DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 11th July 2017

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Fiasp Insulin	GREEN after specialist recommendation
Liraglutide (Saxenda®)	BLACK
Linaclotide	BROWN after consultant initiation and stabilisation
Follitropin delta (Rekovelle®)	RED
Rolapitant (Varuby®)	RED (NHS England)
Pembrolizumab (Keytruda®)	RED (NHS England)
Idebenone	RED
Eliglustat	RED as per HST 5 (NHS England)
Brentuximab vedotin	RED (as per NICE TA 446) (NHS England)
Pembrolizumab	RED (as per NICE TA 447) (NHS England)
Etelcalcetide	RED (as per NICE TA 448
Everolimus and sunitinib	RED (as per NICE TA 449) (NHS England)
Blinatumomab	RED (as per NICE TA 450) (NHS England)
Ponatinib	RED (as per NICE TA 451) (NHS England)
High Cost drugs (tariff excluded) and High Risk Cytotoxic drugs	Selection of drugs RED - see details in minutes

Clinical Guidelines

Treatment of refractory symptomatic chronic constipation in men and women.
Management of emergency contraception.
Primary Care Management of Irritable Bowel Syndrome.
Melatonin guidance for the treatment of sleep disorders in children with neurodevelopment disorders.

Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Ms H Murch	Pharmacist
North Derbyshire CCG	
Dr C Emslie	GP
Mrs K Needham	Assistant Chief Quality Officer (Medicines Management) (also representing Hardwick CCG)
Ms J Town	Head of Finance
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
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 J Shaw	Principal Pharmacist
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

Item		Action
1.	**APOLOGIES**	
	Mr S Hulme, Dr T Narula, Mr C Newman, Mrs S Qureshi and Dr M Watkins.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	Dr Mott reminded committee members of their obligation to declare any interest they may have on any issues arising at committee meetings which might conflict with the business of JAPC. No conflicts of interest were declared.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Hypurin® Bovine insulin • Clexane® injections • Norethisterone progesterone • Midlands Regional Medicines Optimisation Committee (RMOC) • Discontinuation of Modecate® (fluphenazine decanoate)	
4.	**MINUTES OF JAPC MEETING HELD ON 13 JUNE 2017**	
	The minutes of the meeting held on 13th June 2017 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Attention Deficit Hyperactivity Disorder (ADHD) BP Monitoring** Dr Mott reported that Hardwick CCG had been contacted about the lack of a defined monitoring service for adult patients with ADHD and this would be taken via the commissioning route.	
b.	**Traffic Lights** Mr Dhadli reported that work was still in progress on the production of a comprehensive list of all the classified drugs (except Green). This would be placed on the Action Tracker as an outstanding action and brought to either the August or September JAPC meeting.	**SD**
c.	**Fiasp Insulin** Dr Mott reported that discussions had been held about the use of Fiasp with the diabetologists who had highlighted the necessity of gaining experience with the drug before it was routinely used and therefore the previous classification of GREEN assigned by JAPC should be modified to indicate usage on specialist recommendation only. This was agreed by JAPC.	**SD**
d.	**Etanercept Biosimilar – Flixabu/Erelzi** Mr Dhadli stated that it was proposed that a paper be presented to the Drugs and Therapeutic Finance Committees which would list all the biosimilar drugs currently available in order to highlight the opportunity costs for each Trust. This would enable assurance to be given to JAPC that the process for agreeing the biosimilar opportunity costs was taking place.	
6.	**NEW DRUG ASSESSMENTS**	
a.	**Liraglutide (Saxenda®)** Mr Dhadli reported that Saxenda® was a new GLP1 receptor agonist which was licenced as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with an initial BMI of 30kg/m2 or more (obese) or ≥ 27kg/m2 to <30kg/m2 (overweight) in the presence of at least one weight-related comorbidity.	

