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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 8th September 2020

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Naloxegol	BROWN specialist initiation and stabilisation for 3 months, in line with NICE TA345 for treating opioid induced constipation
Delafloxacin (Quofenix)	BLACK
Fostamatinib disodium (Tavalisse)	RED as per NHS England commissioning intentions
Insulin lispro (Lyumjev)	BLACK
Rurioctocog alfa pegol (Adynovi)	RED as per NHS England commissioning intentions
Turoctocog alfa pegol (Esperoct)	RED as per NHS England commissioning intentions
Treosulfan with fludarabine	RED NICE TA640: for malignant disease before allogeneic stem cell transplant (NHS England as per NICE TA640)
Brentuximab vedotin	RED NICE TA641: in combination for untreated systemic anaplastic large cell lymphoma (NHS England as per NICE TA641)
Gilteritinib	RED NICE TA642: for treating relapsed or refractory acute myeloid leukaemia (NHS England as per NICE TA642)
Entrectinib	RED NICE TA643: for treating ROS1-positive advanced non-small-cell lung cancer (NHS England as per NICE TA643)
Entrectinib	RED NICE TA644: for treating NTRK fusion-positive solid tumours (NHS England as per NICE TA644)

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Depo-Medrone with Lidocaine	GREEN 1ml and 2ml vials
Semaglutide oral (Rybelsus)	BLACK once daily oral preparation
Balsalazide	GREEN specialist initiation for patients who are unresponsive to mesalazine.

Patient Group Directions

Public Health England PGD's
Hepatitis A Vaccine
Combined Hepatitis A Virus (Inactivated) and Typhoid Polysaccharide Vaccine Inactivated
Inactivated influenza vaccine
Live attenuated influenza vaccine nasal spray suspension (LAIV)
Pneumococcal polysaccharide vaccine
BCG Vaccine AJV

PGD's on behalf of Derbyshire Community Health Services NHS Foundation Trust (DCHSFT)
Integrated Sexual Health Services
Supply of a progestogen only contraceptive pill (POP)

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Supply of a combined oral hormonal contraceptive (COC)
Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception
Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception (UPA EC)

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
Dr R Gooch	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
Ms A Brailey	Deputy Chief Pharmacist
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	
Dr K Markus	Chief Executive Officer
Derbyshire Health United	
Staffordshire and Stoke-on-Trent CCG's	
Ms S Bamford	Medicines Optimisation Senior Lead Pharmacist
In Attendance:	
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 S Taylor, Mr S Hulme, Ms A Braithwaite	
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**	
a.	New measures to support development of safe COVID-19 vaccines for the UK	
4.	**MINUTES OF JAPC MEETING HELD ON 11 AUGUST 2020**	
	The minutes of the meeting held on 11th August 2020 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Immunomodulating drugs monitoring** Mr Dhadli reported that he has received communication from University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) in regards to the alignment of DMARD monitoring guidelines with the national Specialist Pharmacy Service (SPS) guidance. Feedback from consultants suggest 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.	
b.	**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 recommended not to be prescribed, within the Derbyshire traffic light classification list. This debate extended to the BROWN classification. This was tabled at the previous month's JAPC meeting where a discussion took place to consider alternative options and what further action should be taken. There are currently 308 BLACK classified drugs, 210 BROWN classified drugs, 51 BROWN after consultant/specialist initiation and 17 BROWN after consultant/specialist recommendation listed within the Derbyshire traffic light classification system. These traffic lights are also embedded into clinical guidelines, policies, GP systems etc. Consideration was given to what other areas do, most neighbouring CCG's use a traffic light classification, however they also include other colours such as grey. Mr Dhadli advised that he is still awaiting feedback from Ms C Haynes Involvement Manager Derby and Derbyshire CCG (DDCCG) who has planned to discuss this at the Derbyshire County Council BME forum. In the meantime, an options proposal has been produced. Option 1 suggests the use of GREEN/RED/AMBER 1/AMBER 2/GREY/Do Not Prescribe (DNP), option 2 suggests the use of GREEN/RED/AMBER 1/AMBER 2/BLUE/GREY. Option 3 includes the use of symbols to represent	

