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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 14th March 2017

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Ciclosporin (Ikervis®) eye drops	BROWN specialist initiation
Glycopyrronium oral medication (Sianalar®)	BROWN 2nd line specialist/consultant initiation for children after trial or consideration of hyoscine (oral and/or patches)
Donepezil	GREEN 1st line after specialist initiation and stabilisation for three months
Galantamine	GREEN 2nd line after specialist initiation and stabilisation for three months
Memantine hydrochloride	GREEN 2nd line after specialist initiation and stabilisation for three months
Rivastigmine	GREEN 2nd line after specialist initiation and stabilisation for three months
Rubefacients	All rubefacients to be classified as BLACK.
Medroxprogesterone acetate (Sayana Press®)	GREEN (after appropriate patient training)
Migalastat	RED
Everolimus	RED (as per NICE TA432)
Apremilast	RED (as per NICE TA433)
Alpha-1 antitrypsin (Respreeza®)	RED
Dalbavancin (Xydalba®)	RED
Dapagliflozin + Saxagliptin (Qtern®)	BLACK
Liraglutide (Saxenda®)	BLACK for weight management
Tobramycin (Xydalba®)	RED
Zoledronate	RED
Influenza vaccines	GREEN as per National Vaccination Programme

Clinical Guidelines

Management of Dementia in Primary Care.
Osteoporosis.
Phosphate binders guideline for the long-term treatment of hyperphosphataemia in patients on dialysis.
Vitamin supplementation in alcohol misuse.
Sayana Press® (Medroxyprogesterone Acetate) primary care protocol.

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Patient Group Directions

- Administration of meningococcal group A, C, W, and Y conjugate vaccine (MenACWY) to individuals with an underlying medical condition which puts them at increased risk from Neisseria meningitidis.
- Administration of meningococcal group B vaccine (rDNA, component, adsorbed) to individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from Neisseria meningitidis group B.
- 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 B vaccine (rDNA, component, adsorbed) to individuals from 8 weeks of age eligible for the national routine immunisation programme and to individuals for the prevention of secondary cases of meningococcal group B disease for active immunisation against Neisseria meningitidis group B. This Meningococcal Group B PGD was a replacement of the existing one for the routine Men B immunisation programme.

Shared Care Guidelines

Methotrexate between Stepping Hill Hospital and North Derbyshire CCG.
Denosumab for the prevention of osteoporotic fractures in men and post-menopausal women.

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management
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	
Dr R Dewis	Consultant in Public Health Medicine
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr J Leung	Acting Chair – Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Assistant Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms J Shaw	Principal Pharmacist
In Attendance:	
Ms V Griffiths	Assistant Director of Planning, Southern Derbyshire CCG
Mr A Thorpe	Derby City Council (minutes)
Ms D Tomlinson	Project Support Officer, Southern Derbyshire CCG

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Item		Action
1.	**APOLOGIES**	
	Ms S Bassi and Ms B Thompson.	
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**	
	• Braltus Inhalation Powder • Ibandronic Acid use in North Derbyshire	
4.	**MINUTES OF JAPC MEETING HELD ON 14 FEBRUARY 2017**	
	The minutes of the meeting held on 14th February 2017 were agreed as a correct record after the following amendments: Doxazosin MR – Amend to: 'Mrs Qureshi advised that doxazosin modified release (MR) was included in the PrescQIPP Drugs Of low Priority (DROP) List and the Guideline Group had recommended a re-classification of this drug from BROWN to BLACK.' Low Molecular Weight Heparins (LMWH) – Amend to: 'Dr Parkin referred to the use of LMWH in patients with suspected DVT.' Outpatient and Parenteral Antimicrobial Therapy (OPAT) Policy for Primary Care (Step-Up Pathway) – Amend to: 'The range of IV medications used had historically involved IV antibiotics and, as a consequence of the expansion of the outpatient antibiotic team and pathways, there was now an opportunity to widen the range of IV antibiotics used to help avoid hospital admissions.' Any Other Business – Amend to: 'Concern had been expressed by Chesterfield GPs about their liability to prescribe this for unlicensed use.'	
5.	**MATTERS ARISING**	
a.	**<u>Suspected DVT Pathway</u>** Mrs Needham reported that work on the suspected DVT pathway had now been transferred to Dr Eleanor Rutter, Consultant in Public Health, Derbyshire County Council, and a meeting had been arranged to take this forward. An issue had been highlighted concerning near patient testing in primary care and this would be discussed at this meeting. Dr Henn queried the involvement of clinicians and was assured that GPs would be fully engaged in the ongoing work.	
b.	**<u>Outpatient and Parental Antimicrobial Therapy (OPAT) Policy for Primary Care (Step-Up Pathway)</u>** It had been queried whether local pharmacies would be able to hold sufficient stocks of IV antibiotics to enable the DCHSFT Rapid Response Team to manage patients in the community and therefore avoid unnecessary hospital admissions.	