Item		Action
	The initial dosage was 0.6mg titrated weekly to a maintenance dose of 3mg daily administered by subcutaneous injection. Treatment should be discontinued after twelve weeks on the maintenance dose, if patients had not lost at least 5% of their initial body weight. Liraglutide (Saxenda®) was a different licensed product to liraglutide (Victoza®), the doses of liraglutide (Saxenda®) used for weight management were lower than those used in managing type 2 diabetes (Victoza®), and Victoza® was not licensed as a pharmacological treatment option for weight management. A MTRAC review had been undertaken in June 2016 which had concluded that the evidence for liraglutide (Saxenda®) was relatively strong. A NICE evidence summary had been published in June 2017 based on four double-blind randomised control trials (RCTs) in adults who were obese or overweight; with the fourth trial being an extension. All of these studies compared liraglutide with placebo and all participants had also received lifestyle interventions for weight loss. The main efficacy outcomes from the four studies included weight loss outcomes, time to onset of type 2 diabetes and change in apnoea-hypopnea index. The results showed an average of 5.4 to 4.0% weight loss across all four studies after 32 to 160 weeks of treatment. It was unclear how long the benefits would last after stopping use and it was also less efficacious in men. A phase 2 RCT used liraglutide compared to orlistat but the trial was small and open label. In terms of safety the side effects were similar to Victoza® with the exception of gastro-intestinal disorders which were more frequent. There was insufficient evidence to determine whether there was a difference between the people treated with liraglutide 3.0 mg and those treated with liraglutide 1.8 mg. There was a lack of data for its use for people aged 75 years and over, under 18s and those with severe renal impairment, severe hepatic impairment, congestive heart failure class III to IV and obesity secondary to endocrine or eating disorders or obesity caused by another medicinal treatment. Liraglutide was not recommended for use in people with inflammatory bowel disease and diabetic gastroparesis. Very common adverse reactions in the use of liraglutide (Saxenda®) were nausea, vomiting, diarrhoea and constipation. The cost of liraglutide (Saxenda®) was £2,387 per year compared to oral treatment of orlistat of £220 per year. The general conclusion was that there was robust evidence for the use of liraglutide (Saxenda®) as there had been good sized studies which had used patient orientated outcomes. However the dropout rates resulting from adverse effects were high in all of the four studies. A query had also been raised as to whether pancreatitis and neoplasms occurred more frequently with liraglutide 3.0 mg daily compared with liraglutide 1.8 mg daily. Dr David Hughes, DTHFT Consultant in Diabetes and Edocrinology, had indicated that liraglutide 3mg should only be prescribed by doctors within a tier 3 weight management programme in obese non-diabetic patients. It should initially be prescribed by the hospital, but Dr Hughes had suggested that a shared care agreement could be developed in order that GPs could take on the care if the patient achieved a 5% weight loss. During discussion about a possible traffic light classification, Dr Mott commented that the use of liraglutide (Saxenda®) clearly fitted in with Tier 3 and Tier 4 bariatric services which were commissioned by the CCGs.	

Item		Action
	Dr Dewis highlighted that there were significant side effects to the use of liraglutide (Saxenda®) and weight loss was not sustained when treatment was stopped. Liraglutide (Saxenda®) should only be used within the obesity pathway and continuation would be dependent on behavioural support and dietetic advice. Dr Parkin suggested that a traffic light classification of BROWN specialist initiation for use only within the tier 3 service would be appropriate. Dr Mott proposed that either a classification of RED, on the strength of the evidence about its efficacy and place in the pathway, or BLACK should be assigned pending a formal submission via the Drug and Therapeutic Committees. Mr Dhadli added that other Area Prescribing Committees had assigned a traffic classification of grey or black and the drug had only been highlighted through horizon scanning. Mr Dhadli also stated that an SMC review had not recommended this treatment with the absence of a submission by the manufacturer so cost effectiveness could not be determined. **Agreed:** Liraglutide (Saxenda®) classified as a **BLACK** drug pending a submission by the service.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**<u>Refractory Constipation in Men and Women</u>** Mr Dhadli reported that the guideline for the treatment of refractory symptomatic chronic constipation in men and women was due for review in June 2017 and no changes had been made. The guideline mainly concerned the use of prucalopride and lubiprostone in line with NICE TAs 211 and 318. Dr Goddard suggested that a link to the use of linaclotide for irritable bowel syndrome should be included. **Agreed:** JAPC ratified the guideline for the treatment of refractory symptomatic chronic constipation in men and women with a review date of two years.	**SD** **SD**
b.	**<u>Emergency Contraception and Quick Starting Contraception</u>** Mr Dhadli reported that the JAPC guidance on the management of emergency contraception with ulipristal acetate (ellaOne®) would now need to be reviewed in the light of updates to the Emergency Contraception (EC) and Quick Starting Contraception guidelines produced by the Faculty of Sexual and Reproductive Health (FSRH). Mr Dhadli highlighted some of the key points in the FSRH guidance: • The intrauterine device (IUD) remains the most effective method of EC. • Ulipristal acetate was more effective than levonorgestrel in the five days prior to ovulation. Oral EC administered after ovulation was ineffective. • Ulipristal acetate or a double dose of levonorgestrel could be used for women >70kg or with a BMI>26kg/m². For women weighing >85kg or with a BMI>30kg/m2 it was unknown which was more effective. • In the event that a woman had already taken oral EC once or more in a cycle then the same oral EC could be offered again after further unprotected sexual intercourse in the same cycle. • The effectiveness of oral EC could be reduced by enzyme-inducing drugs. Women requiring EC who were using enzyme-inducing drugs should be offered an intrauterine device. • Information about quick start contraception (referring to the lack of a five day delay) with the use of levonorgestrel compared to ulipristal acetate was also now included.	