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	'use in caution' (previously BROWN) and 'do not prescribe' (previously BLACK), however it was noted that symbols would be difficult to describe. A discussion took place and option 1 was considered to be consistent with other CCG's. A suggestion was made to align Derbyshire traffic light classifications to that of Staffordshire CCG, which might also be of some benefit to UHDBFT clinicians. Mr Dhadli felt concerned that AMBER 1/AMBER 2 could potentially cause confusion and suggested that the current Derbyshire classifications of GREEN/AMBER/RED should remain unchanged, with the addition of GREY to replace BROWN and DNP (Do Not Prescribe) to replace BLACK categories. The committee agreed that this would be the simplest way of maintaining current systems with limited changes. This will be discussed further at a future JAPC meeting following feedback from Ms C Haynes.	**SD**
c.	**<u>Luteinizing hormone-releasing hormone agonists (LHRH)</u>** Mr Dhadli advised that LHRH agonists had been discussed at the previous month's JAPC meeting and it had been agreed that further clarity was needed in regards to the timing of when the LHRH dose should be administered following the oral bicalutamide. Mr Dhadli has received a response which states that the 1st injection should be administered after 7 days of bicalutamide i.e. from day 7 to 21. This would mean that the patient has 3 weeks to book the appointment, however the strict timeframe of administration is in the last 14 days. If the patient misses the administration interval they would need to contact the hospital on the number provided. Further clarity is needed as to whether the Enhanced Service Review Group has given final agreement to this. Dr Markus added that she has been involved in discussions about this and it was previously highlighted that clarity is needed as to where the responsibility lies for contacting the patient if they do not book, or fail to attend an appointment. It was also noted that advice is being sought from Urology at Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) and UHDBFT to provide GP practices with further information as to what the process is if a patient misses the 21 day interval. JAPC agreed in principle to the change in service delivery and traffic light changes, but the committee require assurance that the service specification has been updated to reflect the comments provided by Dr Markus and feedback from Urology. This will be tabled at a future JAPC meeting.	**SD**
d.	**<u>NICE chronic pain consultation</u>** Mrs Qureshi reported that NICE is consulting on its draft guidance for chronic pain, which is now open to public consultation until 14th September 2020. Feedback has now been received from CRHFT and UHDBFT pain consultants and JAPC members. Feedback has shown that consultants have raised concerns in regards to the term chronic primary pain and have asked for clarity on what is and is not included under this term, along with what NICE define as chronic secondary pain. There are various concerns on evidence base for some non-pharmacological treatments included within the guidance and the local availability of these. The committee agreed that they are happy for the feedback to be submitted to NICE.	**SQ**

