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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 9th June 2020

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Omeprazole oral suspension (2mg/ml & 4mg/ml)	BROWN licensed preparation to be used only when dispersible tablets and MUPs have been tried and not tolerated or in cases where doses cannot be safely rounded to the nearest quarter.
Sativex	RED for spasticity in adults with multiple sclerosis as per NICE NG144 (CCG commissioned). THC:CBD (combination of delta-9-tetrahydrocannabinol with cannabidiol - Sativex)
Isocarboxazid	BROWN after specialist initiation for treatment resistant depression
Benzathine benzylpenicillin	BLACK await national guidance or clinician request
Caplacizumab (Cablivi)	RED (as per NHS England commissioning intentions)
Dienogest (Zalkya)	BLACK await national guidance or clinician request
Polatuzumab vedotin (Polivy)	RED (as per NHS England commissioning intentions)
Romosozumab (Evenity)	BLACK await national guidance or clinician request
Brolucizumab (Beovu)	BLACK await national guidance or clinician request
Siponimod (Mayzent)	RED (as per NHS England commissioning intentions)
Recombinant human parathyroid hormone	BLACK – terminated appraisal as per NICE TA625
Lenalidomide with rituximab	RED (NHS England as per NICE TA627)
Lorlatinib	RED (NHS England as per NICE TA628)
Obinutuzumab with bendamustine	RED (NHS England as per NICE TA629)
Larotrectinib	RED (NHS England as per NICE TA630)
Fremanezumab	RED (as per NICE TA631)

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Ulipristal Acetate (Esmya)	BLACK MHRA (March 2020) licence suspension due to risk of serious liver injury
Beclometasone inhaler (Soprobec)	GREEN to be prescribed by brand
Desogestrel	GREEN: cost effective to prescribe generically BLACK: brands above £5 e.g. Cerazette
Co-careldopa	GREEN: cost effective to prescribe generically BLACK: Not to be prescribed by brand e.g. Sinemet for new patients
Sildenafil	Removed ‘unclassified’ powder for oral suspension 10mg/ml Added formulation 10mg/ml oral suspension (Revatio) to RED Removed BROWN chewable tablet as discontinued

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Clinical Guidelines

The management of emergency rescue medication (buccal/oro-mucosal midazolam) for children, young people and adults with prolonged or repeated generalised, convulsive (tonic–clonic, tonic or clonic) seizures in the community

Present:	
Derby and Derbyshire CCG	
Dr C Emslie	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)
Mr S Hulme	Director of Medicines Management and Clinical Policies
Mrs K Needham	Assistant Director of Medicine Optimisation and Delivery
Mrs S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Dr H Hill	GP Prescribing Lead
Dr R Gooch	GP
Ms N Bridge	Deputy Chief Finance Officer
Ms A Reddish	Clinical Quality Manager – Primary Care
Ms S Taylor	Deputy Medical Director
Ms A Cargill	Assistant Director of Quality
Derby City Council	
Derbyshire County Council	
University Hospitals of Derby and Burton NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr D Moore	Lead Pharmacist Commissioning & High Cost Medication
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Chief Pharmacist
Derby and Derbyshire Local Medical Committee	
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 K Rogers	Derby and Derbyshire CCG Senior Administrator (minutes)

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Item		Action
1.	**APOLOGIES**	
	Ms J Derricott, Ms J Savoury, Ms A Brailey, Dr S Lloyd	
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. Mr Dhadli stated that an Annual Declaration of Interest form would be circulated to JAPC members for completion.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	There were no declarations of any other business.	
4.	**MINUTES OF JAPC MEETING HELD ON 10 MARCH 2020**	
	The minutes of the meeting held on 10th March 2020 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**JAPC interim Terms of Reference (ToR)** Mr Dhadli reported that due to the current COVID-19 pandemic an interim JAPC Terms of Reference has been devised to ensure that there is continuity of JAPC meetings during these extraordinary times. The interim arrangements involve the running of JAPC on a reduced model. The document highlights that JAPC meetings are to be held virtually, ideally through Microsoft Teams where face-to-face meetings are not possible and the frequency of JAPC meetings are to be reduced to three monthly. Only guidelines/papers requiring a minor change that are non-controversial and requires minimal/no clinician engagement to be tabled into the agenda and minimum core membership for JAPC meetings to be quorate has been reduced. JAPC approved governance/operational papers requiring ratification are to be submitted to an executive level ratifying decision making group and JAPC approved clinical guidelines/papers requiring ratification are to be submitted to the Clinical Cell Committee for ratification.	
b.	**Clinical Cell Terms of Reference (ToR)** Mr Dhadli stated that the NHS Derby and Derbyshire CCG (DDCCG) Clinical Cell, operating virtually consists of a small team of CCG members and has been established to provide a rapid review and decision making process in relation to clinical guidelines, policy and procedures during the exceptional circumstances of COVID-19. The Clinical Cell's primary focus is on maintaining safety in terms of the decisions made and informing the Executive Team of those decisions and rationales. The team looks at all new and revised clinical and medicines policies, procedures and guidelines received by NHS Derby and Derbyshire CCG (DDCCG).	

