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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 9th May 2017

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Rituximab biosimilar (Truxima®)	RED (NHS England)
Ceftazidime + avibactam (Zavicefta®)	RED
C1-esterase inhibitor (Cinryze®)	RED (NHS England)
Aminolevulinic acid hydrochloride (Ameluz®)	RED (NHS England)
Alectinib	BLACK (as per NICE TA 438)
Cetuximab + Panitmumab	RED (as per NICE TA 439)
Pegylated liposomal irinotecan	BLACK (as per NICE TA 440)
Daclizumab	RED (as per NICE TA 441)
Ixekizumab	RED (as per NICE TA 442)
Obeticholic acid	RED (as per NICE TA 443)
Panitumumab	BLACK (as per NICE TA 240)
Silk Garments	BLACK
Sodium oxybate	RED in line with the NHS England commissioning policy for symptom control of narcolepsy with cataplexy in children.

Clinical Guidelines
Asthma for children and adults.
Management of Clostridium difficile Infection in Primary Care.
Adult lipid modification therapy in non-familial (non-FH) hyperlipidaemia.
Identification and management of familial hypercholesterolaemia (FH).

Patient Group Directions
Administration of low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) to women from 16 weeks of pregnancy in accordance with the pertussis vaccination for pregnant women national immunisation programme.

Shared Care Guidelines
Cinacalcet in primary hyperparathyroidism.
Nebulised colistimethate injection (Colomycin®) in pseudomonas aeruginosa lung infections in adults with bronchiectasis (non-cystic fibrosis).

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Mrs L Hunter	Assistant Chief Finance Officer
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
Dr C Emslie	GP
Dr T Narula	GP
Mrs K Needham	Assistant Chief Quality Officer (Medicines Management) (also representing Hardwick CCG)
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair – Drug and Therapeutics Committee
Derbyshire Healthcare NHS Foundation Trust	
Ms S Bassi	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Head of Medicines Management
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Dr R Dewis, Mr C Newman and Ms J Shaw.	
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 additional conflicts of interest were declared in respect to this agenda.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Derbyshire Repeat Prescription Management Code of Practice. • Liothyronine. • Agomelatine. • Liothyronine.	
4.	**MINUTES OF JAPC MEETING HELD ON 11 APRIL 2017**	
	The minutes of the meeting were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Osteoporosis** Mr Dhadli confirmed that hyperprolactinemia had been added as a risk factor to the osteoporosis guideline.	
b.	**Medication after Bariatric Surgery** Mrs Qureshi had pulled together a combined paper which had been sent to the consultants at Sheffield Teaching Hospitals NHS Foundation Trust, DTHFT, and also to Sheffield Area Prescribing Committee. An update report back will be given to a future JAPC meeting.	**AM/SD**
c.	**Gastro-oesophageal Reflux Disease: Recognition, Diagnosis and Management in Children and Young People** Ms Bassi and Ms Braithwaite would check that the GORD guidance and Infant Feeding guidance had been cascaded to all Derbyshire health visitors via DHcFT and DCHSFT as the relevant providers.	
d.	**Luteinising Hormone-Releasing Hormone (LHRH) Agonists in Prostate Cancer** It was agreed that the proposal that intermittent therapy for men who were having long-term androgen deprivation therapy should be considered by the prescribing groups.	**CN/SH/KN**
e.	**Vitamin D Maintenance Therapy** This would go back to the Guideline Group in order that a position statement could be produced and an update made to the guideline to reflect the JAPC decision concerning maintenance therapy.	**SD**
f.	**Substance Misuse and Alcohol Services Update** Ms Bassi advised that details of the circulation of the letter which gave details of the new Derbyshire Recovery Partnership were available.	

