type 1 and Type 2 diabetics. Analyses on time-in-range and incremental AUC of postprandial glucose concentration strongly support the clinically relevant difference between Lyumjev and Humalog on postprandial control. The results obtained by several different methods measuring glucose fluctuations during mixed-meal tolerance test, self-monitoring of glucose, and continuous and flash glucose monitoring indicate that Lyumjev should optimally be injected prior to meal to achieve improvement in postprandial glycaemia compared with Humalog. However, if dosing prior to meal is not feasible, post-meal dosing is possible and results in comparable glycaemic excursions as achieved with pre-meal Humalog. Lyumjev is available in 100unit/ml (vial, cartridge, KwickPen, junior KwickPen) and 200unit/ml (KwickPen). A discussion took place at UHDBFT September 2020 Drugs and Therapeutics (DTC) meeting in regards to only stocking the 100unit/ml strength, as there doesn't appear to be a need for the higher strength and it would mitigate the risk of overdose. There is currently no published national appraisal (NICE, SMC, AWMSG) or neighbouring CCGs evaluation to date. Mr Shepherd from Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) confirmed that he was in agreement for the use of Lyumjev.	

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	Mr Dhadli advised that this should be prescribed by brand, to mitigate the risk of dispensing errors. **Agreed:** JAPC classified insulin lispro (Lyumjev) as **GREEN** 100units/ml and **BROWN** 200units/ml see MHRA April 2015, high strength, fixed combination and biosimilar insulin products to minimise the risk of medication error.	**SD**
b.	**<u>Insulin glargine + lixisenatide (Suliqua)</u>** Mr Moore reported that this was tabled at UHDBFT Drugs and Therapeutics meeting in September 2020. Suliqua is a fixed ratio combination of insulin glargine, a basal insulin analogue, and lixisenatide, a glucagonlike peptide-1 receptor agonist (GLP-1 RA). It is licensed in combination with metformin for the treatment of adults with type 2 diabetes mellitus (T2DM) to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering drug or with basal insulin. The combination of its individual components is licensed in the UK for treatment of T2DM. This is available as insulin glargine 100 units/ml + lixisenatide 50 mcg/ml pre-filled pen (Suliqua 10-40 pen), which gives a dose range of 10-40 units of insulin glargine + 5-20 mcg lixisenatide and insulin glargine 100 units/ml + lixisenatide 33 mcg/ml pre-filled pen (Suliqua 30-60 pen), which gives a dose range of 30-60 units of insulin glargine + 10-20 mcg lixisenatide. Suliqua would only be used upon recommendation by a specialist for patients who are already on lixisenatide and insulin glargine and who are struggling to manage multiple injections. The patients will be stabilised on a dose of Suliqua by a specialist before prescribing responsibility is transferred to primary care. A Regional Drugs and Therapeutics Committee (RDTC) paper (August 2019) has compared the evidence for Suliqua. There were two 30 week randomised, open-label, active-controlled, parallel group studies named LixiLan-L and LixiLan-O. Both studies looked at patients who had been on one other oral anti-diabetic drug. Results show that it had a positive effect on HbA1c and body weight. Its use is supported by both the RDTC and Scottish Medicines Consortium (SMC); however NICE have not currently reviewed this. Suliqua would be cost effective for those patients who have previously been taking two separate products and are able to switch to this combined product. There are two strengths available so care must be taken when selecting the pen. Mr Dhadli highlighted that the naming of the pen could potentially cause confusion, however this should be overcome with clear communication and advising the patient on how to use this. Greater Manchester reviewed Suliqua in April 2019, however there was concern over the two different strengths and the likelihood of dispensing/dosing errors. A discussion took place and the committee agreed that this should be restricted for use only in those patients who are already on insulin glargine and lixisenatide and are struggling to manage multiple injections. **Agreed:** JAPC classified insulin glargine + lixisenatide (Suliqua) as **BROWN specialist initiation and stabilisation of dosage:** restricted for those patients struggling to manage multiple injections. Ongoing specialist support should be maintained for patients on this treatment.	**SD**