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e.	**Buccal Midazolam** Mr Dhadli reported that at the previous month's JAPC meeting a discussion was held in regards to buccal midazolam, as a result of concerns raised by a consultant neurologist at Sheffield Teaching Hospital. Following the committee's discussion an email to reflect this was sent to Sheffield Teaching Hospital. The consultant neurologist has since made further contact with the CCG with some additional queries, which Mr Dhadli has responded to. The contracting team at Sheffield Teaching Hospital have also contacted DDCCG contracting team in regards to this matter. Epact data shows prescribing of Epistatus which gave some assurance of patients not being switched wholesale. Mrs Needham highlighted that Derbyshire GP practices are still receiving discharges from Sheffield Teaching Hospital for patients on Epistatus. It was also noted that some patients attending review appointments at the hospital are not having their treatment changed to the preferred formulary choice. Mr Dhadli responded to say that he has contacted the Professional Secretary of Sheffield Area Prescribing Committee and has included information as to how Derbyshire JAPC reached their decision, however he has not received a response.	
6.	**JAPC ACTION SUMMARY**	
a.	**Luteinizing hormone-releasing hormone (LHRH)** Awaiting final ratification by the Enhanced Service Review Group, following an update to the service specification.	
7.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Naloxegol** Mr Moore advised that naloxegol is currently classified as BROWN for palliative care patients; however it is classified as RED for all other indications. UHDBFT would like a classification change to BROWN after specialist initiation and stabilisation of treatment. Consultants wish for GP's to be able to prescribe naloxegol after the specialist has initiated and stabilised the patient on this treatment. If the patient is responsive to treatment a request will be made to the GP to continue prescribing naloxegol. There are low levels of prescribing and no ongoing monitoring is required, therefore a shared care agreement would not be an appropriate option. Local neighbouring areas have a similar classification for naloxegol to what UHDBFT are proposing. Mr Dhadli informed the committee that naloxegol is recommended, within its marketing authorisation as per NICE TA345 published July 2015, as an option for treating opioid induced constipation in adults whose constipation has not adequately responded to laxatives. NICE provides details of what it defines as an inadequate response and a suggested response time. Most discontinuations for this drug have been due to adverse effects, however this typically happens shortly after initiation and it is anticipated that any adverse effects would be detected by secondary care prior to transferring prescribing responsibilities to primary care. Mr Dhadli compared the amount of prescribing for naloxegol with methlynaltrexone, there has been no prescribing of methlynaltrexone in the past 12 months and it appears to be a more costly treatment option to naloxegol.	

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	Agreed: JAPC classified naloxegol as **BROWN specialist initiation and stabilisation for 3 months**, in line with NICE TA345 for treating opioid induced constipation. Agreed to remove RED for other specialities.	**SD**
8.	**PATIENT GROUP DIRECTIONS**	
a.	The following Public Health England (PHE) PGD's were noted at JAPC: • Hepatitis A Vaccine • Combined Hepatitis A Virus (Inactivated) and Typhoid Polysaccharide Vaccine Derbyshire CCG's local PGD's for Hepatitis A Vaccine adult, Hepatitis A Vaccine child and Hepatitis A and Typhoid Vaccine are nearing their expiry. The recommendation is to adopt the national templates. Mr Dhadli referred to paper 9a where a comparison table highlighted differences between the local PGD's and the national PGD's, there does not appear to be any areas of concern. The local Hepatitis A and Typhoid Vaccine PGD mentions the preparation Hepatyrix, which was discontinued in 2018. The exclusion criteria lists patients under 15 years of age (under 16 for VIATIM) and pregnancy or breastfeeding except where high risk of infection, however the PHE PGD is more up to date and the Green Book states that there is no evidence of risk for that. PHE/NHS England PGD's • Inactivated Influenza This version includes amendments to: ○ extend the characteristics of staff to include all registered practitioners legally able to work under PGD ○ include household contacts of those on the NHS Shielded Patient List, health and social care workers employed through Direct Payments or Personal Health Budgets and, subject to vaccine supply, extension of the programme to individuals from 50 years of age and children in routine age cohorts unable to receive LAIV • Live attenuated influenza vaccine nasal spray suspension This version includes amendments to: ○ extend the characteristics of staff to include all registered practitioners legally able to work under PGD ○ include the 2020/21 influenza programme eligible DOB cohorts and household contacts of those on the Covid-19 Shielded Patient List • Pneumococcal polysaccharide vaccine This version includes amendments to: ○ recommend vaccination of contacts if not received PPV23 in the preceding 12 months ○ insert a note on immunisation of welders in the inclusion section and remove mention elsewhere • BCG Vaccine AJV Mr Dhadli advised that it will be noted in the JAPC bulletin that PHE/NHS England has extend the characteristics of staff who are able to administer the flu vaccination, additional groups have been added into the PGD's and there are a larger cohort of patients who will need to be vaccinated.	**SD**