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g.	**Bronchiectasis** Mr Dhadli referred to the query which had been raised at the last JAPC meeting concerning the recommendation that longer term use of a short-acting inhaled beta²-agonist such salbutamol should be referred and whether this was an excessive requirement. Dr I Wahedna, DTHFT Respiratory Consultant and Bronchiectasis Lead, had advised that a short-acting inhaled beta²-agonist should be prescribed in the acute phase. However, spirometry should be considered for longer term use to assess for underlying airflow obstruction. In addition, doxycycline had been recommended, in the absence of a culture, for first-line treatment of an infective exacerbation. These amendments had been included in the guideline. Dr Henn queried whether the *haemophilus* section in the table which referred to the recommended antibiotics (for adults) for acute infective exacerbations of bronchiectasis would be amended as it still indicated that doxycycline was third line. Dr Henn also highlighted that there was a higher risk of side effects and resistance with the first line recommended antibiotic co-amoxiclav, as it was broad spectrum with a high dosage. There should be a reference to those exacerbations to prompt for smoking cessation, pneumonia and influenza vaccinations and pulmonary rehabilitation for those people with exercise limitations. Mr Dhadli commented that the table referred to by Dr Henn indicated the recommended antibiotics if results from a previous sputum sample were available but would raise the points which had been made with Dr Diane Harris, Lead Antimicrobial Pharmacist.	**SD**
h.	**Glycopyrronium Bromide** Mr Dhadli reported that glycopyrronium bromide had been discussed by the Guideline Group and a traffic light classification of BROWN assigned alongside the recommended children's formulation of glycopyrronium oral treatment (Sialanar®), which was the first licensed glycopyrronium product. For adults the off-licence use of glycopyrronium bromide had been recommended with a preferred option of the 1mg/5 ml oral solution/suspension.	
6.	**NEW DRUG ASSESSMENTS**	
a.	**Drug and Therapeutics Bulletin (DTB) Reviews and Publications** Mr Dhadli reported that the DTB had produced reviews on two products which had already been classified by JAPC: (i) Conjugated oestrogens and bazedoxifene acetate. This was licensed for oestrogen deficiency symptoms in postmenopausal women for whom progestogen-containing therapy was inappropriate and a traffic light classification of BLACK had been assigned by JAPC in January 2017 due to lack of data on safety and comparison to an active comparator. Mr Dhadli stated that clinical trials had indicated that conjugated oestrogens + bazedoxifene produced a modest reduction in the number of moderate and severe hot flushes and improvements in measures of quality of life and sleep in younger post-menopausal women for periods of up to two years. However, the majority of the evidence came from a single series of clinical studies with no direct comparisons with conventional HRT.	

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	In addition, the combination of oestrogen with a selective oestrogen receptor modulator could provide HRT without a risk of breast cancer although there was some uncertainty about endometrial safety during long-term treatment. (ii) Lidocaine/prilocaine spray for premature ejaculation. A traffic light classification of BLACK had been assigned by JAPC in January 2017. Mr Dhadli stated that some local guidance on premature ejaculation had already been developed and there were a number of products which were used off-label for this. The DTB review referred to the evidence for off-licence use for the treatments and this drugs review came from a number of short-term studies funded by the company. It was highlighted that patients with erectile dysfunction had been excluded and the long term benefits were unknown. **Agreed:** The previously assigned traffic light classifications of BLACK for conjugated oestrogens and bazedoxifene acetate for oestrogen deficiency symptoms in postmenopausal women and lidocaine/prilocaine spray for premature ejaculation were confirmed by JAPC.	
7.	**CLINICAL GUIDELINES**	
a.	**Asthma** Mr Dhadli reported that the asthma guidelines for children and adults were due for review. However a request had been made for an extension of the review period to November 2017 due to the impending publication of two asthma guidelines by NICE. In addition, a Cochrane review on leukotriene receptor antagonists (LTRAs) would be included and this referred to the earlier routine use of LRTAs before going to high-dose inhaled corticosteroids (ICS). The NICE draft revised guidance also referred to the use of DuoResp Spiromax Maintenance and Reliever Therapy (MART) and spirometry (if less < Fev1 70%) and the use of the bronchial challenge test to assist in the diagnosis of asthma. **Agreed:** JAPC ratified an extension of the existing asthma guidelines for children and adults to November 2017.	**SD**
b.	**Management of Clostridium difficile Infection in Primary Care** Mr Dhadli reported that the existing guidance was due for review in March 2017 but Dr Diane Harris, Lead Antimicrobial Pharmacist, had requested an extension until October 2017 when it was anticipated that Professor Wilcox would have produced new primary care guidance. **Agreed:** JAPC ratified an extension of the existing management of clostridium difficile infection in primary care to October 2017.	**SD**
c.	**Lipid Modification Guidance for Non – Familial Hyperlipidaemia and Familial Hypercholesterolaemia** Mr Dhadli advised JAPC that the two sets of guidance were due to be updated in January/March 2017 and had been based on NICE CG181 Cardiovascular disease: risk assessment and reduction, including lipid modification; NICE CG71 Familial hypercholesterolaemia: identification and management and NICE TA385 Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia (February 2016).	