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Item		Action
c.	**Micronised Progesterone (Utrogestan)** Mr Moore advised that this had been reviewed at UHDBFT Drugs and Therapeutics meeting in September 2020 and was put forward by two of their Consultant Gynaecologists. Utrogestan is indicated for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT). Utrogestan was included in the recent update (March 2020) of Derbyshire Menopause Management guideline as an alternative option, for the progesterone element of combined HRT, in response to ongoing HRT shortages, as per British Menopausal society advice. Although it is recommended, there is not a lot of detail in regards to dosing and indication. The UHDBFT DTC looked at the request to use Utrogestan for a particular sub-group of patients, i.e. for women requiring combined HRT who are unsuitable for or intolerant of standard combination preparations. The other currently available licenced options for endometrial protection are the Mirena IUS and medroxyprogesterone (MPA). Evidence suggests that micronised progesterone compared favourably with MPA with respect to bleeding patterns and lipid metabolism. Limited safety evidence suggests a lower risk of breast cancer with micronised progesterone compared with synthetic progestogens. An updated meta-analysis has recently shown that among transdermal oestrogen users, there was no change in VTE risk in women using micronized progesterone. UHDBFT DTC approved Utrogestan with the following criteria specified for usage: Progesterone only component of combined HRT, oral alternative to Mirena IUS. A 2nd line option for women requiring combined HRT but unsuitable for or intolerant of standard combination preparations. Patient group includes women at high risk of VTE (e.g. migraines, BMI >30 kg/m2, PMH of VTE) in whom transdermal oestrogen is recommended, but in whom Evorel Conti is not tolerated or unsuitable because of the need for variable oestrogen dose. This criteria is aligned to the Nottingham guidance where Ustrogestan is classified as GREEN. It was proposed that the Derbyshire Menopause Management guideline also be updated to bring it in line with this. A discussion took place and the committee agreed to classify micronised progesterone (Utrogestan) as GREEN. It is a cost effective option compared with other transdermal preparations. **Agreed:** JAPC classified micronised progesterone (Utrogestan) as **GREEN** (oral capsules): Progesterone only component of combined HRT. Oral alternative to Mirena IUS. 2nd line option for women requiring combined HRT but unsuitable for or intolerant of standard combination preparations. Patient group includes women at high risk of VTE (e.g. migraines, BMI >30 kg/m2, PMH of VTE) in whom transdermal oestrogen is recommended, but in whom Evorel Conti is not tolerated or unsuitable because of the need for variable oestrogen dose.	**SD** **SD**
8.	**CLINICAL GUIDELINES**	
a.	**PPI antiplatelet gastro-protection** Mr Dhadli advised that NICE Clinical Knowledge Summaries (CKS) have updated their guidance on PPI gastroprotection for patients on antiplatelet	

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	treatment. It went out for consultation and feedback was received from gastroenterologists at UHDBFT, and Mr M Shepherd CRHFT. Mr Dhadli referred to paper 8ai – *Advisory guidance on when to initiate a PPI with a NSAID (or antiplatelet) for gastro-protection.* This has been amended to include the definition of high dose aspirin (over 300mg and/or daily dose 1200mg) and those over 70 years of age receiving antiplatelet treatment e.g. low dose aspirin or clopidogrel, as a criteria for potential high risk. **Agreed:** JAPC ratified the partial update to Advisory guidance on when to initiate a PPI with a NSAID (or antiplatelet) for gastro-protection.	**SD**
b.	**<u>NICE pain guideline update</u>** Mr Dhadli reported that NICE NG59 Low back pain and sciatica in over 16s has received a partial update. Pain consultants at UHDBFT and CRHFT were notified to seek their views on this, as some of the recommendations are non-pharmacological. New pharmacological recommendations include do not offer gabapentinoids, other antiepileptics, oral corticosteroids, benzodiazepines and do not offer opioids for managing chronic (3 month or longer) sciatica. Mr Dhadli expressed the need to either update the Derbyshire Chronic Pain guideline to include a section on sciatica or to produce a separate sciatica guideline. Dr. D Farquharson, Clinical Director Integrated Surgery CRHFT agreed with the NICE recommendation on not using oral steroids and opioids for chronic sciatica. Gabapentinoids can be useful in the short term for acute chronic episodes but not for chronic use. There is a very strong reservation about not using all antiepileptics e.g. carbamazepine, as there are people with severe otherwise untreatable pain who can respond to these older drugs and it would be wrong to preclude them. Comments were also received from Ms V Sands, Specialist Nurse CRHFT and Dr J Hui, Consultant in Anaesthesia and Pain Medicine CRHFT. Dr J Hui sees little benefit in patients being referred to a specialist pain clinic for lower limb radiculopathy. Previously patients may have been trialled on carbamazepine or oxcarbazepine with a degree of benefit, but these are not recommended by NICE. Mr Moore advised that UHDBFT are in the process of formulating a response to this. A discussion took place and the committee agreed that a separate back pain/sciatica guideline should be produced and tabled at a future JAPC meeting. Mr Dhadli felt that further discussions with the consultees would be beneficial to consider how some of the information in regards to services can be localised. Mr Jones noted that there is a rise locally and nationally of patients on multiple antidepressants for pain relief. There was support for wider guidance on pain/antidepressant use.	**SD** **SD**
9.	**PATIENT GROUP DIRECTIONS**	
a.	**<u>Typhoid Vi Polysaccharide Vaccine</u>** Mr Dhadli advised that the Derbyshire Typhoid vaccine for children and adults PGD is due to expire in October 2020. A Public Health England (PHE) PGD	

