

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 13th June 2017

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Insulin Aspart (Fiasp®)	GREEN for use in adults
Liothyronine	Provisional decision of BLACK
Sodium Oxybate	BLACK for adults
Relvar® (fluticasone/vilanterol)	BROWN after respiratory consultant/specialist recommendation
Ultibro® (indacaterol/glycopyrronium)	BROWN 1st line LABA/LAMA for COPD
Duaklir® (formoterol/aclidinium)	BROWN 2nd line LABA/LAMA for COPD
Anoro® (vilanterol/umeclidinium)	BROWN 2nd line LABA/LAMA for COPD
Spiolto® (olodaterol/tiotropium)	BROWN 2nd line LABA/LAM for COPD
Tofacitinib (Xeljanz®)	BLACK
Baricitinib (Olumiant®)	BLACK
Albutrepenonacog alfa	RED
Afatinib	BLACK (as per NICE TA 444)
Certolizumab pegol	RED (as per NICE TA 445)
Secukinumab	RED (as per NICE TA 445)
Tenofovir and emtricitabine	RED
Dabrafenib (Tafinlar®)	RED
Mometasone nasal spray	GREEN 1 st line options alongside beclometasone

Clinical Guidelines

Bisphosphonate Length of Treatment Guideline in Osteoporosis

Management of Chronic Obstructive Pulmonary Disease (COPD)

Continence Appliance Prescribing

Prevention, Diagnosis and Management of Vitamin D Deficiency in Primary Care

Children's Referral Guideline for Sub-Lingual ImmunoTherapy (SLIT) – Grass Pollen Extract (Grazax)

Managing Behavioural Problems in Patients with Dementia (BPSD)

Patient Group Directions

Shingles vaccine as per national programme

Pneumococcal vaccine for those at high risk of pneumococcal disease

Meningococcal ACWY vaccine as per national programme

Rotavirus vaccine as per childhood vaccination programme

Shared Care Guidelines

Degarelix for the treatment of adult male patients with advanced hormone-dependant prostate cancer

Methotrexate

Lithium

Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
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	
Dr R Dewis	Consultant in Public Health Medicine
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Dr S Taylor	Chair – Drugs and Therapeutic Committee
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms J Shaw	Principal Pharmacist
In Attendance:	
Dr J Burgess-Allan	Public Health Registrar, Derby City Council
Mr A Thorpe	Derby City Council (minutes)

Item		Action
1.	APOLOGIES	
	Ms S Bassi, Dr C Emslie, Mrs L Hunter and Ms N Smith.	
2.	DECLARATIONS OF CONFLICT OF INTEREST	
	<p>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.</p> <p>Dr Henn declared an interest in degarelix as a partner in a dispensing GP practice. This was not felt to be material to the discussion so no further action was taken.</p>	
3.	DECLARATIONS OF ANY OTHER BUSINESS	
	No declarations of any other business were made.	
4.	MINUTES OF JAPC MEETING HELD ON 9 MAY 2017	
	The minutes of the meeting held on 9 th May 2017 were agreed as a correct record.	
5.	MATTERS ARISING	
a.	<p><u>Bronchiectasis</u> Mr Dhadli reported that a reference to the exacerbations around smoking cessation, pneumonia and influenza vaccinations had been added to the guideline.</p> <p><u>ST Segment Elevation Myocardial Infarction (STEMI) – South</u> Mr Dhadli advised that the dosage of ticagrelor as per NICE TA 420 had been added to the traffic light classifications on the advice of the Guideline Group but not to the guidelines.</p> <p><u>Medication after Bariatric Surgery</u> Mr Dhadli reported that multidisciplinary team (MDT) meetings were taking place at Sheffield Teaching Hospitals NHS Foundation Trust to determine the use of medications and vitamins after bariatric surgery. Dr Sherif Awad, DTHFT General Surgery Consultant, was liaising with the MDT so that the differences between the two bariatric departments could be reconciled and one single guideline produced.</p> <p><u>Identification and Management of Familial Hypercholesterolaemia Guideline</u> In connection with the query as to whether treatment should commence with atorvastatin 10mg or 20mg Dr R Stanworth, DTHFT Consultant Endocrinologist, had advised that treatment should commence with the 10mg strength and then be titrated according to patient response.</p> <p><u>ST Segment Elevation Myocardial Infarction (STEMI) - South</u> Mr Dhadli advised that the Guideline Group had concluded that the current differences between the north and south STEMI guidelines prevented the merging of these into one document.</p>	