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	In addition, NICE had published TA 393 and 394 for the PCSK9 inhibitors, alirocumab and evolocumab, both of which had previously been assigned a traffic light classification of RED by JAPC. Mr Dhadli highlighted some of the changes which had been made following consultation with DTHFT and CRHFT lipid consultants. Adult Lipid Modification Therapy in Non-Familial (Non-FH) Hyperlipidaemia: • Deletion of the paragraph relating to the use of simvastatin and atorvastatin. • Removal of non-HDL cholesterol as this was now routinely reported across Derbyshire. • Primary Prevention for new patients without CKD - Addition of further steps following use of atorvastatin 20mg if a 40% reduction was not achieved. This included the optimisation of treatment to aim for non-HDL cholesterol reduction by 40% and a titration of the dose up to atorvastatin 80mg if appropriate. In the event that levels remained high then a referral to a lipid specialist should be considered together with an understanding of risk factors. • Secondary prevention or patients with CKD - Optimise treatment to aim for non-HDL cholesterol reduction by 40% and use of non-HDL and fasting HDL. It was noted that specialists could advise a change of statin to rosuvastatin and also have an option to use PCSK9 inhibitors. During discussion Mr Dhadli confirmed that the use of PCSK9 inhibitors and atorvastatin 80mg, as first-line statin for secondary prevention rather than just for high risk patients, was in line with the NICE TAs and NICE guidance. Dr Mott queried the reference in the primary prevention section that patients over the age of forty were likely to be at a high risk of CVD and suggested that this should indicate instead that risk assessment be commenced at this age. Dr Emslie referred to the lack of a reference to patient choice at the beginning of the guidance as to whether they would wish to commence treatment. However it was noted that the guidance did refer to lifestyle advice and modification of risk factors. In connection with the secondary prevention section it was noted that this had been defined by NICE and the numbers in the guidance were consistent with this. Dr Narula queried the lack of information about titration of statins and was informed that NICE recommended a period of three months between blood testing and dose changes if required. It was highlighted that the front sheet of the guidance referred to the measurement of total cholesterol, HDL-cholesterol and non-HDL-cholesterol in all people who have been started on a high intensity statin treatment at three months and aim for greater than 40% reduction in non-HDL-cholesterol. However it was agreed that this needed to be emphasised and included in the algorithm on page 2. Mr Dhadli highlighted to JAPC that the lipid levels which could trigger a consultation/referral were pragmatic values put forward by the lipidologists, both for primary and secondary prevention. Mr Dhadli reported that clarification of the use of ezetimibe had been changed in the light of NICE TA 385 'Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia'.	**SD**

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	There was also a reference to low-density lipoprotein cholesterol concentrations above which the PSCK9 inhibitors alirocumab and evolocumab were recommended. The use of PSCK9 inhibitors in primary prevention without CVD was not recommended. For patients with CVD at high risk of CVD recommended only if LDL-C concentration was persistently above 4.0 mmol/l. For those with very high risk of CVD PSCK9 inhibitors recommended only if LDL-C concentration was persistently above 3.5 mmol/l. Mr Dhadli also highlighted the reference to omega-3 fatty acid compounds which had been classified as BROWN after consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia after a trial of statin ± fibrates. **Agreed:** JAPC ratified the revised guideline for adult lipid modification therapy in non-familial (Non-FH) hyperlipidaemia. **Agreed:** The guideline and feedback on referrals would be reviewed when rosuvastatin comes off patent (due late in 2017). Identification and Management of Familial Hypercholesterolaemia: Mr Dhadli advised that this guidance had been amended to include the possible use of the PSCK9 inhibitors and ezetimibe. Dr Mott referred to the reference that treatment should commence with atorvastatin 10 to 20 mg daily and queried the exact dose to be used. Mr Dhadli would check this with the lipid consultants. **Agreed:** JAPC ratified the identification and management of familial hypercholesterolaemia guideline.	**SD** **SD** **SD** **SD**
d.	**<u>ST Segment Elevation Myocardial Infarction (STEMI) - South</u>** Mr Dhadli advised that the STEMI South guideline had been due for review in July 2017 and subsequently updated in line with DTHFT guidance. The changes included the addition of cangrelor as a treatment option; advice for acutely unwell patients using IV cangrelor if oral therapy was not appropriate and removal of the advice concerning reloading with prasugrel following loading with clopidogrel. Mr Dhadli added that the addition of ticagrelor for TA 420 was awaited and, in the interim, a note would be added to indicate that this would be on specialist recommendation on a patient by patient level. The Guideline Group would be requested to compare the north and south STEMI guidelines to determine whether they could be merged into one document.	**SD**
8.	**PATIENT GROUP DIRECTIONS**	
	The following PGD from Public Health England/NHS England was noted and agreed by JAPC: • Administration of low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) to women from 16 weeks of pregnancy in accordance with the pertussis vaccination for the pregnant women's national immunisation programme.	