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	DCHS PGD's • Progesterone Only Pill POP • Combined Oral Contraceptive COC • Levonorgestrel 1500mcg Tablets • Ulipristal	
9.	**MISCELLANEOUS**	
a.	**Migraine with Tariff excluded drugs** Mr Dhadli advised that NICE published TA631 'Fremanezumab for preventing migraine' in June 2020. Fremanezumab is recommended as an option for preventing migraine in adults, only if: the migraine is chronic (15 or more headache days a month for more than 3 months with at least 8 of those having features of migraine) and at least 3 preventive drug treatments have failed. Treatment options for preventing chronic or episodic migraine include beta-blockers, antidepressants and anticonvulsant drugs. If chronic migraine does not respond to at least 3 preventive drug treatments, botulinum toxin type A or best supportive care is offered. A Derbyshire commissioning guidance for preventing migraines algorithm (July 2020) has been produced along with continuation Blueteq forms for Fremanezumab. JAPC members were in support of these forms. Fremanezumab has previously been classified as RED within the Derbyshire formulary. **Agreed:** The JAPC committee accepted the positioning of Fremanezumab, in the treatment algorithm for preventing migraines, along with the continuation Blueteq forms.	**SD**
b.	**Vedolizumab subcutaneous preparation** Mr Dhadli reported that vedolizumab has been tabled at the meeting to accept the insertion of vedolizumab subcutaneous preparation into the Crohn's disease algorithm. Vedolizumab (Entyvio) is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. Vedolizumab IV is in the current Crohn's disease pathway. NICE have issued TA352 for the intravenous product however there are no plans to release a TA for subcutaneous preparation. Subcutaneous vedolizumab is effective as maintenance therapy in adults with moderately to severely active Crohn's disease who had a clinical response to intravenous vedolizumab induction therapy. It is the most cost effective treatment option within the schemes available. The committee were in agreement with this. Dr Goddard advised that within the algorithm there is a duplicated text box, Mrs Qureshi will amend this. **Agreed:** The JAPC committee accepted the positioning of vedolizumab subcutaneous preparation, in the treatment algorithm for Crohn's disease.	**SQ** **SD**
c.	**Withdrawal of Priadel** Mr Jones advised that Essential Pharma have provided notification that they will withdraw the Priadel® brand of lithium carbonate tablets (200mg and	

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	400mg MR) from the market on 6th April 2021. This only applies to tablets; Priadel® liquid (lithium citrate 520mg in 5mL) remains unaffected. Priadel® is the most widely prescribed brand of lithium carbonate, accounting for 98% of such prescription items in Derbyshire primary care. There has already been some supply disruption experienced within Derbyshire and there is a need to make preparations for switching people currently prescribed Priadel® to an alternative brand. The Department of Health and Social Care (DHSC) have recently released a Supply Disruption Alert which also advises that prescribers begin switching patients away from Priadel®. Mr Dhadli referred to the table in paper 11c which lists alternative formulations of lithium carbonate on the UK market, including the preparation, price and manufacturer. As lithium has a narrow therapeutic range it is critical that baseline and regular monitoring takes place when patients are switched to a different brand. Switching will require blood testing approximately one week after a change in formulation. For some patients there will be a need for further dose adjustment and blood testing. Switching may be complicated for some patients by there being no combination of alternative tablets that would deliver the same dose. Mr Jones has produced a table to demonstrate what doses can be achieved with the available products as a starting point for a switch, followed by blood testing and titration. There is a clinical risk as there is no direct dose equivalent, therefore the suggestion would be for elderly patients who sometimes respond to lower levels and are more sensitive to higher levels, to round doses down initially. For patients with bipolar disorder or unipolar depression round the dose up or down depending on the results of their previous stable plasma level, JAPC members were in agreement with this approach. Over the coming months, more than 1000 patients in Derbyshire will need to be switched from Priadel® tablets to an alternative lithium preparation. There will be short-term healthcare capacity impact from this event, it should be noted that pressure created by this situation will apply not only to mental health services but to primary care and community pharmacy in the first instance. It also has long term potential to impact on wider services such as the ambulance service, emergency departments and the police. The cost of the change will be dependent upon choice of formulation for different patients however there is a long-term financial impact from this event. Brands that will remain available are – Camcolit 400mg, Lithium Carbonate Essential Pharma 250mg film-coated tablets, Liskonum 450mg tablets. Switching patients' medication should be managed in a phased way to keep pace with changes in the supply chain, in order to support stock management and continuity of supply. Urgent consideration should be given to beginning this process from September 2020 in the anticipation of disruption to healthcare services due to worsening of the COVID-19 pandemic before April 2021. GP practices will need to identify patients taking Priadel®. Dr Markus raised concerns that GP practices would be unable to distinguish which patients currently taking lithium are under Derbyshire Healthcare NHS Foundation Trust (DHcFT). There are also workload implications for GP practices to monitor patients 7 days after switching and to consider changing their dose. A suggestion was put forward to consider a helpline for individual patient	