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	Template is now available for Typhoid Vi Polysaccharide vaccine and this has been reviewed by Mr V Rai, Senior Pharmacist Quality & Safety DDCCG, who has compared the local Derbyshire PGD with the PHE PGD. It was noted that Typherix had been discontinued in 2018 as per Greenbook chapter 33; this has been removed from the PGD. PHE refer to individuals who are under 12 months of age as an exclusion criteria whereas the Derbyshire local PGD stated patients under 2 years of age (children aged between 1 and 2 years should be immunised if the risk of typhoid fever is considered high). The local PGD also notes in the exclusion criteria pregnancy or breastfeeding except where high risk of infection, however there is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. People at increased risk of hepatitis A infection because of their occupation are not covered by PHE PGD but should be covered by occupational health. **Agreed:** JAPC agreed the Typhoid Vi Polysaccharide Vaccine PHE PGD, pending organisational sign off by DDCCG.	**SD**
b.	**<u>Vitamin K</u>** Mr Dhadli reported that the Derbyshire Vitamin K PGD is due to expire in October 2020. The existing template has been updated to reflect the latest evidence from the Summary of Product Characteristics (SPC) and UHDBFT guidance. The criteria for exclusion in the Derbyshire PGD states children <16 years, this has been amended to patients aged 17 and under, in line with the UHDBFT guidance. Route/method of administration and wording for ampoule content has been updated to bring it in line with the SPC. **Agreed:** JAPC agreed the updated Derbyshire Vitamin K PGD, pending organisational sign off by DDCCG.	**SD**
10.	**MISCELLANEOUS**	
a.	**<u>Atopic Dermatitis high cost drugs algorithm</u>** Mrs Qureshi reported that the Derbyshire commissioning guidance for the treatment of moderate to severe atopic dermatitis was first produced in October 2018 based on the NICE TA534 - Dupilumab for treating moderate to severe atopic dermatitis. This was due for a review and has been updated with no clinical change. **Agreed:** JAPC ratified the Derbyshire commissioning guidance for the treatment of moderate to severe atopic dermatitis.	**SQ**
b.	**<u>Prescribing Specification</u>** Mr Dhadli advised that the Prescribing Specification is reviewed annually by JAPC as it forms part of the contract held between DDCCG and local providers. It has been brought to the October meeting for people to review and comment on. Mr Dhadli highlighted the area of change and clarity which includes transfer of budgetary responsibility from CCG to block contract in situations like COVID. He is seeking clarity on the length of time that this will be in effect for. JAPC members were in agreement with the changes and the agreed version	

