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#### **DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)**

### Minutes of the meeting held on 10 April 2018

# **CONFIRMED MINUTES**

#### **Summary Points**

# **Traffic lights**

Drug	Decision
Trimovate	BLACK
(clobetasone/nystatin/oxytetracycline)	
Cyanocobalamin	BLACK for Vitamin B12 deficiency
Opicapone	BROWN specialist initiation and stabilisation
	2nd line option to entacapone if intolerant or not
	tolerated
Ocrelizumab (Ocrevus®)	BLACK
Tivozanib (Fotivda®)	RED
Dexamethasone (Neofordex®)	RED
Maraviroc (Celsentri®)	RED as per NHS England commissioning
	intentions
Pertuzumab with trastuzumab and	RED (NHS England as per NICE TA 509)
docetaxel	
Daratumumab monotherapy	RED (NHS England as per NICE TA 510)
Brodalumab	RED (as per NICE TA 511)
Tivozanib	RED (NHS England as per NICE TA 512)
Obinutuzumab	RED (NHS England as per NICE TA 513)
Regorafenib	BLACK (NHS England as per NICE TA 514)
Eribulin	BLACK (NHS England as per NICE TA 515)
Cabozantinib	RED (NHS England as per NICE TA 516)

#### **Clinical Guidelines**

Position statement on domperidone metoclopramide prescribing Midodrine in the treatment of orthostatic hypertension

Present:	
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Southern Derbyshire C	CG
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Professional Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management (also representing Erewash CCG)
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
N 4 5 1 11 000	
North Derbyshire CCG	Lon
Dr C Emslie	GP
Mrs K Needham	Assistant Chief Quality Officer (Medicines Management) (also representing all four Derbyshire CCGs)
Hardwick CCG	
Dr T Parkin	GP
Di i i dikili	
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Dr R Dewis	Consultant in Public Health Medicine
Derbyshire County Cou	ıncil
Delbysilie County Cot	
Derby Teaching Hospit	als NHS Foundation Trust
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr D Moore	HCD Pharmacist
<b>Derbyshire Healthcare</b>	NHS Foundation Trust
Dr S Taylor	Chair – Drugs and Therapeutic Committee
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	pital NHS Foundation Trust
Mr M Shepherd	Chief Pharmacist
Derbyshire Community	Health Services NHS Foundation Trust
Ms A Braithwaite	Chief Pharmacist
Derby and Derbyshire I	Local Medical Committee
In Attendance:	
Ms L Gavens	Registrar in Public Health, Derbyshire County Council
Mr A Thorpe	Derby City Council (minutes)
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Item		Action
1.	APOLOGIES	
	Dr K Markus and Dr T Narula.	
2.	DECLARATIONS OF CONFLICT OF INTEREST	
	Dr Mott 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 13 MARCH 2018	
	The minutes of the meeting held on 13 <sup>th</sup> March 2018 were agreed as a correct record.	
5.	MATTERS ARISING	
a.	Dry Eye Formulary  It was confirmed that the dry eye formulary had now been sent to the local optometrists.	
b.	Chlamydia It was noted that there had been no feedback as yet from Dr Fatima Nathani, Lead Clinician Integrated Sexual Health Services, who had undertaken to query the discrepancy about test of cure (TOC) with Public Health England. It was agreed that this would be placed on the action tracker and Ms Braithwaite would contact Dr Nathani about this.	АВ
C.	Omega 3 (Low Value Medicines Review)  Mr Dhadli stated that there was local exceptional use of omega-3 fatty acids for severe hypertriglyceridemia and a query had been raised with NHS England as to whether this indication was included in the production of their list of medicines of limited clinical value. NHS England had advised that its use for this indication should be governed via the local decision-making process. Mrs Needham added that there would be pressure to stop the prescribing of omega-3 fatty acids and the evidence for its use in severe hypertriglyceridemia was limited. It would therefore be necessary to check the amount of prescribing for this indication in order to ascertain the extent of the exceptional use and whether a continuation of this would be defensible.	
d.	Dosulepin Mrs Needham reported that it would now be necessary to undertake some audits in order to determine the extent of its use for depression and for other indications. This would inform any decision to stop the use of dosulepin and the rate at which this could be done.	
e.	Mr Dhadli advised that there were nine patients in Derbyshire who were on naltrexone.	