Item		Action
6.	NEW DRUG ASSESSMENTS	
a.	<p><u>Fiasp Insulin</u> Mr Dhadli reported that the European Medicines Agency (EMA) had undertaken an assessment in November 2016 which had compared Fiasp, an insulin aspart (Novorapid®) with the addition of nicotinamide + L-arginine, with NovoRapid®. Fiasp had an earlier onset of the glucose-lowering effect while the total glucose lowering effect had been similar. The evidence came from the ONSET-1 and ONSET-2 studies. ONSET-1 had been a twenty-six week study involving 1,143 patients with type 1 diabetes and had demonstrated a significantly greater improvement in HbA1c. The ONSET-2 study had involved 689 patients with type 2 diabetes and had met the primary objective of non-inferiority in HbA1c. Fiasp was cost-neutral and had been accepted by the SMC in March 2017. However it was highlighted that Fiasp was only licensed in adults and efficacy and safety had not been established in children and adolescents under the age of eighteen years. In connection with safety, it was noted that there had been a difference in the pattern of hypoglycaemic episodes with a significantly higher rate of hypoglycaemia within the first two hours after food for Fiasp compared to NovoRapid®. However, the overall rate and severity of events had been comparable. Mr Dhadli added that the DTHFT Drugs and Therapeutic Committee had recommended the use of Fiasp.</p> <p>Agreed: Fiasp classified as GREEN for use with adults only. Post meeting note: clarity on TLC following consultant advice. “New fast acting insulin aspart with a faster onset of action than novorapid 4 minutes versus 10-20 minutes, for adults only. Note: FIASP and NovoRapid are not directly interchangeable.”</p>	SD
b.	<p><u>Liothyronine</u> Mr Dhadli reported that liothyronine was not a new drug and had been used in a handful of individuals under a shared care agreement with DHcFT for resistant depression with a traffic light classification of AMBER. It was noted that the DHcFT would be reviewing the use and place of liothyronine in treatment for resistant depression given the rising costs.</p> <p>Liothyronine had also been assigned a traffic light classification of BROWN by JAPC, after consultant endocrinologist initiation in combination with levothyroxine for treatment of hypothyroidism, as a small number of patients could benefit from the addition of small doses of liothyronine in addition to levothyroxine if their quality of life remained poor despite adequate levothyroxine replacement. It had been decided to discuss liothyronine again at a JAPC meeting as there was a national initiative by NHS Clinical Commissioners to reduce the prescribing of ten low value medicines. This list included liothyronine for endocrinology use as the cost of this had risen significantly over the past few years.</p> <p>Mr Dhadli stated that, in the light of this national initiative, other CCGs in England had been looking at the use of liothyronine. These included Nottingham, which had classified liothyronine as grey (not recommended) and produced a position statement, and Leicester which had assigned a classification of red for those patients who had hypothyroidism and inadequate response to thyroxine alone.</p>	

Item	Action
<p>Sheffield had not listed liothyronine and Greater Manchester had assigned a classification of grey only for use in hypothyroid crisis and short-term post thyroid surgery.</p> <p>JAPC advised that PrescQIPP had produced a guide for switching liothyronine (L-T3) to levothyroxine (L-T4) for the management of primary hypothyroidism. Some of the rationale for switching to levothyroxine included:</p> <ul style="list-style-type: none"> • Levothyroxine (L-T4) was a prodrug and was converted to liothyronine (L-T3) in the body. • Liothyronine had a much shorter half-life and steady-state levels could not be maintained with once daily dosing. • The combination of levothyroxine and liothyronine had not consistently been shown to be more beneficial than levothyroxine alone with respect to cognitive function, social functioning and wellbeing. • There was currently insufficient evidence of clinical and cost effectiveness to support the use of liothyronine for the treatment of hypothyroidism. • Liothyronine was considerably more expensive than levothyroxine and many other liothyronine-containing preparations were also unlicensed and therefore raised quality and safety concerns. • A statement produced by the British Thyroid Association (BTA) referred to the patients who had not benefited from L-T4 and instead could benefit from a trial of L-T4/L-T3 combination therapy. The patients should be supervised by accredited endocrinologists with full informed consent together with full documentation about risks and benefits and lack of safety data. <p>The BTA had also produced questions and answers to accompany their statement on the management of hypothyroidism. This highlighted that, although some patients had reported an improvement in symptoms on a T3/T4 combination in blinded clinical trials, they had not been able to tell the difference except perhaps at high dose. The use of the T3/T4 combination was associated with increased risk of stroke and osteoporosis from slight over treatment over many years. The BTA had concluded that it was possible for a small group of patients to improve with a T3/T4 combination.</p> <p>During discussion Dr Goddard reported that the DTHFT endocrinologists had stated that every attempt would be made to prevent patients being put on liothyronine but some were taking the drug due to quality of life issues and had claimed to derive a great deal of benefit from its use. This group of patients were vociferous in their support of the use of liothyronine and the endocrinologists had advised that it would be difficult to supervise complete withdrawal. The endocrinologists had also indicated that they would support a decision that no new patients should be given liothyronine.</p> <p>During discussion Dr Parkin highlighted the need for consistency in making decisions about stopping drugs with no proven clinical benefit and that BLACK would therefore be an appropriate classification with exceptionality for the very small number of patient within DHcFT who did gain benefit from its use. It was highlighted that a position statement from all the Derbyshire CCGs would be crucial to reinforce any revision to the current classification for use in endocrinology.</p>	