Item		Action
	Mrs Needham advised that currently the Rapid Response Team had a limited amount of medication or that these were accessed from CRHFT by relatives or staff. However, it would not be economically viable to look at the feasibility of a pharmacy stockist scheme due to the small numbers of patients involved. Mrs Needham added that feedback had not yet been received concerning the queries from Dr Diane Harris, Lead Antimicrobial Pharmacist, which had been highlighted at the last JAPC meeting.	
c.	**Derby Urgent Care Centre (DUCC) Patient Group Directions** Mrs Qureshi reported that the queries raised by JAPC about the antimicrobial PGDs had been conveyed to DUCC and the responses received back were currently being reviewed by Dr Diane Harris. These would be brought back to a future JAPC meeting.	**SD**
d.	**Psoriasis Pathway** Mr Shepherd reported that the CRHFT dermatologists had now agreed to move to a single psoriasis pathway within Derbyshire and consequently this would now be adopted.	**SD**
6.	**NEW DRUG ASSESSMENTS**	
a.	**Ciclosporin Eye Drops** Mr Shepherd stated that ciclosporin eye drops had been used successfully on a small number of patients with severe dry eye disease with regular review by ophthalmologists. No drug monitoring was required and therefore it had been decided to request a re-classification from RED, which JAPC had assigned in January 2017 following the publication of NICE TA 369 'Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears', to GREEN specialist initiation. Mr Dhadli added that there was no specific monitoring in relation to the drug and no serious common side effects. The SPC was noted which indicated that response to treatment should be assessed at least every six months. A decision was therefore required about the position of ciclosporin eye drops and to determine whether GPs would be comfortable to prescribe. Dr Parkin and Dr Emslie commented that no monitoring would be required with the proviso that the follow up of patients was robust and the drug was not being used over a long period of time. Both DTHFT and CRHFT gave an assurance that these patients were routinely followed up. A definite stop date would also be required in patients on short courses. **Agreed:** Ciclosporin eye drops classified as a **BROWN** specialist initiation drug as a small cohort of patients could benefit from prescribing.	**SD**
b.	**Glycopyrronium Bromide** Mr Dhadli stated that glycopyrronium oral treatment (Sialanar®) was the first licensed glycopyrronium product for short-term intermittent use for severe sialorrhoea (drooling) in children and young people with chronic neurological disorders. Previously, people requiring treatment with glycopyrronium bromide have used imported products or formulations made by specials manufacturers.	

Item		Action
	The NICE Evidence Summary published in February 2017 on severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide had highlighted the following key points: • Two double-blind small randomised controlled trials (RCTs) which compared glycopyrronium bromide with placebo for the treatment of severe sialorrhoea in children and young people with chronic neurological conditions. • The majority of participants with neurological problems had cerebral palsy. • Statistical significant improvement in drooling after eight weeks. • NICE reviewed two small randomised controlled trials (RCTs) n=77. • Lack of long term data. • Studied against placebo with no comparative studies • Most children had cerebral palsy and not extensively studied in other neurological conditions. • One RCT noted to have a high dropout rate of 31% which was excluded from the efficacy studies. However in line with Article 10(a) of Directive 2001/83/EC, license applications for a medicine that had a well-established use with a recognised efficacy and safety profile could be supported by a bibliographic application that did not require the manufacturer to carry out new clinical trials with their formulation of the drug. The SPC had reported that side effects were common with glycopyrronium bromide due to its anticholinergic effects and this could result in dry mouth, constipation, diarrhoea and urinary retention. The SPC had also noted that published safety data was not available beyond twenty-four weeks treatment duration. In view of the limited long-term safety data and the uncertainties around the potential risk of carcinogenicity, the SPC advised that the total treatment duration should be kept as short as possible. It was noted that glycopyrronium bromide 400 micrograms/ml oral solution (Sialanar®) cost had been compared with hyoscine hydrobromide tablets and hyoscine hydrobromide patches and was significantly more expensive than the other treatments which could be used off-licence. Feedback had been obtained from the specialist at DTHFT that GPs would continue to prescribe this for the patients who were on glycopyrronium long-term and that hyoscine was recommended first line. However a number of children developed localised skin reactions to the hyoscine patches so a change to glycopyrronium would be made. Hyoscine patches were also difficult to titrate in small children. A discussion took place on the use in adults. There was some evidence that oral glycopyrronium bromide (tablets and solution or suspension) reduced hypersalivation or drooling in children and young people with a neurological condition, together with adults with Parkinson's disease. There was also limited evidence of its efficacy in adults with schizophrenia and clozapine-induced hypersalivation. It was highlighted that DTHFT and Sheffield would like to use hyoscine off-licence first line and glycopyrronium bromide, although a licensed product, as second line.	