Item		Action
f.	NOACs and Suspected DVT  Ms Braithwaite reported that an update would be given to the May 2018 JAPC meeting.	АВ
g.	Age Related Macular Degeneration  Mrs Qureshi reported that the local ophthalmologists had advised that switching from ranibizumab (Lucentis®) and aflibercept (Eylea®) would only be undertaken if they considered that the patients would derive benefit. It was also confirmed that the local ophthalmologists were compliant with NICE NG 82 age-related macular degeneration and that the resource implications were not significant.	
h.	Freestyle Libre® Mr Dhadli stated that usage and compliance to the RMOC criteria and Association of British Clinical Diabetologists (ABCD) audit requirements was being monitored but the numbers coming through to date were low. It was therefore agreed to add another three months to the timescale in the action tracker so that a more robust picture could be obtained. Dr Mott advised that the DTHFT diabetologists had adopted a multi-disciplinary team approach to the introduction of Freestyle Libre®.	SD
6.	JAPC ACTION SUMMARY	
	Use of NOAC for suspected DVT – To be brought to the May 2018 JAPC meeting.	SD
	Hydroxychloroquine – To be discussed by JAPC at the meeting today.	
	Shared care principles – To be discussed by JAPC at the meeting today.	
	Rosuvastatin – There had now been a price reduction and the FH and non-FH guidance would now be reviewed by the Guideline Group. To be taken off the list.	SD
	Omega 3 - To be discussed by JAPC at the meeting today.	
	Chlamydia - To be taken off the list.	SD
	Dosulepin - To be discussed by JAPC at the meeting today and in the QIPP Working Group to follow.	
7.	NEW DRUG ASSESSMENTS	
a.	Cyanocobalamin  Mr Dhadli reported that JAPC had been requested to consider a reclassification of oral cyanocobalamin and its inclusion in the Derby shared care pathology guidelines for the management of vitamin B12 deficiency. It was noted that, for patients without symptoms who had two borderline vitamin B12 levels, the Derby shared care guidelines recommended a course of four weeks cyanocobalamin 50mcg daily. In the case of those patients who had a normal vitamin B12 level, when this was re-checked after four weeks oral cyanocobalamin, the guidelines had referred to consideration of long-term low dose oral cobalamin if clinically indicated.	

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Action ltem The NICE Clinical Knowledge Summary (CKS) had referred to the intramuscular hydroxocobalamin injection as the first line treatment for vitamin B12 deficiency in the UK, as it was preferred to cyanocobalamin, and had indicated that cyanocobalamin 50 microgram tablets could be prescribed in certain uncommon circumstances for people with vitamin B12 deficiency due to dietary origin. The current classification was BROWN, as it was considered less suitable for prescribing, but it could be used in exceptional circumstances such as for vegan patients with a vitamin B12 deficiency who could not tolerate regular injections. However available brands of cyanocobalamin tablets may not be suitable for vegans. It was agreed that oral cyanocobalamin should not be prescribed as a supplement and that patients should be encouraged to self-care in line with local policy. A traffic light classification of BLACK was proposed and Mr Dhadli advised that an Equality Impact Assessment (EIA) would not be required as alternative products could be purchased over the counter and the intramuscular hydroxocobalamin injection was available if needed. Agreed: Cyanocobalamin classified as a BLACK drug as not routinely SD recommended or commissioned. b. **Opicapone** Mr Moore reported that opicapone was a once-daily catechol-Omethyltransferase (COMT) inhibitor for Parkinson's Disease and end-of-dose motor fluctuations. An application for its use as a second line agent after entacapone had been taken to the DTHFT Drugs and Therapeutic Committee (DTC) in November 2017. It was licensed for adjuvant therapy to preparations of levodopa/DOPA decarboxylase inhibitor (DDCI) in adults with Parkinson's disease who experienced end-of-dose motor fluctuations and could not be stabilised on those combinations. The use of opicapone was proposed where entacapone was contraindicated or not tolerated due to adverse events. The DTHFT DTC had approved the application and this decision had been supported by the Regional DTC bulletin which stated that opicapone may be preferable to tolcapone in patients who had discontinued entacapone; although it was more expensive than generic entacapone. Mr Dhadli advised that JAPC had assigned a traffic light classification of BLACK in December 2016 as it was less cost-effective than the current standard therapy of entacapone. Entacapone and tolcapone were the only other COMT inhibitors licensed in the UK. Entacapone was a well-tolerated Category M drug and also available as a carbidopa + levodopa combination product. Tolcapone had been assigned a classification of RED as second-line adjuvant therapy but was only used when other COMT inhibitors were not tolerated or had failed. Due to the risk of serious hepatic problems it required frequent monitoring of liver function. A NICE Evidence Review on opicapone for Parkinson's disease with end-ofdose motor fluctuations had been published in March 2017. It had the advantage of being a once daily preparation and the evidence came from the BIPARK I and BIPARK II studies.