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9.	**SHARED CARE GUIDELINES**	
a.	**Cinacalcet** The shared care guideline for the use of cinacalcet in primary hyperparathyroidism had expired in December 2016 and no comments or advice had been received. Mr Dhadli advised that the monitoring requirement to test serum calcium every six months had previously been agreed with local endocrinologists and the SPC had referred to the need for periodic checking. The NHS England Clinical Commissioning Policy document on cinacalcet for complex primary hyperparathyroidism in adults referred to the criteria when the drug could be used for those patients for whom surgery was not clinically appropriate or was contraindicated. **Agreed:** JAPC ratified the shared care guideline for the use of cinacalcet in primary hyperparathyroidism with a two year review date.	**SD**
b.	**Colomycin** The shared care guideline for the use of nebulised colistimethate injection (Colomycin®) in pseudomonas aeruginosa lung Infections in adults with bronchiectasis (non-cystic fibrosis) had expired in February 2017. Mr Dhadli advised that an updated document on Colomycin® was due to be published by the British Thoracic Society at the end of 2017 and therefore it would be beneficial to update the guideline in the light of any recommendations in this document. **Agreed:** JAPC ratified the shared care guideline for the use of nebulised colistimethate injection (Colomycin®) in pseudomonas aeruginosa lung Infections in adults with bronchiectasis (non-cystic fibrosis) with a one year review date.	**SD**
10.	**HORIZON SCAN**	
	Monthly Horizon Scan Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuation: New drug launches in the UK: Etanercept (Lifmior®) - Identical product to Enbrel®. There would be a need to look at opportunity costs to determine whether to swap from one biosimilar to another. New formulation launches in the UK: Ceftazidime + avibactam (Zavicefta®) – CCG commissioned line and in tariff. Classified as **RED**. To be reviewed by the Drug and Therapeutics Committees for internal use if needed. C1-esterase inhibitor (Cinryze®) – NHS England. Classified as **RED**. Licence extensions: Aminolevulinic acid hydrochloride (Ameluz®) – NHS England. Classified as **RED**. Canakinumab (Ilaris®) – Already classified as BLACK as per NICE TAs 281 and 302.	**SD** **SD** **SD**

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	Discontinuation: Ebesque XL (Quetiapine®) **Quarterly NICE Updates** Mr Dhadli referred JAPC to the NICE horizon scan and highlighted the following that may change/influence local guidelines if agreed: Clinical Guidelines: • Type 2 diabetes prevention. Standing Committee C update and this would include digitally delivered lifestyle programme changes and metformin for type 2 diabetes. In addition, some of the cardiovascular outcomes for SGLT2 and GLP1 inhibitors had been included. • Chronic obstructive pulmonary disease in over 16s: diagnosis and management (update to include surveillance publication of LABA + LAMA). • Glaucoma: diagnosis and management (update). This would indicate the most cost effective treatments. • Attention deficit hyperactivity disorder (update). This would review the currently used drugs including guanfacine, atomoxetine and dexamfetamine. • Chronic heart failure in adults: diagnosis and management. This would involve sequential use of treatments. NICE Technology Appraisals: • Dupuytren's contracture – collagenase clostridium histolyticum. This was currently commissioned by Southern Derbyshire CCG. • Chronic obstructive pulmonary disease (severe) – roflumilast. • Uveitis (non-infectious) – adalimumab and dexamethasone. • Ustekinumab for previously treated moderate to severe active Crohn's disease.	
11.	**MISCELLANEOUS**	
a.	**<u>Changes to NICE Technology Appraisals</u>** Mr Dhadli reported that NICE had run a consultation on proposed changes to technology appraisals and highly specialised technologies. The summary of proposals was: • Introduction of a 'fast track' NICE technology appraisal process for the most promising new technologies which fell below an incremental cost-effectiveness ratio of £10,000 per QALY (quality adjusted life year) to get these treatments to patients more quickly. • Operation of a budget impact threshold of £20 million, set by NHS England, to signal the need for a dialogue with companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. This would apply to a small number of technologies that, once determined as cost effective by NICE, would have a significant impact on the NHS budget. • Variation of the timescale for the funding requirement when the budget impact threshold was reached or exceeded and there was therefore a compelling case that the introduction of the new technology would risk disruption to the funding of other services.	