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Item		Action
	The Clinical Cell meeting takes place on a weekly basis or as and when needed and the team consists of the following staff members: Dr S Lloyd Clinical Cell Lead/Medical Director, Mr S Hulme Director of Medicines Management, Clinical Policies and Pharmacy, Ms S Taylor Deputy Medical Director, Mr S Dhadli Assistant Director of Medicines Management, Clinical Policies and Pharmacy, Ms A Cargill Assistant Director of Quality and Dr K Bagshaw Deputy Medical Director and Clinical Director of Strategic Clinical Conditions and Pathways. The document also details further information about the role and purpose of the Clinical Cell, how each meeting shall be recorded and how it reports further within NHS DDCCG.	
c.	**<u>Clinical Cell delegated responsibilities</u>** Mr Dhadli discussed how the decision had been taken to delegate some of the duties down that JAPC would usually do; he then referred to paper 5c which outlines the details of this in a summary table. Ms Bridge stated that she was in support of the Clinical Cell which would help to enable a quick turnaround time for decisions; however Ms Bridge queried how often the Clinical Cell Terms of Reference along with the JAPC interim Terms of Reference would be reviewed and updated, to ensure they remain relevant amidst the changing business continuity levels within DDCCG. Mr Dhadli responded to say that he is actively reviewing the JAPC interim Terms of Reference and the original Terms of Reference are detailed beneath the interim section. Mr Dhadli explained that the Clinical Cell will need to run alongside JAPC for a period of time and the Terms of Reference will be updated in due course when reporting procedural change within DDCCG. Ms Bridge advised that the Clinical and Lay Commissioning Committee (CLCC) was to restart this week, Mr Dhadli noted this and informed members that the Terms of Reference were a correct reflection at that moment in time, however they will be under continuous review. Ms Braithwaite informed the committee that Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) will be re-starting their meetings on a monthly basis and questioned whether JAPC meetings could look to do the same. Mr Dhadli responded to say that consideration has gone into whether GP's/clinicians would have the capacity for monthly meetings during the pandemic and also whether they would be able to offer clinical engagement to help support guidelines and implementation. He then went on to say that the clinical guidelines looked at by Clinical Cell members were extended by 6 months based on safety and whether they are still clinically effective. Mr Hulme added that some of the Medicines Management team are currently involved in work which is supporting the CCG in its response to the COVID-19 pandemic; therefore he felt that JAPC could potentially re-start monthly meetings, however with a more streamlined agenda to ensure that there is capacity for team members to engage in the outcomes from the meetings. Dr Goddard expressed concern in regards to clinical guidelines that may go through the Clinical Cell meeting where a decision would affect the trusts. He asked that in this scenario the trusts be consulted with before a final decision is made. Mr Dhadli responded to say that he is mindful of this and any decisions made through Clinical Cell have so far been in regards to minor things that are not controversial and these were evidence in the output	

Item		Action
	reporting of the Clinical Cell. Dr Hill advised that General Practice is still very busy and therefore she may not have the capacity for JAPC meetings on a monthly basis. Mr Dhadli suggested that feedback be collated on the availability of JAPC members so that a decision can be made around the frequency of these meetings. A short survey would be produced and emailed out.	**SD**
6.	**JAPC ACTION SUMMARY**	
a.	**Continence guidance** Mr Dhadli confirmed that the Continence guidance was listed as Ms H Greaves Lead Clinical Nurse was in the process of planning a meeting with the continence team at UHDBFT, as the continence nurses are not complying with some of the formulary choices. This has now been put on hold due to the COVID-19 pandemic.	
b.	**Dapagliflozin and insulin/Sotagliflozin and insulin** Mr Dhadli advised that the dapagliflozin and sotagliflozin has also been put on hold due to the COVID-19 pandemic.	
c.	**Theoloz Duo** Mr Dhadli advised that he is awaiting feedback from the ophthalmologists at Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) in regards to Theoloz Duo and its place alongside formulary products.	
d.	**RMOC shared care agreement** Mr Dhadli reported that Appendix 1 in the RMOC shared care guidance states that primary care prescribers should reply to specialist colleagues by letter within 14 days so that arrangements can be made for the ongoing provision of prescriptions and monitoring arrangements under shared care. As the Derbyshire local shared care guidelines don't currently have any time restrictions JAPC members were asked if they wished to adopt a 14 day response. Ms Derricott advised that she would ask the Enhanced Services Review group if they felt a timeframe would be beneficial for Drugs affecting the Immune Response (DMARDS) and shared care drugs agreements. A response has not yet been received.	
e.	**Cannabis based medicine** Mr Dhadli advised that the cannabis based medicine paper is on the agenda.	
7.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Omeprazole** Mr Dhadli stated that the local GORD in children guideline recommends using omeprazole dispersible tablets. This is off-label for children under 1 year old. Unlicensed omeprazole 10mg/5ml and 20mg/5ml oral suspension listed in drug tariff part VIIIB special products have now been removed. In regards to alternatives that could be used there is a new licensed preparation now available. It has a more accurate dosage, it is licensed for children over 1 month of age, once reconstituted it is easy for a patient/carer to use and it is suitable for NG/PEG administration. However, it requires	