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Item		Action
	During discussion Mr Hulme stated that there would be a need to define its place in treatment and to determine whether glycopyrronium would be used intermittently on a short-term basis or long-term. It would be useful to ascertain the numbers of children involved. Dr Henn referred to the decision by Nottinghamshire Area Prescribing Committee to defer a decision on gylcopyrronium pending the arrival of different brands of the drug and highlighted that hypersalivation was a significant clinical problem in some children with disabilities. The risk of long-term use without any benefit was small as parents would notice whether it worked or not. **Agreed:** Glycopyrronium bromide classified as a **BROWN** 2nd line specialist/consultant initiation drug after hyoscine for sialorrhoea in children with chronic neurological conditions. **Action:** More information would be obtained on the numbers involved and further consideration given to the use of glycopyrronium in adults.	**SD** **SD**
c.	**<u>Juxta CURES</u>** Mr Dhadli reported that some GPs had been requested to prescribe Juxta CURES, an adjustable compression system for the treatment of venous leg ulcers, by the DTHFT vascular department although no traffic light classification had been assigned. Juxta CURES was currently unclassified and JAPC had previously decided that requests to use medical appliances, which were prescribed via FP10, should be assessed by the requesting Trust Drugs and Therapeutics Committees. DCHSFT had advised that the Juxta CURES system was mainly used for patients who could not tolerate compression bandaging/leg ulcer hosiery kits and where there were no primary care services to support patients. Other uses were for patients with chronic oedema and in lymphoedema clinics. The NICE Evidence Summary on chronic wounds, advanced wound dressings and antimicrobial dressings had indicated that the use of Juxta CURES would free up GP and practice/district nurse time and was therefore cost effective. Key points from the Evidence Summary were: • There were a small number of published case reports. • Evidence included posters and an abstract • The number of patients involved in these studies had made the data unreliable. • Non-comparative studies versus 4- or 3-layer bandaging. • Patient training would be required. • Thirty-one trials had been initially identified and twenty-one had been excluded due to not meeting the inclusion criteria. Mr Dhadli advised that the evidence was very low level and that the cost effectiveness of the Juxta CURES system had been queried and some specialists had erroneously thought that NICE had recommended their use as it did for technology appraisals. There had also been some low level prescribing locally since 2012. During discussion Dr Mott commented that the use of the Juxta CURES system had the potential to save money but questioned whether there was sufficient evidence to recommend use.	

Item		Action
	Mr Hulme suggested that a traffic light classification of RED for new patients should be assigned and the dressings sub-group then to define the cohort of patients who would benefit from use. Mr Dhadli highlighted that the use of the Juxta CURES system would require patient training and education on adjustments to be made but the overall aim would be to promote self-care. The evidence did not support its routine use over established treatment (3/4 layer compression bandaging). **Agreed:** JAPC agreed that there was insufficient information at present to assign a traffic light classification and consequently the Juxta CURES system would remain unclassified at present. It was noted that the DTHFT Drugs and Therapeutic Committee had not been requested to consider the Juxta CURES system. **Action:** The dressings sub-group would be asked give a view on the Juxta CURES system within a two month timescale and this would be placed on the action tracker.	**SD** **SD**
7.	**CLINICAL GUIDELINES**	
a.	**Management of Dementia in Primary Care** Mr Dhadli reported that there were currently two shared care guidelines for dementia medications which required specialist follow up. The new guidance recommended patients would continue to be normally screened in primary care and then referred for a specialist memory assessment process who would give a diagnosis, if appropriate, and stabilise the patient on treatment, if indicated. It was then proposed that primary care would take over the management of repeat prescribing once the patient was stable (after three months), with annual QOF reviews being sufficient for ongoing reviews, to include assessment of any adverse events and drug interactions. A guideline for the management of dementia in primary care had therefore been developed which effectively merged the two existing shared care agreements for the acetylcholinesterase inhibitors (AChEI) and memantine which had been in place between primary and secondary care. The memantine shared care guideline had been developed following the publication of NICE technology appraisals of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease which were now dated. There had also been a significant reduction in the cost of AChEI and memantine due to the increasing availability of generic versions of these drugs. It was proposed that the specialist would monitor the initial response to treatment with a three month review, and then identify those patients that could be safely managed in primary care and those who needed ongoing review within the specialist service. Dr Mott reported that agreement had been reached with DHcFT that the prescriber of the new drug must take responsibility for ensuring that this was safe and to consider ECG if clinically necessary. It was also noted that the Guideline Group had added a reference to de-prescribing in how to manage reduction of doses. Dr Henn asked if the guidance could include the type of patients to de-prescribe in e.g. patients in end of life and Mr Dhadli agreed to follow this up with DTHFT.	**SD**