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	• Automatic funding, from routine commissioning budgets, of treatments for very rare conditions (highly specialised technologies) up to £100,000 per QALY (five times greater than the lower end of NICE's standard threshold range) and provide the opportunity for treatments above this range to be considered through the NHS England process for prioritising other highly specialised technologies.	
b.	**Position Statement for Commissioning Medicines in Children** Mr Dhadli advised that NHS England had published a document 'Commissioning Medicines for Children in Specialised Services'. The document referred to children under eighteen years of age who may have restricted access to medications such as high cost drugs covered by NICE TAs - these usually covered young people over the age of eighteen. This had led to the receipt of some Individual Funding Requests (IFRs). The NHS England policy therefore aimed to indicate when it would be cost effective for young people, who fulfilled the conditions set out in a NICE TA/HST or NHS England policy relating to adults, to obtain the medications without going through the IFR process. A JAPC position statement had been developed, which incorporated the principles of the NHS England document, to indicate when the CCGs would fund medication for children already approved for adult use by a NICE TA or CCG policy. This would happen when one of the following criteria applied: • The medicine was listed in the BNF for Children with a recommended dosage schedule relative to the age of the child. • The child was post pubescent. • An expert working group for the particular medicine/indication using methodologies described by the FDA provided robust data to support an appropriate dosing schedule. All of the following conditions must apply: • The patient met all the NICE TA/CCG policy criteria for the proposed treatment. • The patient did not meet any exclusion criteria for the proposed treatment. • Approval for use of the medicine had been agreed by an appropriately constructed Multidisciplinary Team (MDT) and approval given by both the internal Trust Drug and Therapeutics Committee and the host commissioning CCG. Dr Parkin referred to the lack of a reference to mental capacity in the document and Mrs Needham advised that it should be made clear that anything that was not a CCG commissioned line would not be funded - Mr Dhadli would add to the position statement. Dr Mott highlighted the need to agree that the position statement was clinically sound and to ensure that there were adequate governance arrangements in place in view of the potential financial implications for the CCGs. There would be a need for the position statement to be ratified via the appropriate processes in each of the CCGs. **Agreed:** JAPC ratified the commissioning medicines for children position statement with the agreed amendments.	**SD**

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	The position statement would be sent to the Derbyshire CCGs with a request that it be considered by the appropriate governance mechanism within each organisation.	**AM/SD**
c.	**Rituximab Biosimilar** Mr Dhadli reported that UKMi had produced a document to explain any differences between rituximab (Mabthera®) and the new biosimilar product, Truxima®, which was licensed for intravenous use in adults with rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, non-Hodgkin's lymphoma and chronic lymphocytic leukaemia. There was also a letter from NHS England Specialised Commissioning to the East Midlands Acute Providers which gave the background to biosimilars; the procurement process and the NHS England commissioning position. This stated that, in Quarter 1 2017/18 prior to this procurement process and framework prices being in place, NHS England would not require Trusts to move to the rituximab biosimilar. It was noted that the framework prices would not be in place until September 2017. **Agreed:** JAPC acknowledged that a rituximab biosimilar had now become available and agreed that local implementation would take place in September 2017 following the conclusion of the procurement process and consultation with local specialist clinicians.	**SD**
d.	**Regional Medicines Opitimisation Committees** JAPC was informed that NHS England had decided to establish four Regional Medicines Optimisation Committees (RMOCs) for England that will operate as one entity. Mr Dhadli highlighted the following key points: • The four RMOCs would be for London, the South, the North and Midlands and East of England supported by four Regional Directors. • The RMOCs would be overseen by the Medicines Optimisation Oversight Group (MOOG) and supported by the NHS England Specialist Pharmacy Service (SPS). • The MOOG was responsible for the governance, oversight of RMOC processes and the new RMOC system to ensure consistency in operation and for ratifying the prioritised RMOC annual work programme. It was noted that Mr Dhadli was now a member of the MOOG. • There would be a RMOC coordinating hub to be run by the NHS SPS. • The membership of the RMOCs would be drawn from a wide range of health professionals including providers, senior medicines management pharmacists and CCG senior level representation (a membership schematic had been included on page 28 of the paper). Dr Watkins queried the future role of JAPC once the new structures were in place. Mr Dhadli stated that it was expected that a number of implementation tools for use by primary care would be developed but Area Prescribing Committees would still continue to exist and have a statutory decision making responsibility for the promotion of safe and cost-effective medicines use across Derbyshire. JAPC would be kept fully informed of developments with the RMOCs and minutes of the meetings would be circulated for information.	