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Item		Action
	reconstitution, has a 28 day expiry once reconstituted and it is expensive. It was sent out for consultation to Mr M Shepherd head of Medicines Management CRHFT, consultant paediatricians at UHDBFT and CRHFT and the Derbyshire Medicines Management Shared Care and Guideline Group (MMSCGG). The MMSCGG have produced a summary of the financial implications of using 10mg dispensable tablets (MUPs), 20mg dispensable tablets (MUPs), the licenced preparations and the unlicensed oral suspension. A cost effective analysis was done and there is a cost pressure. Based on current usage there is an estimate that there would be a 347% rise in potential cost. The recommendation is to only use if omeprazole dispersible tablets have been tried and not tolerated or in cases where doses cannot be safely rounded to the nearest quarter dispersible tablet. Mrs Needham asked if a message can be added to review the ongoing need when it is used, as when children get older there may be alternative options available. Mr Dhadli advised that this will be added with a partial update to the Gastro-Oesophageal Reflux Disease (GORD) in children & young people guideline; it will then be taken to the MMSCGG meeting in June. **Agreed:** Oral suspension (2mg/ml & 4mg/ml) classified as **BROWN**. To be used only when dispersible tablets and MUPs have been tried and not tolerated or in cases where doses cannot be safely rounded to the nearest quarter.	**SD** **SD**
b.	**<u>Sativex</u>** Mr Dhadli referred to the JAPC meeting in January 2020 where members discussed Cannabis for spasticity and agreed that further information is needed in regards to scoping when Sativex would be used, what treatments would be used prior to this and the number of existing and projected patient numbers. UHDBFT agreed to produce a clinical guideline similar to other trusts. Chesterfield confirmed that they would not be using this. UHDBFT's guideline follows NICE recommendation NG144 'recommended treatment Sativex (THC:CBD) for Multiple Sclerosis (MS) patients with spasticity'. The clinical guideline looks at when to offer treatment with sativex, following other treatment options first. NICE guidance states Sativex to be offered as a 4-week trial for moderate to severe spasticity in adults with MS, if other pharmacological treatments are not effective and the company provides Sativex® according to its pay-for-responders scheme. It advises that after the 4-week trial, Sativex® can be continued if the patient has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale (NRS). There is also mention of some pharmalogical treatments, initial monitoring, monitoring during treatment and follow up. It advises a Specialist Nurse-led follow-up at 4 weeks followed by 3 monthly intervals for the next 1 year and thereafter annual Consultant-led review appointments. The recommendation is to re-classify Sativex from BLACK to RED. Mr Moore added that there will be no drug monitoring for Sativex, however there is the potential for abuse/misuse which should be closely observed. Initial prescribing would be under secondary care and they would oversee how patients progress during their treatment. Dr Goddard queried why the recommendation was to classify Sativex as RED.	