Item		Action
	BIPARK I had been a randomised controlled trial involving 600 patients aged 30 to 83 years who were on a stable dose of levodopa and allowed to take other medications for Parkinson's disease. The aim was to demonstrate superiority over placebo and non-inferiority to entacapone which was the active comparator. All participants had a clinical diagnosis of Parkinson's disease for three or more years and were taking a stable dose of levodopa (immediate and controlled-release). The results of this study showed that once-daily opicapone was non-inferior to entacapone which was dosed multiple times per day. The limitations of the BIPARK I study were that it had only been for a duration of up to fifteen weeks and excluded a broad population of people with Parkinson's disease. Opicapone had been investigated in mainly white people with Parkinson's disease who were taking a stable optimised regimen of three to eight daily doses of levodopa and other medicines for Parkinson's disease.	
	The BIPARK-II study was a placebo-controlled study of approximately 400 patients that also showed a significant decrease in off-time periods for Parkinson's patients. In both studies, opicapone was associated with significant improvements in both patient and clinician global assessments of change. Opicapone had the advantage of being a once-daily preparation and was well tolerated with a low incidence of adverse effects.	
	NICE had published guidance on Parkinson's disease in adults (NG 71) in July 2017 and no recommendations had been made for a first line adjuvant to levodopa. Opicapone was cheaper in price to tolcapone but not to generic entacapone. It was highlighted that opicapone could only be used if there was true intolerance or contraindications to entacapone and should not be considered as another option if entacapone was found to be ineffective. It was also necessary to determine that opicapone was effective in secondary care following specialist initiation before any prescriptions were issued in primary care.	
	<b>Agreed:</b> Opicapone classified as a <b>BROWN</b> drug after specialist initiation and stabilisation only for intolerance or contraindication to entacapone. It must be evidenced that it had been effective before prescribing was transferred to primary care.	SD
8.	CLINICAL GUIDELINES	
a.	Domperidone and Metoclopramide  Mr Dhadli reported that there had been no change to the JAPC position statement on 'domperidone and metoclopramide prescribing for gastroparesis and other gastric outlet physiological impairment; babies and children and nursing mothers to promote lactation'. This had been produced following the publication of the MHRA updated advice on domperidone prescribing in 2014 and was now due for review.	
	<b>Agreed:</b> JAPC approved the position statement on domperidone and metoclopramide prescribing with a review date of two years.	SD