Item		Action
c.	<p>In this event Mrs Needham stated that the Individual Funding Request (IFR) process would be a way by which patients could potentially gain access to the drug if there were exceptional circumstances.</p> <p>Agreed: A provisional classification of BLACK would be given to liothyronine for use in endocrinology pending production of a position statement. A final traffic light classification would be confirmed at the July JAPC meeting.</p> <p>Agreed: Ms B Thompson, DHcFT Deputy Chief Pharmacist, would be requested to undertake a review of the use and place of liothyronine in treatment for resistant depression before any decision was taken by JAPC to change the current shared care traffic light classification.</p> <p>Dr Henn highlighted that the NHS England funding review for some NHS prescription items had included doxazosin MR for high blood pressure not doxazosin as stated in the JAPC background papers.</p> <p>Sodium Oxybate</p> <p>Mr Dhadli stated that JAPC had assigned a traffic light classification of BLACK for sodium oxybate in September 2012. However sodium oxybate had been re-classified as a RED drug in May 2017 in line with the NHS England commissioning policy for symptom control of narcolepsy with cataplexy in children. It had also been agreed that sodium oxybate should remain classified as a BLACK drug for all indications in adults pending a review of the evidence. Sodium oxybate was used to treat cataplexy and reduce daytime sleepiness in patients with narcolepsy.</p> <p>Mr Dhadli advised that the European Medicines Agency had reviewed the effects of sodium oxybate in narcolepsy and cataplexy in 707 patients in four studies. In all of the studies, sodium oxybate had been given at a daily dose of between 3g and 9g and had been compared with placebo.</p> <p>The review by the Scottish Medicines Consortium (SMC) had involved two randomised placebo-controlled trials to evaluate the efficacy of four doses of sodium oxybate in the treatment of cataplexy associated with narcolepsy. The first study had recruited 136 patients over the age of eighteen years with narcolepsy. The trial completed by 120 patients had revealed that at baseline the median frequency of weekly cataplexy attacks was 20.5, 20.0, 23.0 and 23.5 for the placebo and sodium oxybate 3g, 6g and 9g groups respectively. The median percentage change in cataplexy attacks from baseline to endpoint had been 28%, -49%, -49% and -69% for the placebo and sodium oxybate 3g, 6g and 9g groups respectively. This reached statistical significance at the higher dose. The second trial had similar inclusion and exclusion criteria to the first trial and involved 228 patients over the age of sixteen years with current symptoms of narcolepsy including cataplexy. The median percentage changes in the number of cataplexy attacks per week from baseline to endpoint had been 21.3%, -57.0%, -65.0% and -84.7% for the placebo, sodium oxybate 4.5g, 6g and 9g groups respectively (p<0.003 for all sodium oxybate groups versus placebo). The SMC had concluded that, due to a lack of an active comparator, the cost per QALY was approximately £120,000 and the manufacturer had confirmed that its original economic submission was flawed.</p>	<p>SD</p> <p>ST</p>