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	will go into the contracts to providers.	**SD**
c.	**DMARD monitoring during COVID-19** Mr Dhadli advised that currently the COVID-19 SPS recommendations for 6 monthly DMARD monitoring are being followed. Consultants have suggested that it should now revert back to regular 3 monthly DMARD monitoring, as these are high risk patients. JAPC previously discussed this matter and feedback from UHDBFT consultants suggested that the decision was previously made based on safety and local consensus, however now the initial peak of the COVID-19 pandemic has passed; there should be sufficient capacity to revert to standard regular monitoring given the balance of risk. There have been issues with access and capacity to phlebotomy services. North Derbyshire, Hardwick and Erewash phlebotomy is provided in practices, additional collections and extended hours have been put in place. South Derbyshire, the phlebotomy is provided by UHDBFT and there is a 2-3 week wait at community clinics including London Road and Derby Hospital on a regular basis. Walk in appointments for urgent bloods are being seen at some of the sites. The service is being restored and Derby Hospital is seeing an increase as outpatient clinics are restored. SPS has been contacted to provide further guidance; Mr Dhadli is awaiting a response to this. In the meantime the SPS guidance for DMARD monitoring has been removed whilst further consultation and reviews are undertaken. A discussion took place and it was felt that Derbyshire should revert back to the local DMARD monitoring schedule. JAPC recognised that there are current challenges, with GP practices finding it increasingly difficult to provide appointment slots for patients and there is limited capacity with phlebotomy services. However it was noted that these are cytotoxic drugs where close monitoring is necessary.	**SD**
d.	**Glaucoma eye drops** Mr Dhadli stated that DDCCG has been made aware via the Ophthalmology Clinical Improvement Group of an issue relating to the provision of medication for the ongoing treatment for Glaucoma. Patients considered by hospital Consultants as stable are provided with their eye drops to treat the condition and will be placed on a routine review. Due to COVID-19, routine reviews of patients with Glaucoma have been delayed, which will have an impact on the prescribing of drops/medication by GPs. Guidance has been developed to facilitate continuing provision of glaucoma/ocular hypertension (OHT) treatment in primary care. Dr J Tildsley, Consultant Ophthalmologist UHDBFT, has produced the guideline in conjunction with Dr M Wood, DDCCG GP Clinical Lead for Ophthalmology. Key messages from the guideline include: • The approach is supported by The Royal College of Ophthalmologists. • In order to ensure that patients are able to continue to receive their eye drops, GPs will be asked to continue to prescribe outside of the recommended interval. • GPs will not be expected to review patients in order to continue to prescribe nor be required to change the drops prescribed as this would be	

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	done within the (Hospital Eye Service) HES if applicable. • GPs may contact the Hospital Eye Services (HES) for advice in the event of patients presenting with any of the described symptoms associated with their eye drops or refer to HES in the event of any concern. • GPs are being asked to issue repeat prescriptions for the eye drops as an interim measure, without the need to review the patient and it is safe to do so. The guideline contains advice in regards to preservative free eye drops and common side effects from glaucoma and Ocular Hypertension drops, which may warrant a review. Mr Dhadli advised that as this has been developed outside of JAPC, the remit of JAPC is to ensure that the committee agree with the content and formulary choices within the guideline. JAPC formulary eye drops have been listed within this. Mr Dhadli raised concerns in regards to capturing patient numbers for those who live in neighbouring areas and have had their treatment transferred to Derbyshire. He also highlighted that patients should be risk stratified on the timing of their follow up appointments. The Clinical Improvement Group is to advice on timelines and include this within the guideline before final ratification.	**SD**
11.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in September 2020 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Dorzolamide – reclassified as GREEN specialist initiation from BROWN specialist initiation. Replaces brinzolamide as first line carbonic anhydrase inhibitor (CAI) for glaucoma treatment • Brinzolamide – reclassified as BROWN specialist initiation from GREEN specialist initiation. Alternative CAI for glaucoma treatment. • Alfentanil – dual classification 5mg/1ml injection RED, 5mg/10ml injection BROWN palliative care specialist recommendation only, for use in patients with severe renal impairment. • Venlafaxine – reclassified as GREEN. Brown TLC for MR preparations removed due to frequent cost fluctuation. Generic MR capsules currently more cost effective than normal release preparations (with the exception of 225mg MR caps). Formulary Update (Chapter 11 – Eye): • Message added to remind prescribers that preservative free formulations are usually less cost effective and should only be considered under specified circumstances. • Dorzolamide replaces brinzolamide as 1st line carbonic anhydrase inhibitor (CAI) for glaucoma treatment due to cost-effectiveness. Clinical Guidelines:	