Item		Action
b.	<ul> <li>Midodrine</li> <li>Mr Dhadli reported that advisory guidance on the prescribing of midodrine for orthostatic hypotension (OH) had been produced following its licensing in 2016 as a treatment option. The advisory guidance was now due for review and comments had been received from DTHFT and CRHFT consultants:</li> <li>Fludrocortisone could be used off-label treatment as a treatment option for OH.</li> <li>Blood pressure of 180/110 should trigger a discussion with the team that had initiated midodrine and the dose reduced accordingly. If the patient was on midodrine 2.5mg BD or TDS then it should be stopped pending that discussion.</li> <li>A continued blood pressure of &gt;140/90 should prompt regular reviews whereby the risk of hypertension was balanced against the risk of hypotension.</li> </ul>	, totalen
	During discussion Dr Goddard reported that Dr Jane Youde, DTHFT Consultant in Medicine for the Elderly, had advised that no changes were necessary as it had been developed in the light of NICE ESN 61 'Orthostatic hypotension due to autonomic dysfunction: Midodrine'. Dr Youde did not feel that the use of fludrocortisone was compatible with standard practice and therefore should not be added to the advisory guidance. Dr Youde had also referred to the inclusion of blood pressure readings which could trigger discussions about cessation of midodrine and had highlighted that these were not supported by an evidence base. Mr Dhadli commented that GPs had requested guidance as to the point at which a referral to secondary care would be required and it was considered that patient-specific plans would be advantageous. In connection with fludrocortisone NICE had produced an evidence summary ESUOM 20 'Postural hypotension in adults: fludrocortisone' in 2013 which referred to limited evidence obtained from two small short-term studies that fludrocortisone improved postural blood pressure and orthostatic symptoms.	
	Dr Mott proposed that the guidance could just be restricted to midodrine in OH and include the actions to be taken by consultants in certain circumstances. However a decision would also need to be made about the use of fludrocortisone.	
	<b>Action:</b> An amendment would be made in the consultant responsibilities section to remove the references to blood pressure readings and to specify what should be included in individualised patient plans which would be developed. The revised guidance would then be sent for comment to the group of consultants who had reviewed the original version.	SD AM
	<b>Action:</b> The patterns of use of fludrocortisone for OH would be reviewed by the Guideline Group for possible future action. Dr Goddard would send the reference to the Systematic Review on fludrocortisone for orthostatic hypotension to Mr Dhadli.	SD WG
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<ul> <li>B. MISCELLANEOUS Hydroxychloroquine Mr Dhadli reported that the Royal College of Ophthalmology (RCO) had published 'Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Screening' in February 2018. The new guideline had been developed in the light of the publication of evidence which highlighted that hydroxychloroquine retinopathy was more common than had previously been reported. The prevalence of retinal damage with patients who had used hydroxychloroquine over a long period of time appeared to be around 7.5% and, dependent on dose and duration of therapy, could increase to 20 to 50% after twenty years of therapy. The RCO had therefore made the following recommendations:  • All patients who planned to take hydroxychloroquine over five years should have a baseline examination in a hospital eye department within six to twelve months of commencing therapy.</li> <li>• All individuals who had taken hydroxychloroquine for more than five years or chloroquine for over one year should have an annual retinopathy screen.</li> <li>• All patients on hydroxychloroquine, who had additional risk factors for retinal toxicity, could commence annual screening earlier.</li> <li>The current traffic light classification for hydroxychloroquine was GREEN after consultant/specialist initiation. Mr Dhadli highlighted that there would be increased activity as a result of the new screening requirement as patients would now be called back in. Dr Mott commented that the screening could not be undertaken by optometrists, due to the need for fluorescence angiography, and secondary care would therefore be responsible for a new cohort of patients not currently being seen in ophthalmology – this would be a commissioning issue for the CCGs. It was noted that work had been initiated by Dr Raj Komal, GP and Southern Derbyshire CCG commissioners across the Derbyshire CCGs concerning the development of a system-wide commissioning proposal.</li> <li>b. Conditions for which over the counter items should not routinely be prescri</li></ul>			
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ophthalmologists. Dr Mott would liaise with the appropriate commissioners across the Derbyshire CCGs concerning the development of a system-wide commissioning proposal.  b. Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs  Dr Mott reported that NHS England had now published commissioning guidance on over the counter items which should not routinely be prescribed in primary care and CCGs would be expected to take this into account when local polices were developed. This national framework would therefore need to be adopted into the local self-care policy and new indications and a reference to red flag risky drug interactions added. The local self-care policy would then need to be implemented as widely as possible - this would be taken forward via the QIPP working group.  c. Principles of Shared Care  Mr Dhadli advised that NHS England had published guidance on the		Hydroxychloroquine Mr Dhadli reported that the Royal College of Ophthalmology (RCO) had published 'Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Screening' in February 2018. The new guideline had been developed in the light of the publication of evidence which highlighted that hydroxychloroquine retinopathy was more common than had previously been reported. The prevalence of retinal damage with patients who had used hydroxychloroquine over a long period of time appeared to be around 7.5% and, dependent on dose and duration of therapy, could increase to 20 to 50% after twenty years of therapy. The RCO had therefore made the following recommendations:  • All patients who planned to take hydroxychloroquine over five years should have a baseline examination in a hospital eye department within six to twelve months of commencing therapy.  • All individuals who had taken hydroxychloroquine for more than five years or chloroquine for over one year should have an annual retinopathy screen.  • All patients on hydroxychloroquine, who had additional risk factors for retinal toxicity, could commence annual screening earlier.  The current traffic light classification for hydroxychloroquine was GREEN after consultant/specialist initiation. Mr Dhadli highlighted that there would be increased activity as a result of the new screening requirement as patients would now be called back in. Dr Mott commented that the screening could not be undertaken by optometrists, due to the need for fluorescence angiography, and secondary care would therefore be responsible for a new cohort of patients not currently being seen in ophthalmology – this would be a commissioning issue for the CCGs. It was noted that work had been initiated by Dr Raj Komal, GP and Southern Derbyshire CCG Commissioner, with DTHFT to ascertain the number of patients and determine who were still on	
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February 2018 to provide clarity on the responsibilities of all professionals involved in commissioning and prescribing across primary, secondary and		prescribed in primary care: Guidance for CCGs  Dr Mott reported that NHS England had now published commissioning guidance on over the counter items which should not routinely be prescribed in primary care and CCGs would be expected to take this into account when local polices were developed. This national framework would therefore need to be adopted into the local self-care policy and new indications and a reference to red flag risky drug interactions added. The local self-care policy would then need to be implemented as widely as possible - this would be taken forward via the QIPP working group.  Principles of Shared Care  Mr Dhadli advised that NHS England had published guidance on the responsibility for prescribing between primary and secondary/tertiary care in February 2018 to provide clarity on the responsibilities of all professionals	SD