Item		Action
	<p>A second cost effective analysis had been submitted and this had compared sodium oxybate to placebo and the benefits were not now expressed in terms of cost per QALY so it was not possible to determine whether this was good value for money compared to other NHS resources.</p> <p>Mr Dhadli highlighted that there was no real new evidence since the original review relevant to the indication nor any indication that prices had changed. Dr Mott stated that it would be necessary to decide what should happen in the transition period when a young person with the condition became nineteen years of age and then became the responsibility of the CCG. Dr Dewis commented that these patients would need to be reviewed and queried whether there was a service for this.</p> <p>Mr Hulme advised that, in the event of a traffic light classification of BLACK, a general statement would be required to indicate the need for a review and use of the drug to be stopped except in cases of exceptionality when the IFR process would be used.</p> <p>Agreed: Sodium oxybate to remain classified as a BLACK drug for the treatment of narcolepsy with cataplexy in adults due to lack of data on effectiveness compared with standard therapy. Sodium oxybate was noted as a dual classified drug.</p>	SD
7.	CLINICAL GUIDELINES	
<p>a.</p> <p>b.</p>	<p><u>Attention Deficit Hyperactivity Disorder (ADHD) BP Monitoring</u> JAPC was advised of a service gap in adult mental health services concerning blood pressure and pulse monitoring for ADHD cases. Dr Taylor gave the background to the current situation and highlighted that there was currently no specific commissioned follow up in DHcFT for adult patients with ADHD and this was currently undertaken by local Community Health Teams.</p> <p>Dr Mott referred to the current shared care guideline which had a defined nurse-led service for children with a review every three months and annual follow up about prescribing. However there was no equivalent service for adults and this gap in service would need to be highlighted to Hardwick CCG as the lead commissioner for mental health services. It was agreed that best practice for adult patients should be a defined monitoring schedule with GP and consultant/specialist for HR and BP before and after dose changes, and then every three months</p> <p>Action: Dr Mott would write to Mr D Gardner, Hardwick CCG Commissioner, and update JAPC accordingly.</p> <p><u>Bisphosphonate Length of Treatment Guideline in Osteoporosis</u> Mr Dhadli stated that guidance had been developed for those patients on long-term bisphosphonates to indicate when it would be appropriate to have a drug holiday (suspension of active therapy) dependent on whether they were classified as high, medium or low risk. Mr Dhadli referred to the changes which had been made after consultation with DTHFT and CRHFT consultant pathologists, rheumatologists and endocrinologists.</p>	AM

Item		Action
	<p>Dr Mott queried the reference in the guideline to routine prescribing of calcium and vitamin D as it had been agreed that this should not be done except in cases of proven deficiency. Mrs Needham stated that this should be clarified to indicate that patients should have suitable dietary intake of calcium. Mr Dhadli highlighted the inclusion of 'if no fracture on treatment' in the treatment algorithm and the subsequent consideration of DEXA and FRAX.</p> <p>Agreed: JAPC ratified the amended bisphosphonate length of treatment in osteoporosis guideline with a review date of two years.</p>	SD
c.	<p><u>Continence Appliance Prescribing Guidelines</u> Mr Dhadli reported that the four continence guidelines had been updated by the DCHSFT Clinical Continence Nurse Specialist and only minor changes made.</p> <p>Agreed: JAPC ratified the Continence Appliance Prescribing Guidelines with a review date of two years.</p>	SD
d.	<p><u>Management of Chronic Obstructive Pulmonary Disease (COPD)</u> Mrs Qureshi stated that the COPD guidance had been updated and Ultibro® added as the LABA/LAMA of choice based on emerging evidence from the FLAME study and NICE surveillance report. Two tables had been added on pages 10 and 11 to indicate the range of LAMA inhalers and LABA/LAMA combination inhalers.</p> <p>The guideline group had recommended that Relvar® (fluticasone/vilanterol) should be re-classified from BLACK to BROWN respiratory consultant/specialist recommendation. This recommendation had been based on a positive review by the SMC on Relvar® in which it had been stated that a once-daily dosing regimen of LABA + ICS may be preferred by patients and could offer benefits in terms of compliance rather than twice-daily dosing. The device was a breath-activated inhaler which may be easier for patients to use and the price had now decreased. The guideline group had also recommended that the three LABA/LAMA products Duaklir® (Formoterol /aclidinium), Anoro® (Vilanterol/umeclidinium) and Spiolto® (Olodaterol/tiotropium) should all be re-classified to 1st line alternative LABA/LAMA. Mrs Qureshi added that no comments had been received from the DTHFT clinicians and Dr A Darby, CRHFT Consultant Acute and Respiratory Physician, had requested consideration of eosinophils count.</p> <p>During discussion it was agreed that the three LABA/LAMA products previously referred to should be classified as BROWN 2nd line after Ultibro® as the first line choice. Dr Henn referred to the COPD value pyramid in the guideline and advised that this could be out of date due to a reduction in costs for tiotropium and LAMAs. Dr Henn also advised that Symbicort® pressurised inhaler was currently GREEN second line to DuoResp® but, as it had now reduced in price, should be on the same level.</p> <p>Agreed: Relvar® classified as a BROWN drug following respiratory consultant/specialist recommendation. Ultibro® classified as BROWN 1st line. Duaklir® (Formoterol /aclidinium), Anoro® (Vilanterol/umeclidinium) and Spiolto® (Olodaterol/tiotropium) classified as BROWN 2nd line.</p>	SD