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	• Derbyshire self-care policy updated with no major change. A link to Health Education England e-learning programme has been added; new references including PrescQIPP Bulletin and letter from NHS England's Medical director to GPs added. • Dronedarone SCG – clarification to wording under consultant responsibility - to provide at least 4 weeks supply upon transferring prescribing responsibility to GP. Consultant to retain overall responsibility for patient and the prescribing for the first 12 months. Website Changes/Miscellaneous: • Formulary GI chapter – MHRA drug safety update August 2020 advice on stimulant laxatives added. Manage constipation with lifestyle changes and short-term OTC laxatives (bulk-forming followed by osmotic). Stimulant laxatives should only be used if others are ineffective. Children <12 years should not use stimulant laxatives without advice from a prescriber. • A link to NHS England's Low Calorie Diet programme has been added – support materials include LCD essential info to support referrals and Guidance for GP practices and referrers. • Gaviscon advance – use by exception only after formulary choice Acidex advance is thought to be inappropriate due to intolerance or inadequate symptom control. Not to be routinely used as first-line choice. • CKD detailing aid – reviewed with no change. • Opioid resource pack – appendix 15 opioid dose conversion charts updated as per Faculty of Pain Opioid Aware website updates, to bring in line with BNF. 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 September 2020 bulletin was ratified pending the amendment of Priadel to include that patient switching has been presently paused. The DMARD section is to be removed and added to the October bulletin.	**SQ**
14.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for September 2020 was noted. Mr Dhadli highlighted the following MHRA advice: • Opioids: risk of dependence and addiction There are new recommendations following a review of the risks of dependence and addiction associated with prolonged use of opioid medicines (opioids) for non-cancer pain. Health Care Professionals are to discuss with patients that prolonged use of opioids may lead to drug dependence and addiction, even at therapeutic doses – warnings have been added to the labels (packaging) of UK opioid medicines to support patient awareness. Before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment. At the end of	

Item		Action
	treatment, taper dosage slowly to reduce the risk of withdrawal effects. • Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines (CHM) has recommended that fentanyl transdermal patches are contraindicated in opioid-naive patients in the UK. Health Care Professionals are not to use fentanyl patches in opioid-naive patients and use other analgesics or other opioid medicines (opioids) for non-cancer pain before prescribing fentanyl patches. Make patients and caregivers aware of the signs and symptoms of fentanyl overdose and advise them to seek medical attention immediately if overdose is suspected. • Methotrexate once-weekly for autoimmune diseases: new measures to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing In autoimmune conditions and some cancer therapies, methotrexate should be taken only once a week; New measures have been implemented to prompt healthcare professionals to record the day of the week for intake and to remind patients of the dosing schedule and the risks of overdose. Prescribers and dispensers are to remind the patient of the once-weekly dosing and risks of potentially fatal overdose if they take more than has been directed • Insulins (all types): risk of cutaneous amyloidosis at injection site Cutaneous amyloidosis at the injection site has been reported in patients using insulin and this may affect glycaemic control. Remind patients to rotate injection sites within the same body region. A recent European review of reports of insulin-derived cutaneous amyloidosis at insulin injection sites concluded that there is a clear causal relationship between cutaneous amyloidosis and all insulins and insulin-containing products. The Summaries of Product Characteristics and Patient Information Leaflets for all insulins and insulin-containing products are being updated to include this risk.	
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 (Zirabev) – to remain classified as **BLACK** await national guidance or clinician request • Entrectinib (Rozlytrek) – to remain classified as **RED** (as per NHS England commissioning intentions) • Givosiran (Givlaari) – classified as **RED** (as per NHS England commissioning intentions) • Isatuximab (Sarclisa) – classified as **RED** (as per NHS England commissioning intentions) • Mogamulizumab (Poteligeo) – classified as **RED** (as per NHS England commissioning intentions) • Relebactam + cilastatin + imipenem (Recarbrio) – classified as **BLACK** await national guidance or clinician request	

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

Item		Action

	• Rituximab biosimilar (Ruxience) – to remain classified as **RED** (as per NHS England commissioning intentions)
	