Item		Action
	Mr Dhadli advised that secondary care clinicians could gain experience of use in this cohort of patients; they can then share their experience with primary care if the disease monitoring were to be transferred to them. Dr Goddard asked what period of assessment was being envisaged, Mr Dhadli felt that the trust would need to be able to give assurance that the patient is stable, noting also its high discontinuation rates, and they would need to bring a case back to JAPC of when they felt this most appropriate. Dr Markus commented that if the prescribing is eventually transferred to primary care there will need to be an assessment of the effectiveness of the drug periodically. Dr Markus asked if this would take place in a secondary care clinic, as there would be a cost attached to the monitoring of this in primary care. Mr Moore advised that if patients were still stable after the first year of follow up appointments, they would then receive an annual Consultant-led review appointment. Dr Goddard stated that Sativex could still be prescribed in primary care even though review appointments would be carried out in secondary care. **Agreed:** JAPC classified Sativex as **RED for spasticity in adults with multiple sclerosis (CCG commissioned). THC:CBD (combination of delta-9-tetrahydrocannabinol with cannabidiol - Sativex).** The JAPC committee will review this in 12 months time.	**SD** **SD**
8.	**CLINICAL GUIDELINES**	
a.	**Midazolam** Mr Dhadli reported that this is for the management of emergency rescue medication (buccal/oro-mucosal midazolam) for children, young people and adults with prolonged or repeated generalised, convulsive (tonic–clonic, tonic or clonic) seizures in the community. The guideline was last updated in May 2018 and was sent to consultees with feedback received in February 2020. Ms R Wheway Children's Epilepsy Nurse Derbyshire Children's Hospital confirmed that the guideline is relevant and up to date. Mr Dhadli advised that the guidance was updated with minor amendments replacing the Joint Epilepsy Council (JEC) sample management plan with a document published in 2019, by the Epilepsy Specialist Nurse Association (ESNA) in conjunction with International League Against Epilepsy (ILEA) and Royal College of Psychiatry. There is also a key contact change for learning disabilities as Marie Hooper will replace Gaynor Ward from May 2020. Dr Markus referred to a paragraph in the guideline which made reference to buccal midazolam being initiated in primary care and asked whether this was correct, as it is usually initiated by secondary care. Mr Dhadli confirmed that he will remove this paragraph as it is not in the context of what this guideline was produced for. Mr Shepherd asked if this guideline has been seen by the epilepsy team within CRHFT. Mr Dhadli responded to say that Ms A Holmes has had sight of the document; however it was earlier in the year. **Agreed:** JAPC ratified the management of emergency rescue medication (buccal/oro-mucosal midazolam) for children, young people and adults with prolonged or repeated generalised, convulsive (tonic–clonic, tonic or clonic) seizures in the community guideline, with a review date of 3 years.	**SD**

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Item		Action
9.	**CLINICAL CELL OUTPUTS**	
a.	**Summary of amendments from Clinical Cell** Mr Dhadli shared the key decisions that have been ratified through the Clinical Cell: • Colestipol – BROWN after gastroenterology consultant initiation and assessment for chronic diarrhoea secondary to bile salt malabsorption. See position statement. • Chenodoxycholic acid – RED NHSE commissioned • Ranitidine – BROWN (CHMP recommends suspension of ranitidine in the EU due to the presence of low levels of an impurity NDMA) (Children GORD guideline to be updated) • Cyancobalamin – Cyanocobalamin has been relaxed to BROWN during the COVID-19 period to allow prescribing in accordance to the vitamin B12 guidance. Continue hydroxocobalamin IM injection if possible, where this is not possible, delaying the next injection by 3-6 months can be considered. When giving or delaying are not viable options, then cyanocobalamin 1000 microgram daily (unlicensed) can either be prescribed or the patient can purchase over the counter. • Recombinant human parathyroid hormone – BLACK as per NICE TA625 • Lenalidomide – RED as per NICE TA627 Mr Dhadli informed the committee that a COVID-19 section has been set up on the Derbyshire Medicines Management website, he referred to a list of NICE guidelines and NICE rapid review guidelines that are primary care focused and have been uploaded to the website. Clinical guidelines that have been reviewed and updated include: • ACEi/ARB. BSH and BCS Joint Statement – 'no evidence to support the assertion that treatment with ACEi or ARB could predispose individuals to adverse outcomes • Anticoagulation – Warfarin. Clinical guide for the management of anticoagulant services during the coronavirus pandemic including advice for switching warfarin to NOACs during the coronavirus pandemic. Locally edoxaban is the preferred NOAC. • Alternative inhalers due to shortage – local guidance. Information on switching to alternative steroid containing inhalers. • DMARD monitoring – SPS guidance on the management of drugs requiring monitoring which includes specific advice on DMARD (azathioprine, leflunomide, mercaptopurine, methotrexate, sulfasalazine, ciclosporin and penicillamine). • Psychotropics – management of psychotropics (lithium) during COVID-19 pandemic from Derbyshire Healthcare NHS Foundation Trust. • Vitamin B12 injections in primary care – local guidance for primary care during COVID-19. • Derbyshire Wound Care formulary - Eclipse dressing has been swapped to C-sorb – Eclipse dressing has been de-listed from the relevant wound care supply tower. An alternative to this product has been identified by NHS Supplies which are effective for use under compression therapy - C-Sorb. • FSRH contraceptive advice – to support provision of effective contraception during the COVID-19 outbreak. A summary document has been produced	