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Item		Action
	Mrs Needham highlighted the cost differences between treatments and that a further reference should be made to choices of drug. Dr Watkins and Dr Narula highlighted the importance of additional emotional and social support at point of discharge at three months and this should include the provision of information about available help from social care. Dr Emslie commented that no patients in North Derbyshire were followed up after discharge to primary care but the community matron often provided useful resources and advice. Mr Dhadli advised that the Southern Derbyshire CCG specification referred to the provision of support and advice to the ongoing treatment of patients with dementia including personalised care plans. **Agreed:** JAPC ratified the Management of Dementia in Primary Care guideline with the agreed amendments. **Agreed:** Donepezil classified as a **GREEN** 1st line drug after specialist initiation and stabilisation. **Agreed:** Galantamine, memantine and rivastigmine classified as **GREEN** 2nd line drugs after specialist initiation and stabilisation.	**SD** **SD** **SD**
b.	**<u>Nicotine Replacement Therapy Direct Supply Protocol</u>** Dr Dewis reported that the Derbyshire County Smoking Cessation Service would be brought in-house later in the year and a Protocol for the Direct Supply of Nicotine Replacement Therapy (NRT) for Advisors of the Live Life Better Derbyshire Service had been developed. Mrs Needham highlighted that a key change would be the direct supply of Nicotine Replacement Therapy (NRT) products rather than on prescription or via vouchers. An initial draft of the NRT direct supply protocol had been discussed by the Shared Care and Guidelines Group in August 2016 and revisions had subsequently been made. Mrs Needham referred to ongoing discussions concerning the financial implications of direct supply including the re-charging issue. Mr Jones queried whether the section in the protocol on clozapine should indicate the need for patients who were on this drug to be referred back to a GP. It was agreed therefore that the wording on clozapine would be amended. **Action:** The protocol would be brought back to JAPC in October/November 2017 in order that the NRT products could be assigned a traffic light classification. A reference to the protocol would be included in the JAPC bulletin and newsletter.	**SD** **SD**
c.	**<u>Osteoporosis</u>** Mr Dhadli reported that a new osteoporosis guideline had been developed in line with national guidance, relevant Royal College publications, medical opinion obtained via a meeting with the DTHFT and CRHFT endocrinologists, Dr P Masters and Dr R Stanworth. As with cardiovascular disease, a risk assessment should be carried out for primary prevention of osteoporosis and only those at significant risk of osteoporotic fracture should be treated.	

Item		Action

	On the specific issue of the assessment tool it had been decided to use FRAX rather than QFracture and it was noted that this was the tool recommended by the National Osteoporosis Guideline Group (NOGG).
	
	Mr Dhadli outlined other key points in the revised guidance:
	• The guideline included some of the recommendations from SIGN, NICE, NOGG and local expert opinion.
	• Assessment of fracture risk in patients with significant risk factors or three other risk factors was a pragmatic decision.
	• Patients are stratified as low risk, intermediate risk or high risk.
	• Unlike SIGN men should be investigated for underlying causes before being referred for specialist assessments.
	• Changes from the current recommendation of oral steroids included:
	  ○ People under 40 years of age who could not be risk assessed using FRAX and taking 7.5mg or more per day of oral prednisolone for three months or longer, would require a BMD assessment using DEXA.
	  ○ Patients on equivalent of 15mg or greater of prednisolone require preventative treatment
	  ○ Patients on lower doses of prednisolone should be assessed through FRAX
	• Calcium and Vitamin D supplementation not now routinely recommended unless proven deficiency existed. However patients who are elderly housebound or living in residential/nursing homes are likely to gain benefit from lifelong calcium + vitamin supplementation.
	• No changes to current traffic light classifications recommended except to classify zoledronate infusions as RED.
	• Once daily TheiCal D3 (calcium + Vitamin D) chewable tablets for patients with compliance issues included in formulary choices.
	