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	Mr Dhadli highlighted that the recruitment process for the Midlands and East RMOC had been extended from 5th May to 25th May 2017 so that membership applications could still be made.	
e.	**Silk Garments** Mr Dhadli reported that JAPC had discussed silk garments at the June 2014 meeting and assigned a traffic light classification of BROWN specialist initiation following an assessment of efficacy. It had been noted that some CCGs outside of Derbyshire had listed silk garments as not routinely recommended due to the lack of evidence or cost effectiveness data available. It had also been noted that Nottingham was recruiting children to the Clothing for the relief of eczema symptoms (CLOTHES) trial run by the National Institute for Health Research. This was an observer-blind, parallel group randomised controlled trial to evaluate the addition of silk therapeutic clothing compared to standard eczema care over a period of six months. The results of this study had now been published by the National Institute for Health Research. It was noted that, for the primary outcome of atopic eczema severity, there was no difference between the groups in the nurse-assessed eczema area and severity index (EASI) scores. For the secondary outcomes there were no between-group differences in nurse-assessed atopic eczema severity, quality of life or medication use. Some small differences had been observed for two of the participant-reported secondary outcomes. The adjusted incremental cost per QALY was £56,811 and the trial had concluded that there was no evidence of clinical or economic benefit in using silk garments compared with standard care in children with moderate to severe atopic eczema. **Agreed:** Silk garments classified as **BLACK** due to new evidence which had confirmed lack of data on effectiveness compared with standard therapy, lack of data on cost-effectiveness compared with standard therapy and less cost-effective than current standard therapy.	**SD**
f.	**Sodium Oxybate** Mr Dhadli reported that NHS England had issued a new clinical commissioning policy for sodium oxybate, used for symptom control of narcolepsy with cataplexy in children, in the light of a judicial review. The policy stipulated that sodium oxybate would be prescribed for post-pubescent children where attempts to control symptoms of narcolepsy with cataplexy had failed despite a trial of first and second line medications from each symptom group for at least three months. The CCGs were responsible for the funding of sodium oxybate for adults and it would therefore be necessary for Trusts to liaise with them concerning treatment following a patient's nineteenth birthday. Sodium oxybate was currently classified as a BLACK drug for both children and adults and was excluded from tariff. In view of the new NHS England commissioning policy the traffic light classification for the use of sodium oxybate for symptom control of narcolepsy with cataplexy in children would need to be changed. A decision would also be needed as to whether the current classification for its use for adults would need to be changed also.	

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	During discussion Dr Watkins queried what would happen currently if an adult was referred with this condition and was informed that an IFR application would have to be made. Dr Mott highlighted that there were two separate cohorts of patients; those who transitioned into adulthood and those who were already adults and therefore not currently commissioned. The financial implications would need to be highlighted and the evidence for sodium oxybate reviewed. Mr Hulme advised that a general position statement on transitions would be advantageous to address the broader issues associated with this drug, and others, which involved transitions from childhood to adulthood. **Agreed:** Sodium oxybate classified as a **RED** drug in line with the NHS England commissioning policy for symptom control of narcolepsy with cataplexy in children. **Agreed:** Sodium oxybate to remain classified as a **BLACK** drug for all indications in adults pending a review of the evidence next month.	**SD** **SD**
g.	**<u>Self-Care Policy and Public Consultation</u>** Mrs Needham referred to the recent discussions at the JAPC working group about self-care and a draft Derbyshire CCGs self-care policy had now been produced. It was highlighted that the Derbyshire CCGs had spent a very significant amount of money in 2015/2016 on prescriptions for medicines which were available to buy over the counter (OTC) and considerable savings could be made by the adoption of a self-care policy. A number of other CCGs now had self-care policies which prevented the prescribing of OTC drugs for these minor conditions and encouraged patients to purchase these medicines themselves. Mrs Needham stated that the Derbyshire self-care policy would go out for consultation after the forthcoming General Election and to date approval for this had been obtained from the governing bodies of Southern Derbyshire and North Derbyshire CCGs. It was noted that there would be an opportunity to submit comments during this consultation period. **Agreed:** JAPC supported the need for a self-care policy and gave approval for a public consultation.	**KN**
h.	**<u>Psoriatic Arthritis</u>** Mrs Qureshi advised that comments from a consultant rheumatologist were awaited about the Derbyshire-wide psoriatic arthritis treatment algorithm.	**SQ**
12.	**JAPC BULLETIN**	
	The bulletin was noted for information and ratified by JAPC.	**SD**
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for April 2017 was noted. Mr Dhadli highlighted the following MHRA advice: Valproate and neurodevelopmental disorders: new alert asking for patient review and further consideration of risk minimisation measures. Advice had been provided for health professionals not to prescribe valproate medicines for epilepsy or bipolar disorder in women and girls unless other treatments are ineffective or not tolerated.	