Item		Action
	and uploaded to Derbyshire Medicines Management COVID-19 website page. • Drugs for the management of dental problems – patients should be encouraged to manage their symptoms at home where possible as treatment options are severely restricted at this time. Mild and moderate dental symptoms should be managed remotely by providing advice and analgesics and/or antimicrobials where necessary. Mr Dhadli then referred to a list of guidelines in paper 11a, where their expiry date was approaching. They have been out for consultation and where consensus was received across both UHDBFT and CRHFT the guidelines have been extended by 6 months. Dr Goddard asked if H2 antagonists have been discussed. Mr Dhadli advised that there has been a new Committee for Medicinal Products for Human Use (CHMP) released however they have only made recommendations. Mr Dhadli is also aware that there is a supply issue with all H2 antagonists so he advised that if a patient is on ranitidine they are recommended to go onto a PPI, if they cannot go onto a PPI then other cost effective H2 antagonists must be considered.	
10.	**MISCELLANEOUS**	
a.	**Direct Oral Anticoagulants (DOACs)** Mr Dhadli reported that NHS England and NHS Improvement (NHSE/NHSI) have sent a letter to CCG pharmacy leads detailing arrangements for the prescribing and positioning of two DOACs (rivaroxaban/apixaban) during the COVID-19 pandemic. To help protect patients and staff during the COVID-19 pandemic the Clinical guide for the management of anticoagulant services during the coronavirus pandemic advises moving patients from warfarin to a DOAC, where clinically appropriate. This is to reduce the need to visit anticoagulant hubs and to reduce demand on nursing staff to carry out international normalised ratio (INR) monitoring. This applies only to patients in England switched from warfarin to apixaban or rivaroxaban between 1st May 2020 and 31st December 2020. The first line choice for a Novel Oral Anticoagulant (NOAC) in Derbyshire is currently edoxaban; Derbyshire has a local arrangement in place for an edoxaban rebate. The NHSE/NHSI letter advises that they have secured a discounted price which is cheaper than what CCG's may already have in place. This takes effect from 1st April 2020 to the 31st July 2020; however it may be appropriate to extend the date. Mr Dhadli advised that JAPC members review the recommendations within this letter and consider whether to follow this advice or whether to continue with the current Derbyshire arrangements. Within primary care, patients with non-valvular atrial fibrillation are often prescribed edoxaban where clinically appropriate, therefore a lot of Derbyshire patients have already been taken off warfarin, or they have been assessed, with the outcome that it would not be appropriate for them to switch. Mr Dhadli presented a draft position statement and asked for comments from the committee. Mr Hulme advised that DDCCG has assurance of the long term costs of edoxaban, however it is not known what the long term costs will be for apixaban or rivaroxaban. DDCCG has also	

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Item		Action
	received confirmation that NOACS will be part of NHSE/NHSI reimbursement costs due to COVID-19. Ms Bridge stated that finance are currently capturing COVID-19 expenditure on a monthly basis, which must be evidenced for the reimbursement to take place. Ms Bridge asked if the information can be captured when patients are switched from warfarin to a NOAC. Mrs Needham advised that the increase in prescribing can be captured however the switching cannot. Ms Bridge confirmed that an increase in prescribing due to COVID-19 seemed a reasonable way to evidence this; however she would need to look at this further. Mr Dhadli added that there is also a clinical risk of advising the use of another NOAC that is less familiar. A discussion took place and members of the committee were in agreement that edoxaban should remain Derbyshire's first line choice for patients switching to a NOAC. Mr Dhadli would circulate the draft position statement to JAPC members and asked that they review this and comment on it as a priority so that it can be agreed and communicated to primary care.	**SD**
b.	**<u>Medicines for treatment resistant depression</u>** Mr Jones advised that Derbyshire Healthcare NHS Foundation Trust (DHcFT) are experiencing difficulty with accessing treatments for patients who have treatment resistant depression. There are ongoing supply issues with moclobemide and phenelzine. The UK has been experiencing unavailability of phenelzine stock since July 2019 and there is currently no end date for this. In a number of cases community pharmacists have been able to support patients by sourcing unlicensed imports, and where there have been difficulties DHcFT has stepped in to provide prescriptions and supplies in the short term. The current plan is for DHcFT to continue to do so, with anticipation that if the supply situation worsens the initial effect will be a greater pressure on DHcFT and this might ultimately lead to a need to review and switch patients if no supply can be obtained at all. If patients need to be switched to another MAOI, isocarboxazid would be the preferred option as it is the most similar to phenelzine. Isocarboxazid is currently classified as BLACK in Derbyshire, so a review of this would need to be considered by JAPC members. Mr Dhadli advised that due to the current import costs of phenelzine, isocarboxazid would be more cost effective to use, even though it appears more expensive in the drug tariff. JAPC members were in support of re-classifying isocarboxazid as an alternative to phenelzine. Mrs Needham asked whether isocarboxazid is readily available in community pharmacies or if there will be difficulties in obtaining this. Mr Jones advised that it does have more than one manufacturer in the UK and the wholesalers currently have stock, there is also some national use of this drug. Ms Taylor advised that there would need to be a proactive approach to identify patients who are currently taking phenelzine in primary care, this would help to minimise a delay in switching them onto isocarboxazid if phenelzine were to become unavailable. Mrs Needham offered for the DDCCG Medicines Management Team to run a report that could identify the number of patients taking phenelzine and this would also show whether they are under primary or secondary care, the findings will be reviewed at a future Derbyshire Prescribing meeting.	**KN**