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## ltem Action Mr Dhadli highlighted that the JAPC shared care agreements were mostly compliant with the guidance and that NHS England had produced a list of the possible circumstances where shared care was not appropriate. Some of these had now been added to the JAPC amber traffic light classification as follows: • Medicines requiring ongoing specialist intervention and specialist monitoring. • Patients receive the majority of ongoing care, including monitoring, from the provider and the only benefit of transferring care would be to provider costs. Medicines, which are unlicensed and/or are being used outside of product licence, unless there is a recognised evidence base and/or it was standard • Individual treatment as part of specified packages of care often under specialised commissioning. Dr Goddard reported that letters had been received from some practices in Staffordshire to say that they intended to withdraw from shared care agreements due to pressure of workload on the practices and GPs. Dr Goddard gueried whether the fact that GP practices felt that they did not have the capacity to take on shared care agreements should be included as a possible reason. It was agreed that this was not consistent with the guidance, although the pressure on general practice was recognised. Action: Mr Dhadli would send a list of all the shared care agreements, to include an indication of when they had last been reviewed, to Dr Kath Markus at Derbyshire Local Medical Committee. A discussion would be held with Dr Markus about the future action concerning the LMC shared care agreement work. SD/AM d. **Prioritisation Framework** Mr Hulme advised JAPC that the four Derbyshire CCGs were currently going through a re-organisation and as part of this a review of the governance structure was being undertaken. This would include the formation of a number of joint committees and it was planned that JAPC would link to two of these committees: the Clinical Quality Committee and the Clinical Commissioning Committee. Mr Hulme highlighted that the CCGs faced a very challenging financial position and it was therefore highly important that all investment decisions received robust scrutiny. Some of the decisions made by JAPC would have financial consequences and there was currently no process for the prioritisation of these clinical decisions. A draft Derbyshire CCGs commissioning priority tool had been developed and this detailed the important aspects, such as cost and clinical effectiveness, which would need to be taken into consideration when investment decisions were being made by JAPC. Mr Hulme also referred to the draft clinical prioritisation algorithm which would give prioritisation scores and indicate high, medium and low (disinvestment) thresholds. This would have implications for JAPC when cases or recommendations were put forward due to the need for all the stages in the final version of the algorithm to be followed.