	Mr Jones queried whether there had been any discussion about the inclusion of hyperprolactamemia as a risk factor. Mr Dhadli would enquire and report back.
	
	Agreed: Zolendronate classified as a **RED** drug.
	
	Agreed: JAPC ratified the osteoporosis guideline with a two year review date.
		SD
		
		SD
		
		SD
		
		SD

d.	**<u>Phosphate Binders</u>** Mr Dhadli reported that the existing phosphate binders guideline for the long term treatment of hyperphosphataemia in patients on dialysis had been sent to the DTHFT and CRHFT renal specialists for comment. Comments had now been received back and the use of generic sevelamer carbonate had been referred to. Sevelamer was available as hydrochloride or carbonate salts and there are now generic sevelamer products available which are considerably cheaper than the branded versions. Dr R Fluck, DTHFT Nephrologist, had indicated that he was happy with the switch to generic sevelamer and it was noted that North Derbyshire patients were treated in Sheffield where sevelamer has a RED traffic light classification. Dr Leung highlighted that a problem with phosphate binders was patient compliance.	

Item		Action
	Sevelamer had previously been classified as GREEN and a note would be added to prescribe generically as the preferred cost effective choice. **Agreed:** JAPC ratified the phosphate binders guideline for the long-term treatment of hyperphosphataemia in patients on dialysis.	**SD**
e.	**<u>Vitamin Supplementation in Alcohol Misuse</u>** Mr Dhadli reported that the position statement for vitamin supplementation in alcohol misuse is had been sent out for review to DHTHFT, CRHFT and DHcFT and only minor changes had been made. **Agreed:** JAPC ratified the guideline for vitamin supplementation in alcohol misuse with a two year review date.	**SD**
8.	**PATIENT GROUP DIRECTIONS**	
	The following PGDs from NHS England were noted and agreed by JAPC: • Administration of meningococcal group A, C, W, and Y conjugate vaccine (MenACWY) to individuals with an underlying medical condition which puts them at increased risk from Neisseria meningitidis. • Administration of meningococcal group B vaccine (rDNA, component, adsorbed) to individuals, from 2 years of age, with an underlying medical condition which puts them at increased risk from Neisseria meningitidis group B. • 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 B vaccine (rDNA, component, adsorbed) to individuals from 8 weeks of age eligible for the national routine immunisation programme and to individuals for the prevention of secondary cases of meningococcal group B disease for active immunisation against Neisseria meningitidis group B. This Meningococcal Group B PGD was a replacement of the existing one for the routine Men B immunisation programme.	
9.	**SHARED CARE GUIDELINES**	
a.	**<u>DMARDs/Immunomodulating Drugs</u>** Mr Dhadli stated that the British Society for Rheumatology (BSR) had published guidelines on Disease-modifying anti-rheumatic drugs (DMARDs) in 2008 and subsequently some of the shared care guidelines had been reviewed with minor changes following consultation with clinicians. An update had now been published by the BSR and changes included: • Harmonisation of the DMARDS monitoring schedules had now been made to the DMARDS monitoring schedules to indicate that all the DMARDs which required laboratory monitoring followed the same frequency of testing. The only exceptions were tacrolimus, ciclosporin and methotrexate/leflunomide combinations for which extended monthly monitoring beyond six months was recommended. • Use of methotrexate in lung disease using information from two large meta-analyses which had been recently published.	