Item		Action
e.	<p>Agreed: The Management of Chronic Obstructive Pulmonary Disease (COPD) guideline was ratified by JAPC with the agreed amendments with a two year review date.</p> <p><u>Children's Referral Guideline for Sub-Lingual ImmunoTherapy (SLIT) – Grass Pollen Extract (Grazax)</u> JAPC noted that the reviewer of the guideline, Dr D Traves DTHFT Consultant Paediatrician, had declared a conflict of interest due to previously being provided with funds towards education events by ALK, the producers of Grazax. It was further noted that this has not been within the past twelve months.</p> <p>Mr Dhadli advised that this was an update to an existing guideline and Dr Traves had reported no major changes. Mr O Judd, Consultant ENT Surgeon, had advised that long-term use of beclomethasone drops was contraindicated and long term use of beclometasone spray should be monitored as the high bioavailability could suppress growth and the adrenal axis. Mr Judd had suggested fluticasone furoate or mometasone as preferred options. The guideline group had reviewed the submitted evidence for this and had ratified the addition of mometasone furoate nasal spray as a treatment alongside beclometasone nasal spray.</p> <p>Agreed: JAPC ratified the Grazax guideline with the addition of mometasone furoate as a treatment alongside beclometasone. All other relevant rhinitis guidelines would need to be consistently updated with mometasone nasal spray as an alternative 1st line steroid nasal option.</p>	SD
f.	<p><u>Lithium</u> Mr Dhadli reported that the lithium shared care guideline had not been due for review until October 2017 but it had now been updated by DHcFT with the addition of a flowchart to indicate how patients currently on lithium were managed. These included the patients who stayed under the service and those who went back to the community based teams. It was noted that the remainder of the guideline was unchanged.</p> <p>Agreed: JAPC ratified the lithium guideline with a two year review date.</p>	SD
g.	<p><u>Managing Behavioural Problems in Patients with Dementia (BPSD)</u> Dr Taylor stated that this was an update to existing guidance and there had been no major changes. The changes that had been made included:</p> <ul style="list-style-type: none"> • The evidence that mortality was greater with first generation antipsychotics had been enhanced. • Temazepam had been moved to second line in the poor sleep section for Alzheimer's Disease due to increased cost. • Trazodone had been added to the poor sleep section for Alzheimer's Disease following a recent RCT. • New information in the swallowing difficulties section of the dose guidelines for dementia. • Advice added for haloperidol to check ECG. 	SD

Item		Action
h.	<p>Agreed: JAPC ratified the Managing Behavioural Problems in Patients with Dementia Guideline.</p> <p>Vitamin D Mrs Qureshi had updated the vitamin D guidance and this had now been divided into two guidelines: Guidance on the prevention, diagnosis and management of vitamin D deficiency in primary care and a position statement on the prescribing of Vitamin D for the treatment of deficiency, maintenance and insufficiency.</p> <p>Dr Mott referred to the decision made by JAPC to provide the routine treatment to address vitamin D deficiency but not the maintenance. However there was some concern that this decision could impact disproportionately on minority ethnic groups and it was extremely important that a JAPC policy did not do this.</p> <p>However, it was highlighted that the guidelines did cover everybody.</p> <p>Agreed: JAPC ratified the guidance on the prevention, diagnosis and management of vitamin D deficiency in primary care.</p> <p>Action: Mrs Needham would send comments to Mrs Qureshi concerning the importance of aligning these guidelines with the osteoporosis guidance and also check that the stated treatment doses for children were correct.</p>	<p>SD</p> <p>SD</p> <p>KN</p>
8.	PATIENT GROUP DIRECTIONS	
	<p>The following PGDs from Public Health England/NHS England were noted and agreed by JAPC:</p> <ul style="list-style-type: none"> • Administration of shingles (herpes zoster, live) vaccine to individuals who are eligible for the national shingles immunisation programme for the prevention of herpes zoster (“zoster” or shingles) and herpes zoster-related post-herpetic neuralgia (PHN). • Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease. • Administration of meningococcal group A, C, W and Y conjugate vaccine (MenACWY) to individuals eligible for national routine MenACWY vaccination programme; university freshers (catch-up); outbreak control and contacts of confirmed cases, for active immunisation against Neisseria meningitidis. • Administration of rotavirus vaccine (live) to infants aged 6 weeks to 23 weeks and 6 days for active immunisation against rotavirus. 	
9.	SHARED CARE GUIDELINES	
a.	<p>Degarelix The shared care guideline for the treatment of adult male patients with advanced hormone-dependant prostate cancer had been sent to CRHFT and DTHFT clinicians for comment and no changes had been made apart from revised contact details and a reference to NICE technology appraisals.</p> <p>Agreed: JAPC ratified the shared care guideline for the treatment of adult male patients with advanced hormone-dependant prostate cancer with a two year review date.</p>	SD