Item		Action
	Discussion followed and Dr Parkin queried whether the proposed Clinical Quality Committee and Clinical Commissioning Committee would scrutinise every decision made by JAPC, even those which required minimal investment (or produced a cost saving), as this could potentially undermine its function and be very time intensive. Mr Hulme commented that this was a possibility in the light of the pressure and scrutiny from NHS England although the criteria requested, such as clinical and cost effectiveness, were already taken into consideration by JAPC during its decision-making process. Dr Mott asked whether there would be a financial threshold determined so that decisions of less impact could be taken directly, but decisions of potentially greater financial impact would need more scrutiny. Mr Hulme would raise this as the framework was developed.	SH
	Dr Mott commented that JAPC had followed the same robust process for a number of years and its decisions were not usually challenged by CCG governing bodies or elsewhere. In future, it would therefore need to be decided whether JAPC should become a budget holding committee, and constituted and supported accordingly, or would it become of lesser importance. It was highlighted that the new committee would lack the clinical knowledge of JAPC members and therefore its decision making could be a more lengthy process. Mr Hulme stated that the Clinical Commissioning Committee would need to be cognisant of the clinical expertise of JAPC but at the same time would need to be assured that the processes outlined in the final versions of the commissioning priority tool and clinical prioritisation algorithm had been followed.	
	Mr Hulme advised that the commissioning priority tool and clinical prioritisation algorithm would be tested with a number of joint committees and discussions were being held at CCG level about implementation. It was also highlighted that these were based on practice on other parts of the country, including the original 'Portsmouth Scorecard'. The overall aim was to develop a prioritisation framework that was not too onerous but at the same time gave the necessary assurances to the commissioners. Further versions of the commissioning priority tool and clinical prioritisation algorithm would be presented to a future JAPC meeting.	
	Action: Members were requested to convey comments to Mr Hulme.	All
e.	QIPP Working Group Terms of Reference The updated terms of reference were ratified by JAPC.	SD
f.	Liothyronine Mr Hulme referred to the list of eighteen drugs classified as low clinical value which had been produced by NHS England. One of these drugs was liothyronine and JAPC had assigned three traffic light classifications of BLACK for hypothyroidism, RED for cancer indications and AMBER for treatment resistant depression. Mr Hulme highlighted that NHS England were exerting considerable pressure on the Derbyshire CGGs to reduce their expenditure on low value medicines and this was reinforced by the challenging financial position within the local health economy.	

Item		Action
Item	Discussions had therefore been taking place about the desirability of having just one traffic light classification of BLACK for liothyronine to avoid potential confusion and to undertake a clinical review of the patients who were on the drug for hypothyroidism. This was because the current classification of BLACK for this indication did not allow for ongoing prescribing or ensured that patients received specialist reviews. Specialist input would be required in order to review these patients in order to decide whether to stop or continue with liothyronine. A RED classification for all of the indications would avoid any confusion and allow the implementation of the NHS England guidance to be progressed by ensuring that specialist reviews of patients currently on liothyronine for hypothyroidism were undertaken by the hospital endocrinology departments. It was acknowledged that the CCGs would have to commission additional capacity in order to manage this increased workload in secondary care.	Action
	Discussion followed and Dr Parkin highlighted the necessity of ensuring that the traffic light classification of BLACK should have absolutely no exceptions. Mr Hulme commented that NHS England had not assigned traffic light classifications to any of the low value drugs but liothyronine would not be black by their definition as exceptionality and a cohort had been identified this could lead to potential challenges from patients and specialists. Dr Goddard queried the timescale and Mr Hulme advised that it would be desirable that the reviews should be undertaken in the next three months.	SH/KN
	<b>Agreed:</b> Liothyronine re-classified as a <b>RED</b> drug for all indications in the light of the national position on drugs of low clinical value, but notification to be deferred until the necessary referral pathways had been developed.	SD
10.	REGIONAL MEDICINES OPTIMISATION COMMITTEE (RMOC)	
a.	Mr Dhadli highlighted that the RMOCs now had a website which included resources and details of the work programme. Information had also been provided about the implementation of best value biological medicines and the progress to date in planning for the patent expiry of the originator adalimumab product Humira® in October 2018.	
	It was agreed that the minutes/summaries of future RMOC meetings would be included with the minutes of other prescribing committees section on the JAPC agendas. Mr Dhadli would bring any items which required discussion by JAPC to the meetings.	SD
11.	JAPC BULLETIN	
	An amendment was made in the clinical guidelines section to read: 'JAPC has agreed two pieces of asthma guidance in line with NICE. The Asthma management in adults and children ≥ 17 years and the Asthma Management for children and young people.'	
	The amended March 2018 bulletin was ratified by JAPC.	SD