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	queries. Mr Jones responded to say that Derbyshire GPs can access specialist medication advice and support from DHcFT Mental Health Pharmacists through Consultant Connect. Mrs Needham advised that although Essential Pharma is listed as a brand it is currently classed as a generic on the clinical systems; therefore this will need to be adjusted to add the branded generic product to the system formulary. Mr Jones agreed to remove a statement within the local guidance developed by DHcFT where it advises that 'prescribing systems may need amendment to reflect this', as it was confirmed that GP systems will only allow for something to be added or removed. Concerns regarding phlebotomy capacity were also raised. JAPC agreed the supplementary guidance for switching patients who are currently prescribed Priadel® 200mg and 400mg tablets. This will now be circulated to clinicians, medical and non-medical prescribers within DHcFT and shared with primary care. Mr Jones referred to paper 11cii which contains some resources for clinicians. Suggested wording is included in the draft guideline document to assist with the production of patient-friendly information such as leaflets and/or agreed wording for use on organisations' websites. This will help to give a consistent message when explaining the current situation and indicate what future steps are likely to be taken in the event of Priadel® withdrawal. Mr Jones confirmed that DHcFT specialist services would initiate the switching process for patients who are actively under specialist care, GP's within primary care are to identify and switch the remaining patients taking Priadel®, this may include a small number of patients from neurology. DHcFT can host a virtual refresher lithium update for GP's/practices if required. **Agreed:** JAPC agreed the Supplementary guidance for switching patients who are currently prescribed Priadel® 200mg and 400mg tablets, it was agreed to review the position at the February 2021 meeting. **Post meeting note:** 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.	**SJ** **SD**
d.	**<u>Medicines Management website survey</u>** Mr Dhadli reported that the Clinical Policies and Decisions Team within DDCCG have produced a survey monkey to gain a better understanding of users' views of the Derbyshire Medicines Management website and gather information from users to help refine and improve it. The survey ran from 31st July 2020 to 14th August 2020. It was shared amongst Derby and Derbyshire CCG, GP surgeries, LMC, PCNs, community pharmacy and the Trusts and was completed by 99 healthcare professionals including pharmacists, GPs, nurses and pharmacy technicians. The survey results outline who currently accesses the website, it shows an even split between GP practices and Clinical Commissioners which also includes Practice Pharmacists. The survey asked what users like about the website, what they currently use and how it can be improved. A number of responses suggested that the search function was difficult to use and needs to be more specific and user friendly. Some users also find it difficult to navigate on their mobile phone or don't use the website at all. Solutions for improvement areas are to create a new structured search function and to create an app or an advanced mobile	