Item		Action
b.	<p><u>Methotrexate</u></p> <p>Mr Dhadli reported that the recent British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR) guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs (DMARDs) had been circulated to JAPC for reference. The shared care guideline for methotrexate had been sent for comment to CRHFT and DTHFT clinicians but no responses had been received to date. Mr Dhadli advised that a general template would be used for all the DMARD shared care guidelines and highlighted the new references to immunisations, height and weight and blood pressure to be taken before commencement of treatment. The consultant/specialist monitoring schedule had been standardised at two weekly until on a stable dose for six weeks. It would then be monthly for three months when the GP would take over the monitoring.</p> <p>In addition, the section concerning actions to be undertaken had been updated from the previous version and a specific methotrexate section added as follows:</p> <ul style="list-style-type: none"> • Background lung disease should not be considered an absolute contraindication to methotrexate use; although in patients with poor respiratory reserve caution was advised. • Doses included from BNF for all licenced indications where missing previously. • Adverse effects included which were listed as common in BNF and SPC. • Advice regarding chickenpox or shingles exposure. • Drug specific actions regarding methotrexate toxicity symptoms (also added to patient responsibility). • Further drug interactions/contraindications and cautions added from British National Formulary. • Hospital nurse advice line added. • Pro-collagen III remained on shared care for dermatology patients for psoriasis. <p>Mr Dhadli stated that one comment had been received which advised that methotrexate should be stopped when antibiotics were prescribed. However it had been decided to retain this in the guidance as the BSR guidance referred to severe infections only.</p> <p>Dr Mott highlighted that the drug specific page did not mention methotrexate – this would be included. Dr Mott also queried the lack of a reference to minimum time for review and it was agreed that a yearly review should be added to the consultant responsibilities.</p> <p>Mr Dhadli advised that the BSR guidance also referred to combination therapy as opposed to the monotherapy shared care guidelines which were now beginning to come through. This had been queried with clinicians but no response had been received. Mr Dhadli also advised that the BSR guidance had indicated that penicillamine was no longer used. However prescribing data had revealed that there was still usage and Mr Dhadli would liaise with consultant rheumatologists about their use of penicillamine.</p> <p>It was noted that methotrexate was the first in a series of immunomodulating shared cares to be tabled at JAPC.</p>	<p></p> <p>SD</p> <p>SD</p> <p>SD</p>