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Item		Action
	Agreed: JAPC classified Isocarboxazid as **BROWN after specialist initiation as an alternative to phenelzine in treatment resistant depression.**	**SD**
c.	**End of life anticipatory medicine** Mr Dhadli advised that the end of life anticipatory medicines has been tabled at the JAPC meeting to note what arrangements are in place across Derbyshire. It was written and produced by Ms T Omorinoye Head of Medicines Management Safety & Quality, who has been in consultation with Ms J Buxton Derbyshire LPC representative and Mr D Graham Lead Clinical Pharmacist at DHU Healthcare. JAPC members noted this information.	
11.	**JAPC BULLETIN**	
	The March 2020 bulletin was agreed and noted for information.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for March 2020, April 2020 and May 2020 were noted. Mr Dhadli highlighted the following MHRA advice: **March 2020** • Esmya (ulipristal acetate) for uterine fibroids: suspension of the licence due to risk of serious liver injury. The emergency contraceptive ellaOne also contains ulipristal acetate (single dose, 30mg). There are no concerns with this medicine at this time. Mrs Needham confirmed that a search for prescribing of Esmya in primary care has been carried out and where there was prescribing of this, it was investigated, stopped and an alternative treatment option was discussed with the patient. The MMSCGG also ensured that Esmya traffic light classification was changed to BLACK. • Tofacitinib (Xeljanz▼): new measures to minimise risk of venous thromboembolism and of serious and fatal infections. Tofacitinib is associated with a dose-dependent increased risk of serious venous thromboembolism. It is recommended not to exceed the recommended dose of 5mg twice-daily (or 11mg prolonged-release once-daily) for rheumatoid arthritis or 5mg twice-daily for psoriatic arthritis in any patients. In patients with ulcerative colitis who have known risk factors for venous thromboembolism in addition to the underlying disease, use of 10mg twice-daily tofacitinib for maintenance treatment is not recommended unless no suitable alternative treatment is available. • Baricitinib (Olumiant▼): risk of venous thromboembolism Discontinue baricitinib treatment permanently if clinical features of deep vein thrombosis or pulmonary embolism occur. • SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness. SGLT2 inhibitor treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses and ketone levels measured, preferably in blood rather than urine. Treatment may be restarted when the ketone values are normal and the patient's condition has stabilised.	

Item		Action
	• Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression **April 2020** • Coronavirus (COVID-19): latest guidance for medicines safety MHRA are prioritising work including: ○ Supporting and authorising the development of vaccines ○ Clinical trials of medicines ○ Managing the supply of medicines and healthcare products • Ibuprofen and NSAIDs The Expert Working Group has advised there is currently insufficient evidence to establish a link between use of ibuprofen, or other non-steroidal anti-inflammatory drugs (NSAIDs), and susceptibility to contracting COVID-19 or the worsening of its symptoms. • Antihypertensives MHRA have advised there is no evidence from clinical or epidemiological studies to support the concern that treatment with angiotensin-converting-enzyme inhibitors (ACE inhibitors or ACE-i) or angiotensin-receptor blockers (ARBs) might worsen COVID-19 infection. • Chloroquine and hydroxychloroquine MHRA have also issued guidance on chloroquine and hydroxychloroquine (see MHRA statement, 25 March 2020). Clinical trials are ongoing to test chloroquine and hydroxychloroquine in the treatment of COVID-19 or to prevent COVID-19 infection. **May 2020** • Coronavirus (COVID-19): new dedicated Yellow Card reporting site for medicines and medical devices. Reporting to the new site will enable the MHRA to rapidly identify new and emerging side effects and medical device incidents in COVID-19 treatment, including side effects for medicines taken by patients to manage long-term or pre-existing conditions. • Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus (COVID-19) Guidance has been published to support initiation of valproate in female patients and for annual review and pregnancy testing during the coronavirus pandemic. • Immunomodulatory drugs and pregnancy prevention: temporary advice for management during coronavirus (COVID-19) To enable the shielding of patients who are receiving these medicines during the coronavirus (COVID-19) pandemic, the manufacturer (Celgene) has issued a letter to healthcare professionals informing them of temporary modifications to the pregnancy prevention programmes to facilitate remote consultations, where clinically appropriate.	
13.	**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/formulation launches in the UK: **February 2020**	