Item		Action
	• Significant change had been made concerning the evaluation of retinal toxicity for hydroxychloroquine users when patients should have baseline screening within the first year of commencing therapy and then annual OCT assessments after five years. Mr Dhadli advised that work had commenced on the updating of the revised guidance and comments would be sought from all the relevant specialties and from CRHFT and DTHFT clinicians. It was noted that responses from the specialties from the two Trusts would be co-ordinated by Dr A Austin, DTHFT Consultant in Hepatology and Gastroenterology. Mr Dhadli added that work had already commenced to update the methotrexate shared care guideline to act as template for agreeing schedule changes and responsibilities between primary and secondary care. **Agreed:** It was agreed that the remaining shared care guidelines should be updated and presented to the June JAPC meeting. Dr Leung queried whether hydroxychloroquine would be included in the DMARDs review. Mr Dhadli advised that hydroxychloroquine had been re-classified from amber to GREEN specialist initiation and required an enquiry about any visual impairment annually by the GP. Mr Dhadli highlighted a notable change in to local recommendations and BSR in relation to ocular screening.	**SD**
b.	**Shared Care Protocol for Methotrexate between Stepping Hill Hospital and North Derbyshire CCG** Mrs Needham reported that Stockport CCG had a shared care protocol with Stepping Hill Hospital in Stockport which stipulated that, after the baseline blood tests had been undertaken, GPs would initiate prescribing of methotrexate, then titrate the dose and carry out all the blood tests. However JAPC had agreed that the specialist should initiate treatment and titrate the dose for at least twelve weeks before the GP would agree to shared care. This had been a long standing issue but it was now anticipated that a new shared care protocol would resolve the difficulties which had been encountered. This new shared care protocol would require the specialists to initiate and stabilise treatment and patients would be given blood test forms by Stepping Hill Hospital at the time of initiation so that GP practices could carry out the tests, but the results would be sent to the specialist for review and action. Mr Dhadli would include a reference to the new shared care protocol on the medicines management website and added that this would require a revision shortly in view of the BSR publication previously referred to. **Agreed:** JAPC ratified the Shared Care Protocol for Methotrexate between Stepping Hill Hospital and North Derbyshire CCG.	**SD** **SD**
c.	**Denosumab** Mr Dhadli reported that the denosumab shared care guideline had been sent to DTHFT and CRHFT specialists and some changes had consequently been made. The main change concerned all the patients with a eGFR >40ml/min/1.73m², who were given the baseline injection in hospital, and it was now recommended that the second subsequent injection six months later could safely be administered in primary care as part of the shared care guideline if the patient's eGFR was >40ml/min/1.73m².	

Item		Action
	If the patient's eGFR was <40ml/min/1.73m² both injections would be given in secondary care and the patient then discharged to primary care. Clinicians had explained that the 40ml/min/1.73m^2 was taken arbitrarily but cautiously recognised variation between the Cockcroft Gault calculation of creatinine clearance and the more routine use of eGFR in primary care **Agreed:** JAPC ratified the denosumab shared care guideline with the agreed amendments for a period of two years.	**SD**
9.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New drug launches in the UK: Alpha-1 antitrypsin (Respreeza®) – NHS England. Classified as **RED.** Dalbavancin (Xydalba®) - Within tariff. Classified as **RED.** Insulin aspart (Fiasp®) - Guidance to be sent to diabetologists for update. New formulation launches in the UK: Dapagliflozin + saxagliptin (Qtern®) – This was not a combination recommended in the NICE diabetes guidance. Classified as **BLACK.** Licence extensions: Liraglutide (Saxenda®) – Classified as a **BLACK** drug pending receipt of specialist advice of its place in therapy for weight loss. Tobramycin (Vantobra®) – NHS England. Classified as **RED.**	**SD** **SD** **SD** **SD** **SD**
10.	**MISCELLANEOUS**	
a.	**PrescQIPP DROP- list** Full Review and Feedback/Rubefacients: Mr Dhadli reported that the Guideline Group has completed a comprehensive review of the PrescQIPP DROP-List. This included aliskiren (rasilez®), tadalafil (cialis® once-a-day), doxazosin MR, fentanyl immediate release formulations, lidocaine patch (versatis®, lidoderm®) and omega-3 and other fish oils. Rubefacients, commonly prescribed for symptomatic relief of muscular pain and stiffness, sprains and strains and pain due to rheumatic and non-serious arthritic conditions, had also been included in the DROP-List. A paper had been produced on the potential costs savings to be achieved by a partial or total blacklisting of the rubefacients. Three options had been included in the paper: to do nothing, black list all rubefacients except for transvasin and algesal, and blacklist all of the rubefacients. The JAPC working group had discussed the options and recommended the adoption of the blacklisting of all of the rubefacients with the exception of transvasin and algesal. During discussion Mr Dhadli advised that the PrescQIPP document 'Rubefacients for the treatment of soft-tissue disorders and topical pain relief' referred to a number of published systematic reviews which found that the evidence did not support the use of topical rubefacients containing salicylates for acute injuries and suggested that in chronic conditions their efficacy compared poorly with topical NSAIDs.	