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	version to increase mobile usage. The website developer has explained that to design and create an app requires detailed planning and will take a couple of months to develop. It is also unpredictable as Apple/Google may reject it. However an advanced mobile version can be developed to look and act like an app, which comes at less of a financial cost. Costings have also been provided for a 'what's new' part of the website. Mr Dhadli will discuss the quote in more detail with DDCCG corporate and finance teams.	**SD**
10.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in August 2020 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Depo-Medrone with Lidocaine – classified as GREEN 1ml and 2ml vials. • Semaglutide oral (Rybelsus) – classified as BLACK once daily oral preparation. • Balsalazide – classified as GREEN specialist initiation. Initiated by secondary care for patients who are unresponsive to mesalazine. Formulary Update (Chapter 10 – Musculo-Skeletal and Joint Diseases): • Methotrexate – replace North Derbyshire with Chesterfield Royal Hospital NHS Foundation Trust (oral and subcutaneous injection) and South Derbyshire with University Hospitals of Derby and Burton NHS Foundation Trust (oral preparations only) to mirror Methotrexate Shared Care. • Sodium aurothiomalate shared care removed from chapter as discontinued. • Ibuprofen 10% gel (Fenbid) is classified as BROWN. Prescribe Ibuprofen 5% gel (Fenbid) first before moving to Ibuprofen 10% gel (Fenbid) as higher strength does not give more benefit. Website Changes/Miscellaneous: • Chapter 14 Immunological products and vaccines – section updated to include useful resources on antivirals and national flu programme to support primary care. • COVID-19 Clinical guidelines End Of Life – section updated to include The British Geriatric Society resource collating guidance on end of life care in older people, including specific advice for end of life care for patients with COVID-19 who have dementia and NHS England SOP for children and young people with palliative and end of life care needs, who are cared for in a community setting (home and hospice) during the COVID-19 pandemic. • Type 2 diabetes – canagliflozin renal dosage updated as per updated SPC. • Heart failure – DCHSFT have updated their referral forms (Appendix 4) to replace fax contact details with telephone/email contact details and prompt clinicians to provide further details of referral. • Out of Area Prescribing Requests – reviewed with no significant change. • Prescribing in Primary Care – updated to include information on prescribing considerations for vegan patients; updated information added for when	

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	managed repeat prescriptions should be considered; additional information on EHIC and Brexit; and clarification of prescribing position for unlicensed imports. • Recording medicines prescribed by other Healthcare Professionals – reviewed with no significant change. • Vitamin D PIL – reviewed and updated with no significant change. • BNF Chapter 11 Eye – addition of Murine hayfever relief as the preferred brand for sodium cromoglycate. Guideline Timetable: • The guideline table action summary and progress was noted by JAPC.	
11.	**BIOSIMILAR REPORT**	
	Mr Dhadli reported that the biosimilar report has been tabled for information.	
12.	**JAPC BULLETIN**	
	The August 2020 bulletin was ratified with the agreement that the LHRH section would be removed until this has been agreed and confirmed. A statement has been included under buccal midazolam to remind prescribers of the importance that in order to switch to Buccolam patients and their carers need to be trained and or educated on the new product. Care plans should be updated at their next review with the specialist.	**SQ**
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for August 2020 was noted. Mr Dhadli highlighted the following MHRA advice: • Stimulant laxatives (bisacodyl, senna and sennosides, sodium picosulfate) available over-the-counter: new measures to support safe use. Advise patients that dietary and lifestyle measures should be used first-line for relieving short-term occasional constipation and that stimulant laxatives should only be used if these measures and other laxatives (bulk-forming and osmotic) are ineffective. Children younger than 12 years should not use stimulant laxatives without advice from a prescriber. The Commission on Human Medicines (CHM) has also considered evidence that stimulant laxatives are subject to misuse and overuse. Such cases mostly concern people with eating disorders, although misuse and overuse are likely to be under-reported. • Clozapine and other antipsychotics: monitoring blood concentrations for toxicity. Monitoring blood clozapine levels for toxicity is now advised in certain clinical situations such as when: ○ a patient stops smoking or switches to an e-cigarette ○ concomitant medicines may interact to increase blood clozapine levels ○ a patient has pneumonia or other serious infection ○ poor (reduced) clozapine metabolism is suspected ○ toxicity is suspected. If blood clozapine level monitoring is carried out, this should be in addition to the required blood tests to manage the risk of agranulocytosis. It is recognised that blood level monitoring of these medicines can be beneficial in the care and management of patients, particularly those with treatment-resistant conditions. The MHRA has received two separate reports from Coroners raising concerns regarding the need for monitoring of clozapine	