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Item		Action
	It was highly important to ensure that women and girls who were taking valproate medicines understood the 30 to 40% risk of neurodevelopmental disorders and 10% risk of birth defects and were using effective contraception. Valproate use in women and girls of childbearing potential must be initiated and supervised by specialists in the treatment of epilepsy or bipolar disorder. A Patient Safety Alert on resources to support the safety of girls and women who were being treated with valproate had been issued on 6th April 2017 by NHS Improvement and the MHRA. Mr Dhadli stated that DHcFT had participated in the POMH-UK audit of prescribing valproate for bipolar disorder in 2015 and a report had been presented to their Drugs and Therapeutic Committee. DHcFT would also participate in the POMH UK re-audit scheduled for September 2017. It was agreed that a reference to the MHRA alert should be included in the JAPC bulletin. Ponatinib (Iclusig▼): risk of vascular occlusive events – Updated advice on possible dose reduction. Multiple sclerosis therapies: signal of rebound effect after stopping or switching therapy. Healthcare professionals had been requested to report any suspected adverse effects relating to fingolimod (Gilenya▼) or other treatments for multiple sclerosis, including suspected adverse effects which occurred after discontinuation, via the Yellow Card Scheme. Letters sent to healthcare professionals in March 2017: • Nulojix® (belatacept) 250 mg: supply shortage - restricted to existing patients. • Mucodyne Paediatric Syrup 250 mg/5 mL (carbocisteine oral liquid): new double strength presentation - check dose volume to ensure that the appropriate dose was given.	**SD**
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in April 2017. TA438 Alectinib for previously treated anaplastic lymphoma kinasepositive advanced non-small-cell lung cancer (terminated appraisal). Classified as **BLACK.** TA439 Cetuximab and panitumumab for previously untreated metastatic colorectal cancer. This guidance replaced TA 176 and partially replaced TA 240 and both drugs were recommended. Classified as **RED**. TA440 Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine. Not recommended. Classified as **BLACK**. TA441 Daclizumab for treating relapsing–remitting multiple sclerosis. Recommended and classified as **RED.** TA442 Ixekizumab for treating moderate to severe plaque psoriasis. CCG commissioned line. Now recommended and would be included in the algorithm to be sent to the relevant consultants. Classified as **RED.**	**SD/SQ** **SD/SQ** **SD/SQ** **SD/SQ** **SD/SQ**

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Item		Action
	TA443 Obeticholic acid for treating primary biliary cholangitis. Classified as a **RED** drug (NHS England). TA240 (updated from December 2011) Panitumumab in combination with chemotherapy for the treatment of metastatic colorectal cancer (terminated appraisal). Classified as **BLACK.** NG67 Managing medicines for adults receiving social care in the community. This will be sent to the two local authorities. NG68 Sexually transmitted infections: condom distribution schemes. This had been sent to the public health departments of the two local authorities. CG100 (updated from June 2010) Alcohol-use disorders: diagnosis and management of physical complications. This had been sent to DHcFT.	**SD/SQ** **SD/SQ** **SD/SQ**
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Rituximab biosimilar (Truxima®) – **RED** (NHS England and CCG commissioned) Ceftazidime + avibactam (Zavicefta®) – **RED** C1-esterase inhibitor (Cinryze®) – **RED** (NHS England) Aminolevulinic acid hydrochloride (Ameluz®) – **RED** (NHS England) Alectinib – **BLACK** (as per NICE TA 438) Cetuximab + Panitumumab – **RED** (as per NICE TA 439) Pegylated liposomal irinotecan – **BLACK** (as per NICE TA 440) Daclizumab – **RED** (as per NICE TA 441) Ixekizumab – **RED** (as per NICE TA 442) Obeticholic acid – **RED** (as per NICE TA 443) Panitumumab – **BLACK** (as per NICE TA 240) Silk Garments – **BLACK** Sodium oxybate – **RED** in line with the NHS England commissioning policy for symptom control of narcolepsy with cataplexy in children. Remains **BLACK** for all indications in adults.	
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: PCSK9 inhibitors and Lipid/Familial Hypercholesterolaemia guidance – To be taken off. Sacubitril/Valsartan – Mr Dhadli reported that feedback had been received from Dr J Cooke, CRHFT Consultant Cardiologist, who had advised that a traffic light classification of AMBER would be appropriate and that there had been mixed results with patients. The heart failure specialists were supervising the dose titrations but once the patient was stable there was no further need to bring back to hospital for further prescriptions. A response had also been received from Dr R McIntosh, DTHFT Consultant Cardiologist, to say that the use of sacubitril/valsartan was less than expected and that one patient had experienced significant renal toxicity leading to discontinuation.	**SD**