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Item		Action
	• Benzathine benzylpenicillin – classified as BLACK await national guidance or clinician request • Caplacizumab (Cablivi) – classified as RED (as per NHS England commissioning intentions) • Cerliponase alfa (Brineura) – to remain classified as RED (as per NHS England commissioning intentions) • Dienogest (Zalkya) – classified as BLACK await national guidance or clinician request • Voretigene neparvovec (Luxturna) – to remain classified as RED (as per NHS England commissioning intentions) • Exenatide (Bydureon BCise) – to remain classified as BROWN 'by exceptionally defined as intolerance to the preferred 1st line choice or restricted by their licensing' • Tofacitinib (Xeljanz XR) – to remain classified as RED (as per NHS England commissioning intentions) **March 2020** • Polatuzumab vedotin (Polivy) – classified as RED (as per NHS England commissioning intentions) • Romosozumab (Evenity) – classified as BLACK await national guidance or clinician request • Hydroxycarbamide (Xromi) – to remain classified as RED • Infliximab biosimilar (Remsima SC) – to remain classified as RED **April 2020** • Brolucizumab (Beovu) – classified as BLACK await national guidance or clinician request • Siponimod (Mayzent) – classified as RED (as per NHS England commissioning intentions) • Estradiol (Lenzetto) – to remain classified as GREEN Licence extensions/changes: **February 2020** • Bedaquiline (Sirturo) – previously classified as RED • Botulinum A toxin (Dysport) – previously classified as RED • Dulaglutide (Trulicity) – previously classified as BROWN • Fidaxomicin (Dificlir) – previously classified as BROWN after consultant microbiologist recommendation • Ramucirumab (Cyramza) – previously classified as BLACK • Somatropin (Norditropin) – previously classified as AMBER **March 2020** • Aminolevulinic acid hydrochloride (Ameluz) – previously classified as RED • Cobicistat (Tybost) – no current traffic light classification • Darunavir + cobicistat (Rezolsta) – previously classified as RED • Rituximab (MabThera) – previously classified as RED • Venetoclax (Venclyxto) – previously classified as RED **April 2020** • Apremilast (Otezla) – previously classified as RED • Brigatinib (Alunbrig) – previously classified as RED • Carbetocin (Pabal) – previously classified as RED • Nintedanib (Ofev) – previously classified as RED	

Item		Action
	• Tocilizumab (RoActemra) – previously classified as RED	
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in March, April and May 2020: **March 2020** TA625 Recombinant human parathyroid hormone for treating hypoparathyroidism (terminated appraisal) – classified as **BLACK** (as per NICE TA625) TA464 (updated July 19) Bisphosphonates for treating osteoporosis - Osteoporosis guideline updated to replace 1% 10 year fracture risk threshold with 'high risk' as indicated by validated risk assessment tool, as per re-issued TA. NG158 Venous thromboembolic diseases: diagnosis, management and thrombophilia testing – There are some new recommendations in this guidance. Suspended until business level 2 resumes - to be discussed through MMSCGG then for JAPC decision. **April 2020** TA627 Lenalidomide with rituximab for previously treated follicular lymphoma – classified as **RED** (NHS England as per NICE TA627) **May 2020** TA628 Lorlatinib for previously treated ALK-positive advanced non-small-cell lung cancer – classified as **RED** (NHS England as per NICE TA628) TA629 Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab – classified as **RED** (NHS England as per NICE TA629) TA630 Larotrectinib for treating NTRK fusion-positive solid tumours – classified as **RED** (NHS England as per NICE TA630) TA631 Fremanezumab for preventing migraine – reclassified from BLACK to **RED** (as per NICE TA631)	
15.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in March 2020 and May 2020 were noted. Mr Dhadli highlighted the following: **Traffic Lights:** • Ulipristal Acetate (Esmya) – classified as BLACK MHRA (March 2020) licence suspension due to risk of serious liver injury • Beclometasone inhaler(Soprobec) – classified as GREEN. Prescribe by brand. Soprobec MDI: 50, 100, 200, 250 micrograms (standard particles) • Desogestrel – classified as GREEN: cost effective to prescribe generically	