Item		Action
	<p>In time the monitoring schedules for these would become standardised.</p> <p>Agreed: JAPC ratified the shared care guideline for methotrexate with a two year review date.</p>	SD
10.	MONTHLY HORIZON SCAN	
	<p>Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations:</p> <p>New drug launches in the UK:</p> <p>Tofacitinib (Xeljanz®) - Janus kinase (JAK) 3 inhibitor – Classified as BLACK pending NICE review.</p> <p>Rituximab biosimilar (Truxima®) – Already classified as RED.</p> <p>Baricitinib (Olumiant®) - Selective JAK1 and JAK2 inhibitor; JAK3-sparing. An oral alternative to biological therapies - Classified as BLACK pending NICE review.</p> <p>Albutrepenonacog alfa – NHS England. Classified as RED.</p> <p>Licence extensions:</p> <p>Tenofovir disoproxil + emtricitabine (Truvada®) – RED</p> <p>Dabrafenib (Tafinlar®) – RED</p> <p>Drug discontinuations:</p> <p>Ciloxan Ointment (ciprofloxacin)</p> <p>Docusol (docusate sodium)</p> <p>Emadine (emedastine)</p> <p>Oraldene (hexetidine)</p> <p>Actidose-Aqua (activated charcoal)</p>	
11.	MISCELLANEOUS	
<p>a.</p> <p>b.</p>	<p>JAPC Annual Report</p> <p>The JAPC Annual Report April 2016 to March 2017 was noted for information. This should be fed through each CCG Governing Body in line with JAPC's delegated function.</p> <p>Drug and Therapeutics Bulletin Reviews</p> <p>Dequalinium for Bacterial Vaginosis</p> <p>Mr Dhadli stated that dequalinium for the treatment of recurrent bacterial vaginosis was classified as BROWN second line option alongside clindamycin after treatment failure and/or intolerance to metronidazole. The DTB had concluded that dequalinium was more expensive than oral or topical metronidazole, but less expensive than topical clindamycin and non-inferior. Based on the results of the only published trial, the most appropriate place in therapy for dequalinium vaginal tablets was as an alternative to clindamycin cream. The slightly shorter duration of treatment and tablet formulation may be preferred by some women. Although there was limited information on the development of resistance to dequalinium, it provided a possible alternative to reduce the use of topical antibacterial agents.</p> <p>Turning the tide of high-dose inhaled corticosteroids</p> <p>This referred to the fundamental changes that could change the use of high-dose inhaled corticosteroids in many patients and the concern which had been expressed at the extent of high-dose ICS use, partly because of the cost to the NHS, but also because of adverse effects such as pneumonia, osteoporosis and adrenal suppression.</p>	KN/SH

Item		Action
b.	<p>The new asthma guideline has moved away from using stepping up and stepping down terminology and instead referred to options for trials of treatment with assessment of response.</p> <p><u>Principles to Determine JAPC Traffic Light Classifications for Medical Devices and Appliances (MDaA)</u> Mr Dhadli reported that this was an update to an existing guideline and reminded clinicians that any request from a NHS provider/Trust or specialist must come via the appropriate Trust decision making committee responsible for MDaA such as the Drugs and Therapeutics Committee.</p>	
12.	JAPC BULLETIN	
	The bulletin was noted for information and ratified by JAPC.	SD
13.	MHRA DRUG SAFETY UPDATE	
	<p>The MHRA Drug Safety Alert for May 2017 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> • Finasteride: rare reports of depression and suicidal thoughts. • New e-learning modules on reporting suspected adverse drug reactions. • Letters sent to healthcare professionals in April 2017 including reminder of retigabine (Trobal®) withdrawal. 	
14.	NICE SUMMARY	
	<p>Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in May 2017.</p> <p>TA 444 Afatinib for treating advanced squamous nonsmall - cell lung cancer after platinum-based chemotherapy (terminated appraisal). Classified as BLACK.</p> <p>TA 445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs. Certolizumab pegol alone, or in combination with methotrexate, was recommended as an option for treating active psoriatic arthritis in adults. Secukinumab alone, or in combination with methotrexate, was recommended as an option for treating active psoriatic arthritis in adults. No significant resource impact was anticipated for CCGs. Both drugs had been incorporated in the algorithm and sent to Dr S O'Reilly, DTHFT Consultant Rheumatologist. Both drugs classified as RED.</p> <p>NG 69 Eating disorders: recognition and treatment. The guideline was a full update of NICE Clinical Guideline 9 published in January 2004 and would replace it. No significant impact on NHS resources was anticipated.</p> <p>NG 28 (updated from December 2015) Type 2 diabetes in adults: management. The local diabetes guideline has been updated to highlight when the SGLT2 inhibitors could be used as an option when metformin was not indicated.</p>	<p>SD</p> <p>SD</p>