Item		Action
	Patients were being recruited for an industry trial to evaluate treatments using sacubitril/valsartan for patients with Acute Heart Failure. Dr McIntosh had suggested that a traffic light classification of RED be assigned for a period of six months in order to gain more experience for its use. Mr Shepherd would discuss the shared care protocol with Dr Cooke. It was agreed to take sacubitril/valsartan off the action tracker. DMARDS/Immunomodulating drugs – Mr Dhadli highlighted a lack of responses from the specialists. It was agreed that the remaining shared care guidelines be brought to future JAPC meetings and the specialists informed of the date(s) of these. Juxta Cures – To be brought to the June JAPC meeting. Suspected DVT NOAC/D-dimer – To be brought to the September JAPC meeting. NRT and Service Provision – To be brought to the October JAPC meeting. Bariatric Surgery – This was in progress.	**MS** **SD** **SD** **SD** **SD** **SD**
17.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in April 2017 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Azithromycin classified as GREEN as per local antibiotic guidance and GREEN after consultant recommendation for long term use in CF patients. • Procyclidine had a dual classification of GREEN after specialist recommendation for extra pyramidal symptoms and BROWN for clozapine induced sialorrhoea and second line to hysocine hydrobromide. • Aerivio Spiromax® (salmeterol/fluticasone) classified as GREEN third-line behind other formulary choices and based on device acceptability for the patient for COPD. • Soltel® (salmeterol MDI) preferred cost effective choice but contra-indicated for peanut or soya allergies when Serevent® would be a suitable alternative. • Lidocaine 5% plaster classified as BROWN for post herpetic neuralgia and BLACK for all other indications except PHN. For topical treatment capsaicin cream should be considered first. Guidelines: • De-prescribing – This had been sent to Ms Temi Omorinoye.	
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• DHcFT Drug and Therapeutics Committee 26/01/17 Mr Dhadli highlighted the following from the DHcFT Drug and Therapeutics Committee minutes:	

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Item		Action
	➢ A hyperlink to a lithium app had now been placed on the DHcFT Recovery and Wellbeing site. ➢ Development of Antipsychotic Physical Monitoring Guidelines (LESTER) in progress. ➢ Drug review of agomelatine. The Drug and Therapeutics Committee had been informed of further evidence from a Cochrane review in 2013 which concluded that no firm conclusions could be drawn; a NICE review in 2014 which indicated that further research was needed and a meta-analysis of published and unpublished studies published in the BMJ in 2014. The Drug and Therapeutics Committee had found no additional evidence to merit a change to the current traffic light classification. • DTHFT Drug and Therapeutics Committee 21/03/17	
19.	**ANY OTHER BUSINESS**	
a.	**<u>Derbyshire Repeat Prescription Management Code of Practice</u>** The Derbyshire Repeat Prescription Management Code of Practice was tabled. Mrs Needham advised the Code of Practice had been discussed at length by the JAPC working group and would be placed on the website once agreed. It was noted that discussions were still being held with the Derbyshire Local Pharmaceutical Committee about the requirement to agree with the patient or representative exactly which repeat prescriptions were required and that this must be done no more than five days before the repeat prescription request was submitted to the patient's practice. Dr Watkins referred to the statement that practices should ensure that repeat prescriptions were managed for no more than forty-eight hours and pointed out that this should indicate no more than two working days instead to take into account weekends. An amendment would be made to indicate two working days. **Agreed:** JAPC ratified the Derbyshire Repeat Prescription Management Code of Practice with the agreed amendment.	**KN** **KN**
b.	**<u>Liothyronine</u>** Mr Dhadli highlighted the high cost of the prescribing of liothyronine in Derbyshire and advised this would be brought back for further discussion at the June JAPC meeting. Liothyronine currently had a dual classification of AMBER for the treatment of resistant depression within a shared care guideline and BROWN after consultant endocrinologist initiation for use in endocrinology.	
20.	**DATE OF NEXT MEETING**	
	Tuesday, 13th June 2017 at 1.30pm in the Post Mill Centre, South Normanton.	