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Item		Action
	BLACK: brands above £5 e.g. Cerazette • Co-careldopa (Sinemet) – classified as GREEN: cost effective to prescribe generically BLACK: Not to be prescribed by brand e.g. Sinemet for new patients • Sildenafil – removed 'unclassified' powder for oral suspension 10mg/ml Added formulation 10mg/ml oral suspension (Revatio) to RED Removed BROWN chewable tablet as discontinued **Formulary Update:** **Chapter 4 – Central Nervous System** • Inserted JAPC advice on non-cancer pain – patients receiving opioid doses of >50mg/day morphine equivalent should be reviewed at least annually. Clinicians may seek specialist advice for doses >90mg/day morphine equivalent. • Removed domperidone suppository as no longer commonly used. • Inserted MHRA March 2020 drug safety update: Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression. **Chapter 6 – Endocrine** • GlucoRx Carepoint and GlucoRx Carepoint Ultra are the formulary choice of insulin pen needles. If this is unsuitable consider other brands costing less than £5 per 100 needles as per NHSE guidance (previous threshold £6 per 100 needles). • If safety needles are indicated, GlucoRx Safety Pen Needle is the preferred brand. • Insuman Comb 15 removed as product discontinued. **Clinical Guidelines:** **March 2020** <u>Full review:</u> • Adult asthma guideline and children asthma guideline updated with no major change. Inhaler costs have been updated and a message added to promote DPI over MDI for environmental benefit. • Domperidone off-licence use position statement updated to include latest MHRA advice. • Metoclopramide use in gastro-paresis updated with no change. <u>Minor update:</u> • Chlamydia guideline – 'treatment is free from specialist STI service and on FP10s endorsed with 'FS' against the item - see Drug tariff part XVI for further information.' Previously states 'Treatment is free in Specialist STI service but not in Primary Care' • Liothyronine SCA – under consultant responsibility point 6: updated wording 'for established patients agree a follow up schedule'. Previously 'for established patients plan a routine'. • Over Active Bladder guideline – Drug costs updated as per QIPP group/OMOG request. Solifenacin price further reduced and is now cheapest 3rd line treatment. **May 2020** • Emollient guideline – Isomol gel renamed Epimax isomol gel. • Dry eye prescribing guideline – VitA-POS renamed Hylo Night.	

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Item		Action
	Website Changes/Miscellaneous: **March 2020** • COVID-19 section has been added to Derbyshire Medicines Management website to include relevant links to national guidance and local advice. • MHRA drug safety March 2020: SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness. Advice included in BNF endocrine chapter and T2DM guideline. **May 2020** • Social care & care home guidelines section on the Derbyshire Medicines Management website updated. o 'Confirmation of medication direction' removed o Link to NICE guideline managing medicines for adults receiving social care in the community added o Link to NICE guideline managing medicines in care homes added o Link to RMOC homely remedies guidance added o Link to CQC reporting medicine related incidences Care Homes and Social Care added. • Respiratory resources – Asthma Step down guide updated as per asthma guideline • Respiratory resources – Common respiratory inhalers document updated to include all formulary inhalers and picture	
16.	**BIOSIMILAR REPORT**	
	Mr Dhadli stated that the High Cost Drugs group is a sub group of the Derbyshire JAPC. During the COVID-19 pandemic a block contract has been introduced from April 2020 to July 2020. DDCCG are asking for monthly updates about how that budget is being managed.	
17.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Omeprazole oral suspension (2mg/ml & 4mg/ml) – BROWN. To be used only when dispersible tablets and MUPs have been tried and not tolerated or in cases where doses cannot be safely rounded to the nearest quarter. Sativex – RED for Spasticity in adults with multiple sclerosis (CCG commissioned). THC:CBD (combination of delta-9-tetrahydrocannabinol with cannabidiol - Sativex) Isocarboxazid – BROWN after specialist initiation Desogestrel – GREEN: cost effective to prescribe generically BLACK: brands above £5 e.g. Cerazette Benzathine benzylpenicillin – BLACK await national guidance or clinician request Caplacizumab (Cablivi) – RED (as per NHS England commissioning intentions) Dienogest (Zalkya) – BLACK await national guidance or clinician request Polatuzumab vedotin (Polivy) – RED (as per NHS England commissioning intentions) Romosozumab (Evenity) – BLACK await national guidance or clinician request Brolucizumab (Beovu) – BLACK await national guidance or clinician request	

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Item		Action
	Siponimod (Mayzent) – RED (as per NHS England commissioning intentions) Recombinant human parathyroid hormone – BLACK (as per NICE TA625) Lenalidomide with rituximab – RED (NHS England as per NICE TA627) Lorlatinib – RED (NHS England as per NICE TA628) Obinutuzumab with bendamustine – RED (NHS England as per NICE TA629) Larotrectinib – RED (NHS England as per NICE TA630) Fremanezumab – RED (as per NICE TA631)	
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Sheffield Area Prescribing Group 16/01/2020 • UHDBFT Drugs and Therapeutics Group 18/02/2020 • Medicines Optimisation Safety Team 06/02/2020	
19.	**ANY OTHER BUSINESS**	
	Mr Dhadli advised that it would be useful to get feedback from JAPC members in regards to how well they feel the virtual meeting has gone. A survey will be circulated to members of the group to ask for their feedback on regularity of JAPC meetings and how they are conducted virtually.	**SD**
20.	**DATE OF NEXT MEETING**	
	Tuesday, 14th July 2020 at 1.30pm to be held virtually via Microsoft Teams.	