Item		Action
	There was no evidence at all for topical rubefacients with other components. Systematic review and meta-analysis published in the Journal of Pain in 2014 had concluded that there is limited evidence that NSAIDs, heat wraps, and rubefacients provided immediate pain relief for acute back pain and that bed rest and advice were both ineffective. The SIGN clinical guidelines for the management of chronic pain included topical rubefacients treatment and stated that they were more effective than topical placebo for pain reduction. Dr Parkin suggested that all the rubefacients should be blacklisted and Dr Watkins added that this would make it easier for GPs. Dr Emslie highlighted that there was a risk of increased prescribing of oral and topical NSAIDs in the event that all rubefacients were blacklisted. Mr Hulme commented that the use of rubefacients was not evidence based treatment and that the promotion of self-care would need further discussion. Dr Mott advised that a decision to blacklist all the rubefacients would require implementation via the prescribing groups and widely publicised. **Agreed:** JAPC agreed that all rubefacients should be blacklisted, due to the lack of evidence of benefit, for all new patients and that existing patients should be reviewed at the appropriate time.	**SD**
b.	**<u>NHS England Influenza Vaccines</u>** Mr Dhadli reported that the Public Health England Screening and Immunisation Coordinator had provided notification that Fluarix Tetra (Quadravalent vaccine) 2nd line to nasal preparations should be classified as GREEN as per the national immunisation programme for children aged three years up to eighteen years. **Agreed:** Fluarix Tetra classified as **GREEN** as per national immunisation policy. **Agreed:** All influenza vaccines for the 2016/17 influenza season classified as **GREEN.**	**SD** **SD**
c.	**<u>Sayana Press ®</u>** Mr Dhadli reported Sayana Press® (medroxyprogesterone acetate) was a progesterone only Long Acting Reversible Contraceptive (LARC) injection and could be designed to allow patients to self-administer the injection subcutaneously at home at intervals of thirteen weeks (+/- 1) with an annual clinical review. Its licence had been extended in 2015 to include patient self-administration since it had been discussed by JAPC in June 2013 when a traffic light classification of RED had been assigned as it was not licensed at the time for self-administration. Sayana Press® had now been licensed for self-administration and advice had been requested about the provision of a checklist to be given to patients prior to the start of treatment. This was now included in circulated guide for primary care. Dr Emslie commented that the issue in primary care was that few nurses had been trained in the use of Sayana Press® but they would be expected to train patients to self-administer.	

Item		Action
	It was highlighted that, although the manufacturer of Sayana Press® had provided a large amount of information, it would be essential to have assurance from GPs that their nursing staff were content to give Sayana Press®. Dr Emslie added that storage and disposal was an important consideration and the manufacturer would provide sharps bins for this purpose. Dr Mott pointed out the assignment of a traffic light classification indicated that it would be suitable for use in the right circumstances and a traffic light classification of GREEN would therefore be appropriate. It would be difficult to define exceptionality in order for a BROWN classification to be given. **Agreed:** Sayana Press® classified as a **GREEN** drug.	**SD**
11.	**JAPC BULLETIN**	
	The JAPC bulletin was noted for information and ratified by JAPC.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for February 2017 was noted. Mr Dhadli highlighted the following MHRA advice: • Hyoscine butylbromide (Buscopan) injection: risk of serious adverse effects in patients with underlying cardiac disease.	
13.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in February 2017. HST4 Migalastat for treating Fabry disease – This was Highly Specialised Technologies (HST) guidance for the treatment of Fabry disease in people over 16 years of age with an amenable mutation. Classified as a **RED** drug (NHS England). TA432 Everolimus for advanced renal cell carcinoma after previous treatment Previously classified as BLACK following negative appraisal. Now recommended and classified as **RED**. TA433 Apremilast for treating active psoriatic arthritis – To be commissioned by the CCGs and had been previously classified as BLACK due to negative appraisal. Now classified as **RED** and to be included in the psoriatic arthritis algorithm. ES6 Parkinson's disease with motor fluctuations: safinamide – To be discussed by JAPC at the April 2017 meeting.	**SD** **SD** **SD** **SD**
14.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	<u>Classifications</u> Ciclosprin eye drops – **BROWN** specialist initiation Glycopyrronium – **BROWN** 2nd line specialist/consultant initiation after hyoscine Donepezil – **GREEN** 1st line after specialist initiation and stabilisation for three months	