	New formulation launches in the UK:
	• Elexacaftor+ ivacaftor + tezacaftor (Kaftrio) – classified as **RED** (as per NHS England commissioning intentions)
	• Insulin lispro (Lyumjev)
	  ○ Humalog previously classified as **GREEN:** 100units/mL (decision date - June 2016) **BROWN:** 200units/mL (decision date - October 2017)
	  ○ Lispro Sanofi (Insulin Lispro biosimilar) previously classified as **BLACK:** 100units/mL (decision date - September 2018)
	• Semaglutide (Rybelsus) – previously classified as **BROWN** - (Subcut preparation), **BLACK** (once daily oral preparation)
	• Treosulfan (Trecondi) – previously classified as **RED** (as per NHS England commissioning intentions)
	• Vedolizumab (Entyvio) – previously classified as **RED**
	
	Licence extensions:
	• Etravirine (Intelence) – no current traffic light classification
	• Nintedanib (Ofev) – previously classified as **RED**
	• Omalizumab (Xolair) – previously classified as **RED**
	• Secukinumab (Cosentyx) – previously classified as **RED**
	
	Drug discontinuations:
	• Atarax (Hydroxyzine)
	• Erythroped A (Erythromycin)
	• Oilatum Gel (Light liquid paraffin)
	• Pneumococcal Polysaccharide Vaccine
	• Risperdal Liquid (Risperidone)	

16.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in September 2020: TA645 Avelumab with axitinib for untreated advanced renal cell carcinoma – classified as **RED** (NHS England as per NICE TA645) TA646 Glasdegib with chemotherapy for untreated acute myeloid leukaemia (terminated appraisal) – classified as **BLACK** (as per NICE TA646) TA647 Eculizumab for treating relapsing neuromyelitis optica (terminated appraisal) – classified as **BLACK** (as per NICE TA647) TA648 Dupliumab for treating chronic rhinosinusitis with nasal polys (terminated appraisal) – classified as **BLACK** (as per NICE TA648) TA649 Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma – classified as **RED** (NHS England as per NICE TA649) TA650 Pembrolizumab with axitinib for untreated advanced renal cell	

Item		Action
	carcinoma – classified as **BLACK** (NHS England as per NICE TA650) TA651 Naldemedine for treating opioid-induced constipation in adults who have had laxative treatment – classified as **BROWN consultant/specialist initiation and stabilisation for 3 months** (as per NICE TA651)	
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Medication Optimisation Safety Team 02/07/2020 • UHDBFT Drugs and Therapeutics Group 18/08/2020	
18.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Insulin lispro (Lyumjev) – GREEN: 100units/ml and BROWN: 200units/ml* *See MHRA April 2015, High strength, fixed combination and biosimilar insulin products to minimise the risk of medication error Insulin glargine + lixisenatide (Suliqua) – BROWN specialist initiation and stabilisation of dosage: restricted for those patients struggling to manage multiple injections. Ongoing specialist support should be maintained for patients on this treatment. Micronised Progesterone (Utrogestan) – GREEN (oral capsules): Progesterone only component of combined HRT. Oral alternative to Mirena IUS. 2nd line option for women requiring combined HRT but unsuitable for or intolerant of standard combination preparations. Patient group includes women at high risk of VTE (e.g. migraines, BMI >30 kg/m2, PMH of VTE) in whom transdermal oestrogen is recommended, but in whom Evorel Conti is not tolerated or unsuitable because of the need for variable oestrogen dose. Givosiran (Givlaari) – RED (as per NHS England commissioning intentions) Isatuximab (Sarclisa) – RED (as per NHS England commissioning intentions) Mogamulizumab (Poteligeo) – RED (as per NHS England commissioning intentions) Relebactam + cilastatin + imipenem (Recarbrio) – BLACK await national guidance or clinician request Elexacaftor+ ivacaftor + tezacaftor (Kaftrio) – RED (as per NHS England commissioning intentions) Avelumab – RED (NHS England as per NICE TA645) Glasdegib – BLACK (as per NICE TA646) Eculizumab – BLACK (as per NICE TA647) Dupliumab – BLACK (as per NICE TA648) Polatuzumab vedotin with rituximab and bendamustine – RED (NHS England as per NICE TA649) Pembrolizumab with axitinib – BLACK (NHS England as per NICE TA650) Naldemedine – BROWN consultant/specialist initiation and stabilisation for 3 months (as per NICE TA651)	
19.	**ANY OTHER BUSINESS**	
	There were no items of any other business.	
20.	**DATE OF NEXT MEETING**	
	Tuesday, 10th November 2020 at 1.30pm to be held virtually via Microsoft Teams.	