Item		Action
12.	MHRA DRUG SAFETY UPDATE	
12.	<ul> <li>MHRA DRUG SAFETY UPDATE</li> <li>The MHRA Drug Safety Alert for March 2018 was noted.</li> <li>Mr Dhadli highlighted the following MHRA advice:         <ul> <li>Daclizumab (Zinbryta ▼): suspension and recall for safety reasons; review patients as soon as possible and start alternative therapy. This drug had now been discontinued due to reports of serious inflammatory brain disorders in patients with multiple sclerosis. It had been taken off the Medicines Management website and the NICE TA withdrawn.</li> <li>Esmya® (ulipristal acetate) for uterine fibroids. Treatment should not be initiated or re-started and liver function in current and recent users should be monitored.</li> <li>Head lice eradication products: risk of serious burns if treated hair was exposed to open flames or other sources of ignition.</li> <li>Confidential prescribing and patient safety reports on key indicators now available free for GPs.</li> </ul> </li> <li>Mr Dhadli highlighted the following European Medicines Agency (EMA) advice:         <ul> <li>New measures to avoid valproate exposure in pregnancy endorsed. These included a ban on the use of such medicines for migraine or bipolar disorder during pregnancy and a ban on treating epilepsy during pregnancy unless there was no other effective treatment available together with visual warnings of the pregnancy risks. All valproate drugs must not be used in girls and women able to have children unless the terms of a special pregnancy prevention programme were followed. This included an assessment of each patient's potential for becoming pregnant and pregnancy tests before starting and during treatment as needed. The</li> </ul> </li> </ul>	
	local BNF chapter would be updated in the light of the EMA advice and a check made that the appropriate reference was included in Optimise Rx.	SD/KN
13.	HORIZON SCAN	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations:	
	<ul> <li>New drug launches in the UK:</li> <li>Ocrelizumab (Ocrevus®) – Classified as BLACK as not routinely recommended.</li> <li>Tivozanib (Fotivda®) – Classified as RED.</li> </ul>	SD SD
	<ul> <li>New formulation launches in the UK:</li> <li>Budesonide + formoterol (Fobumix®) - Guideline Group to consider a traffic light classification.</li> <li>Dexamethasone (Neofordex®) - This brand classified as RED.</li> <li>Levonorgestrel (Kyleena®) - To be brought to the May 2018 JAPC</li> </ul>	SD
	<ul> <li>meeting.</li> <li>Maraviroc (Celsentri®) – Classified as RED (NHS England).</li> <li>Drug discontinuation:</li> </ul>	SD
	<ul> <li>Trimovate® (clobetasone/nystatin/oxytetracycline) – Dr Parkin advised that this drug was now only available as a special and therefore very expensive. Classified as BLACK.</li> </ul>	SD

Item		Action
14.	NICE SUMMARY	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in March 2018: TA 509 Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer – Classified as <b>RED</b> (NHS England as per NICE TA 509).	
	TA 510 Daratumumab monotherapy for treating relapsed and refractory multiple myeloma – Classified as <b>RED</b> (NHS England as per NICE TA 509).	
	TA 511 Brodalumab for treating moderate to severe plaque psoriasis – Classified as <b>RED</b> (as per NICE TA 511).	
	TA 512 Tivozanib for treating advanced renal cell carcinoma – Classified as <b>RED</b> (NHS England as per NICE TA 512).	
	TA 513 Obinutuzumab for untreated advanced follicular lymphoma – Classified as <b>RED</b> (NHS England as per NICE TA 513).	
	TA 514 Regorafenib for previously treated advanced hepatocellular carcinoma – Classified as <b>BLACK</b> (NHS England as per NICE TA 514).	
	TA 515 Eribulin for treating locally advanced or metastatic breast cancer after one chemotherapy regimen – Classified as <b>BLACK</b> (NHS England as per NICE TA 515).	
	TA 516 Cabozantinib for treating medullary thyroid cancer – Classified as <b>RED</b> (NHS England as per NICE TA 516).	
	NG 87 Attention deficit hyperactivity disorder (ADHD): diagnosis and management - Local shared care agreement with treatment options or review by DHcFT.	
	NG 88 Heavy menstrual bleeding: assessment and management - Since the publication of the original guideline in 2007, equipment and software for Transvaginal ultrasound had improved. Outpatient hysteroscopy had become more widely available, and was more acceptable to women with the advent of modern equipment such as miniature hysteroscopes. Therefore the relative clinical and cost effectiveness of the diagnostic strategies had changed.	
	NG 89 Venous thromboembolism (VTE) in over 16s: reducing the risk of hospital acquired deep vein thrombosis or pulmonary embolism - This guideline was about reducing the risk of VTE in over 16 year olds admitted to or treated as day procedures in hospitals. Ms Braithwaite commented that this did have implications for discharge due to the potential use of aspirin in some cases over a low-molecular-weight heparin.	
	NG 90 Physical activity and the environment - To be reviewed by the City and County Public Health directorates.	RD