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	blood levels in one report and monitoring antipsychotic blood levels during long-term high-dose antipsychotic use in the other. • Denosumab 60mg (Prolia): increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment. Evaluate a patient's individual factors for benefits and risks before initiating treatment with denosumab 60mg, particularly in those with previous vertebral fracture. Since 2015 and up to and including June 2020, 44 cases of vertebral fracture, including multiple fractures, have been reported in the UK in post-marketing settings in patients after stopping or delaying ongoing treatment with denosumab (Prolia). Where reported, these fractures occurred within 18 months of stopping or delaying denosumab treatment, with some in the first 9 months. • Baricitinib (Olumiant▼): increased risk of diverticulitis, particularly in patients with risk factors. Use baricitinib with caution in patients with diverticular disease and in those concomitantly treated with medications associated with an increased risk of diverticulitis. A European review has assessed cases of diverticulitis associated with baricitinib reported in clinical trials and in clinical (post-marketing) use worldwide. The risk of diverticulitis has been added to the product information for baricitinib with an uncommon frequency and healthcare professionals are asked to use caution in patients at risk of this condition. • Isotretinoin (Roaccutane▼): reminder of important risks and precautions. Health Care Professionals are reminded that isotretinoin should only be used for severe forms of acne resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy. Isotretinoin is a powerful teratogen associated with a high frequency of severe and life-threatening birth defects if there is exposure in utero; women of childbearing potential must be under a Pregnancy Prevention Programme. Following concerns raised by patients and patient representatives about the nature and severity of some adverse effects, the Commission on Human Medicines (CHM) has endorsed an independent review of the available evidence by the Isotretinoin Expert Working Group. The review aims to examine the available evidence for the possible risks of psychiatric adverse reactions and sexual dysfunction, including whether they can persist for some time after discontinuation, and to advise the CHM whether further action is needed to minimise or to raise awareness of these risks in the UK. • Emollients and risk of severe and fatal burns: new resources available. Healthcare professionals have been informed of the recent campaign to promote awareness of the risk of severe and fatal burns with all emollients and new resources are available to support safe use following previous advice to health and care professionals.	
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: • Adalimumab biosimilar (Idacio, Kromeya) – to remain classified as **RED** • Delafloxacin (Quofenix) – classified as **BLACK** await national guidance or clinician request • Fostamatinib disodium (Tavalisse) – classified as **RED** (as per NHS	

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	England commissioning intentions) New drug formulation launches in the UK: • Insulin lispro (Lyumjev) – classified as **BLACK** 100units/mL, await national guidance or clinician request • Rurioctocog alfa pegol (Adynovi) – classified as **RED** (as per NHS England commissioning intentions) • Turoctocog alfa pegol (Esperoct) – classified as **RED** (as per NHS England commissioning intentions) Licence extensions: • Canagliflozin (Invokana) – previously classified as **BROWN** • Ixekizumab (Taltz) – previously classified as **RED** • Olaparib (Lynparza) – previously classified as **RED** Drug discontinuations: • Adalat LA (Nifedipine) • Amaryl • Ammonaps Granules (Sodium phenylbutyrate) • Aquamol (White soft paraffin/liquid paraffin) • Carbagen (Carbamazepine) • Carbagen Prolonged Release (Carbamazepine) • Fluad (Inactivated influenza vaccine) • HiBiTane Plus (Chlorhexidine gluconate) • Kogenate Bayer (Octocog alfa) • Ondemet (Ondansetron) • Paramax Tablets (Paracetamol/metoclopramide) • Roferon-A (Interferon alfa)	
15.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in August 2020: TA640 Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant – classified as **RED** (NHS England as per NICE TA640) TA641 Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma – classified as **RED** (NHS England as per NICE TA641) TA642 Gilteritinib for treating relapsed or refractory acute myeloid leukaemia – classified as **RED** (NHS England as per NICE TA642) TA643 Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer – classified as **RED** (NHS England as per NICE TA643) TA644 Entrectinib for treating NTRK fusion positive solid tumours – classified as **RED** (NHS England as per NICE TA644)	
16.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
a.	• UHDBFT Drugs and Therapeutics Group 16/06/2020 • Sheffield Area Prescribing Group 18/06/2020 • Chesterfield Drugs and Therapeutics Committee 21/07/2020	