Item		Action
	Galantamine – **GREEN** 2nd line after specialist initiation and stabilisation for three months Memantine hydrochloride – **GREEN** 2nd line after specialist initiation and stabilisation for three months Rivastigmine - **GREEN** 2nd line after specialist initiation and stabilisation for three months Sevelamer – Note to be added that sevelamer to be prescribed generically. Rubefacients – All rubefacients to be classified as **BLACK**. Sayana Press - **GREEN** Migalastat – **RED** Everolimus – **RED** Apremilast – **RED** Alpha-1 antitrypsin - **RED** Dalbavancin – **RED** Dapagliflozin + saxagliptin – **BLACK** Liraglutide – **BLACK** Tobramycin - **RED**	
15.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: PCSK9 inhibitors and Lipid/Familial Hypercholesterolaemia guidance – To be brought to the May 2017 JAPC meeting. Osteoprosis – To be taken off the list. Sacubitril/Valsartan – To be brought to the April JAPC meeting. Juxta CURES – To be brought to the May JAPC meeting. DMARDS – To be brought to the June JAPC meeting. Deep Vein Thrombosis – Update to be brought to a JAPC meeting in six months.	**SD** **SD** **SD** **SD** **SD** **SD**
16.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in February 2017 was noted. Mr Dhadli highlighted the following: • Asasantin Retard discontinued and replaced with Molita; a branded generic. • Aliskiren classified as BROWN after specialist/consultant initiation for treatment resistance hypertension and after consideration of low dose spironolactone. • Lidocaine 5% plaster classified as BROWN for post herpetic neuralgia, in patients whom alternative treatments have proved ineffective or where such treatments were contraindicated. • Omega-3 classified as BROWN after consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins. • Nortriptyline classified as BROWN as a treatment option as an adjunct in treatment resistant depression. For use as second line to amitriptyline.	

Item		Action
	• TB medication Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, Rifater, Rifinah and Rifabutin classified as RED for TB. • Hydromorphone classified as BROWN after palliative care specialist initiation, and after strong opioids have been tried.	
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Nottinghamshire Area Prescribing Committee • Clinical Commissioning Policy Advisory Group • Clinical Commissioning Policy Advisory Group • DTHFT Drugs and Therapeutic Committee Mr Dhadli highlighted the following from Nottinghamshire Area Prescribing Committee: • Work had been undertaken with the lipidologists to review the lipid modification guidelines although difficulties had been encountered in determining the place in therapy for ezetimibe and rosuvastatin. • A cost saving had been identified by switching from Renagel® to sevelamer carbonate (generic). • Safinamide for Parkinson's Disease - A traffic light classification had been assigned for patients with motor fluctuations experiencing off-periods and dyskinesia. The APC had determined that this medication differered from other MAO inhibitors as it has proven anti-dyskinetic action but this was not indicated in the NICE Evidence Summary.	
18.	**ANY OTHER BUSINESS**	
a.	Mr Hulme advised JAPC of a theoretical safety concern in the form a potential choking hazard in the use of braltus inhalation powder, a branded generic drug of tiotropium, caused by pushing the capsule through the hole in the mouthpiece of the inhaler. Checks had been made with the NPSA and MHRA but no events had been recorded. It had therefore been decided to add a warning in the newsletter that the capsule should not be pushed into the mouthpiece and this would also be included in the community pharmacy newsletter. Mrs Needham added that a reference was also included in the patient information leaflet.	
b.	Dr Narula referred to the decision made by JAPC to classify ibandronic acid 50mg tablets as BROWN for off-licence use in post-menopausal women with breast cancer for Sheffield Teaching Hospital only. Concern had been expressed by Chesterfield GPs about their liability to prescribe this for unlicensed use and the consequent shift in workload from secondary care to primary care due to the need for monitoring. Patients would need to be on this drug for three years after discharge from the hospital. Dr Mott commented that this was a North Derbyshire issue and concerned patient flows to Sheffield and a decision had been made by the Area Prescribing Committee in that area. Mr Dhadli informed the group that the position of JAPC on this was to recognise that a neighbouring health economy had followed due process and engagement in its decision. The papers tabled at JAPC a few months ago gave assurance of commissioner agreement and evidence review by the appropriate Area Prescribing Committee.	

Item		Action
	By not acknowledging this would lead to an inequity of service for patients seen at Sheffield that resided in Derbyshire.	
19.	**DATE OF NEXT MEETING**	
	Tuesday, 11th April 2017 at 1.30pm in the Post Mill Centre, South Normanton.	