Item		Action
	NG 91 Otitis media (acute): antimicrobial prescribing – Self-limiting infection symptoms can be treated by self-care but in the event that antibiotics were required then the first line choice would be amoxicillin or clarithromycin or erythromycin or coamoxiclav.  NG 92 Stop smoking interventions and services – This included the use of ecigarettes which were recommended. Dr Dewis commented that the City and County smoking cessation services would support people who wished to stop	
	smoking using e-cigarettes but would not recommend or provide them. Mrs Needham suggested that a statement on the use of e-cigarettes within the smoking cessation service would be advantageous.	
15.	GUIDELINE GROUP ACTION TRACKER	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in March 2018 was noted. Mr Dhadli highlighted the following:	
	<ul> <li>Formulary Review – Respiratory:</li> <li>Seretide changed to GREEN for children and BROWN for adults.</li> <li>ICS dose table removed and link added to the adult and children's asthma guidance for ICS doses.</li> <li>Triple therapy (Trimbow® and Trelegy®) added to the chapter.</li> </ul>	
	<ul> <li>Formulary Review – CNS:</li> <li>Mirtazapine orodispersible tablets (GREEN) now cheaper than mirtazapine oral solution (BROWN).</li> <li>Advice on oxycodone MR (BLACK) and morphine MXL (BROWN) added.</li> <li>Epistatus PFS added – 10mg/ml (licensed for ten to eighteen year olds).</li> </ul>	
	Guidelines:  • Emollient guidance: Excetra cream had replaced cetraban pump lotion as a cost-effective option. Epimax ointment replaced epaderm ointment. Aproderm colloidal oat cream had been added as a paraffin free option.	
	<ul> <li>Guideline Timetable:</li> <li>Midazolam – This is being reviewed by DHcFT due to the cost of the unlicensed preparations.</li> <li>UTI Diagnosis and Management – This was being updated by Dr D Harris, Specialist Antimicrobial Pharmacist.</li> </ul>	
16.	JAPC SUB-GROUPS	
	Biosimilar and High Cost Drugs (HCD) Working Group  The paper of the top biosimilar medicines list which gave the target annual savings broken down to DTHFT, CRHFT and Burton Hospitals NHS Foundation Trust was received by JAPC - good progress was noted.	
17.	TRAFFIC LIGHTS – ANY CHANGES?	
	Classifications Trimovate – BLACK Cyanocobalamin – BLACK for Vitamin B12 deficiency Opicapone – BROWN specialist initiation and stabilisation 2nd line option to entracapone if intolerant	

Item		Action
	Ocrelizumab (Ocrevus®) – <b>BLACK</b> Tivozanib (Fotivda®) – <b>RED</b> (as per NICE TA 572) Dexamethasone (Neofordex®) – <b>RED</b> Maraviroc (Celsentri®) – <b>RED</b> as per NHS England commissioning intentions Pertuzumab with trastuzumab and docetaxel – <b>RED</b> (NHS England as per NICE TA 509) Daratumumab monotherapy – <b>RED</b> (NHS England as per NICE TA 510) Brodalumab – <b>RED</b> (as per NICE TA 511) Tivozanib – <b>RED</b> (NHS England as per NICE TA 512) Obinutuzumab – <b>RED</b> (NHS England as per NICE TA 513) Regorafenib – <b>BLACK</b> (NHS England as per NICE TA 514) Eribulin – <b>BLACK</b> (NHS England as per NICE TA 515) Cabozantinib – <b>RED</b> (NHS England as per NICE TA 516)	
18.	<ul> <li>MINUTES OF OTHER PRESCRIBING GROUPS</li> <li>Sheffield Area Prescribing Group 16/11/2017</li> <li>Sheffield Area Prescribing Group 18/01/2018</li> <li>DHcFT Drugs and Therapeutic Committee 25/01/2018</li> <li>DTHFT Drugs and Therapeutic Committee 16/01/2018</li> <li>DTHFT Drugs and Therapeutic Committee 20/02/2018</li> </ul>	
19.	DATE OF NEXT MEETING	
	Tuesday, 8 <sup>th</sup> May 2018 at 1.30pm in the Coney Green Business Centre, Clay Cross.	