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	The following items were highlighted in the UHDBFT Drugs and Therapeutics Group • Fremanezumab was considered at the June D&T meeting • Request for the addition of clozapine to the UHDBFT formulary for the management of hallucinations & delirium in Parkinson disease patients which is supported by a NICE quality statement The following items were highlighted in the Sheffield Area Prescribing Group minutes: • A COVID-19 virus and medicines page has been added to the Medicine and Prescribing page of the CCG Intranet • SSRIs in Children and Young people Shared Care Protocol • ADHD in children and adults – the management of patients on guanfacine, transitioning from children's to adult services was discussed • Naloxegol – the decision was made to retain as amber and to remove from the red section	
17.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Naloxegol – BROWN specialist initiation and stabilisation for 3 months, in line with NICE TA345 for treating opioid induced constipation Delafloxacin (Quofenix) – BLACK Fostamatinib disodium (Tavalisse) – RED as per NHS England commissioning intentions Insulin lispro (Lyumjev) – BLACK Rurioctocog alfa pegol (Adynovi) – RED as per NHS England commissioning intentions Turoctocog alfa pegol (Esperoct) – RED as per NHS England commissioning intentions Treosulfan with fludarabine – RED NICE TA640: for malignant disease before allogeneic stem cell transplant (NHS England as per NICE TA640) Brentuximab vedotin – RED NICE TA641: in combination for untreated systemic anaplastic large cell lymphoma (NHS England as per NICE TA641) Gilteritinib – RED NICE TA642: for treating relapsed or refractory acute myeloid leukaemia (NHS England as per NICE TA642) Entrectinib – RED NICE TA643: for treating ROS1-positive advanced non-small-cell lung cancer (NHS England as per NICE TA643) Entrectinib – RED NICE TA644: for treating NTRK fusion-positive solid tumours (NHS England as per NICE TA644)	
18.	**ANY OTHER BUSINESS**	
a.	**New measures to support development of safe COVID-19 vaccines for the UK** Mr Dhadli advised that this paper has been tabled to inform JAPC of the recently outlined government measures, to allow the safe future mass rollout of a COVID-19 vaccine should one be proven safe, effective and approved for use. The measures include reinforced safeguards to support the Medicines and Healthcare products Regulatory Agency (MHRA) to grant temporary authorisation for the use of a new COVID-19 vaccine – provided it meets the	

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	highest safety and quality standards, expanding the trained workforce who can administer COVID-19 and flu vaccines to improve access and protect the public, clarifying the scope of the protection from civil liability for the additional workforce that could be allowed to administer vaccinations. The proposals will allow more fully trained healthcare professionals to administer vaccines under NHS and local authority occupational health schemes, as well as enable an expanded workforce that can administer vaccinations to the public. A consultation was launched from 28th August 2020 and measures could come into force by October, ahead of the winter season. If JAPC members have any comments then Mr Dhadli will forward them on to the DDCCG flu cell, which will be co-ordinating a response.	**SD**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 13th October 2020 at 1.30pm to be held virtually via Microsoft Teams.	