Item		Action
15.	<p>GUIDELINE GROUP ACTION TRACKER</p> <p>The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in May 2017 was noted. Mr Dhadli highlighted the following:</p> <p>Traffic Lights:</p> <ul style="list-style-type: none"> • Prednisolone soluble classified as BROWN as less cost effective than current standard therapy. • Ticagrelor had a dual classification of GREEN after specialist/consultant initiation: NICE TA 236 Acute Coronary Syndromes and BROWN after specialist/consultant initiation: 60mg twice daily as per NICE TA420 for preventing atherothrombotic events after myocardial infarction. • Risedronate 35mg once weekly tablet classified as GREEN. • Insulin Aspart (Fiasp®) classified as GREEN. • Levothyroxine classified as GREEN. • SPAT decisions relating to branded generics: Alzest® preferred brand of rivastigmine patches; Kemadrin® preferred brand of procyclidine and Amoxil® preferred brand of amoxicillin capsules. <p>Guidelines:</p> <ul style="list-style-type: none"> • De-prescribing April 2017 - Update expected in August from the De-Prescribing Group • IBS May 2017 - Addition of linaclotide to the IBS flowchart and a response was awaited from Dr P Blackwell on the laboratory reporting of calprotectin values. 	
16.	<p>TRAFFIC LIGHTS – ANY CHANGES?</p> <p>Classifications</p> <p>Insulin Aspart (Fiasp®) – GREEN</p> <p>Liothyronine – Provisional decision of BLACK</p> <p>Sodium Oxybate – BLACK for adults</p> <p>Relvar® (fluticasone/vilanterol) – BROWN after consultant/specialist recommendation</p> <p>Ultibro® (indacaterol/glycopyrronium) – BROWN 1st line</p> <p>Duaklir® (formoterol/aclidinium) – BROWN 2nd line</p> <p>Anoro® (vilanterol/umeclidinium) – BROWN 2nd line</p> <p>Spiolto® (olodaterol/tiotropium) – BROWN 2nd line</p> <p>Tofacitinib (Xeljanz®) – BLACK</p> <p>Baricitinib (Olumiant®) – BLACK</p> <p>Albutrepenonacog alfa – RED</p> <p>Afatinib – BLACK (as per NICE TA 444)</p> <p>Certolizumab – RED (as per NICE TA 445)</p> <p>Secukinumab – RED (as per NICE TA 445)</p> <p>Tenofovir and emtricitabine – RED</p> <p>Dabrafenib - RED</p> <p>Mometasone nasal spray – GREEN 1st line options alongside beclometasone</p> <p>Mr Dhadli queried whether the Traffic Light Classification for Prescribing list was still required by JAPC. Following discussion it was agreed that a comprehensive list of all the classified drugs would be compiled, with the exception of the green drugs, for the next JAPC meeting.</p>	<p>SQ/SD</p>

Item		Action
17.	JAPC ACTION SUMMARY	
	<p>The action summary was noted by JAPC and amendments made:</p> <p>DMARDS/Immunomodulating shared care – This was a rolling programme and the methotrexate shared care guideline had now been discussed by JAPC.</p> <p>Juxta Cures – An application had been made to the DTHFT Drug and Therapeutic Committee and would be brought to the JAPC in either August or September 2017.</p> <p>Suspected DVT/NOAC/D-dimer – To be brought to the September 2017 JAPC meeting.</p> <p>NRT and service provision – To be brought to the October 2017 JAPC meeting.</p> <p>Bariatric surgery – To be taken off the list.</p> <p>Rosuvastatin – To be brought to the December 2017 JAPC meeting.</p> <p>Etanercept ‘Lifmior’ biosimilar – To be brought to a future JAPC meeting following contract decision with an opportunity cost paper</p> <p>Rituximab biosimilar – To be brought to the September 2017 JAPC meeting.</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
18.	MINUTES OF OTHER PRESCRIBING GROUPS	
	<ul style="list-style-type: none"> • DTHFT Drugs and Therapeutic Group 18/04/17 • JAPC Working Group 14/02/17 • JAPC Working Group 14/03/17 • Nottingham Area Prescribing Committee 19/01/17 • Nottingham Area Prescribing Committee 16/03/17 • Sheffield Area Prescribing Group 19/01/17 • Sheffield Area Prescribing Group 16/02/17 <p>Mr Dhadli highlighted the following:</p> <ul style="list-style-type: none"> • Nottingham Area Prescribing Committee – A current gap in the ADHD service for adults had been discussed. • Sheffield Area Prescribing Group - Mycophenolate mofetil and proposal to transfer the prescribing and monitoring of stable patients to primary care under a shared care guideline. Also liothyronine discussed as a QIPP opportunity. 	
19.	ANY OTHER BUSINESS	
	<p>Mr Dhadli referred to a long-term supply issue of sucralfate and the consequent need to source from specials when prescribed. This was very expensive and providers had been requested not to recommend if possible.</p>	
20.	DATE OF NEXT MEETING	
	<p>Tuesday, 11th July 2017 at 1.30pm in the Post Mill Centre, South Normanton.</p>	