Item		Action
	Dr Mott highlighted the need to advertise the revised EC guidance as widely as possible. It was noted that the PGD in use in community pharmacies would expire in November 2017 so this would need to be updated. This would be undertaken by DCHSFT as they commissioned pharmacies in the county to deliver the service. **Agreed:** JAPC ratified the guideline for the management of emergency contraception with a review date of two years.	**SD**
c.	**<u>Primary Care Management of Irritable Bowel Syndrome (IBS)</u>** Mr Dhadli reported it would be necessary to consider whether faecal calprotectin testing and inflammatory marker values should now be included in the IBS guideline, together with the possible use of the drug linaclotide. However, due to the differences between DTHFT, CRHFT and King's Mill Hospital differing advice for result values for re-testing and referral, and lack of national guidance or consensus, it was proposed that the use of specific inflammatory values should be left out of the guideline. Linaclotide had been assigned a traffic light classification of RED by JAPC in June 2014 as it required specialist assessment to enable patient selection, initiation and ongoing treatment together with long term on-going monitoring of its efficacy by a specialist. Mr Dhadli highlighted the following: • IBS was a common condition and prevalence in the general population was estimated to be between 10% and 20%. • Linaclotide was used to treat IBS with constipation (IBS-C). • Linaclotide was an oral, once-daily, guanylate cyclase-C receptor agonist that caused decreased visceral pain, increased intestinal fluid secretion and accelerated intestinal transit. • The evidence came from two double-blind, randomised, placebo- controlled trials of patients with IBS-C. In both trials, a statistically greater proportion of linaclotide-treated patients, compared with placebo-treated patients, had met the two co-primary efficacy end points required by the EMA, which included ≥30% abdominal pain score and an increase in ≥1 CSBM. The length of the studies was short and there had been no active comparator which was why clinical experience with the drug had been sought. • A local trust audit had been undertaken and linaclotide had been given to twenty-one patients. Of these treated for the first time during the audit period 50% had discontinued the drug due to diarrhoea, lack of efficacy and increased pain and bloating. • The SMC had recommended the use of linaclotide in IBS-C patients and NICE had also issued an evidence summary. The 2015 update to the NICE clinical guideline (CG 61 Irritable bowel syndrome in adults: diagnosis and management) now included in the April 2017 version, the consideration of linaclotide in the treatment of constipation in patients with IBS if the maximum tolerated doses of previous laxatives from different classes had not helped and they have had constipation for at least twelve months. Ongoing effect should be assessed at a three month review.	

Item		Action
	Dr Mott commented that there had now been some local experience of the use of linaclotide and its efficacy had been reflective with the findings of the trials. It would need to be determined at which point the patient should be discharged and there should be some follow up at either three or six months. However it was noted that prucalopride was classified as BROWN after consultant/specialist initiation and that linaclotide would benefit a similarly small group of patients. This would require a four week period of assessment with follow up at six months.	
	Agreed: Linaclotide classified as a BROWN specialist initiation drug.	**SD**
	It was agreed that a reference to linaclotide as a treatment option for patients with difficult IBS-C if optimal or maximum tolerated doses of previous laxatives from different classes had not helped and they have had constipation for at least twelve months should be included.	
	In connection with faecal calprotectin Dr Mott stated that there was variance in normal ranges between the different pathology laboratories. Dr Henn referred to the calprotectin testing in primary care and that it would be helpful to have a consistent guideline with a cut-off point for the referral of people with possible IBS according to faecal calprotectin levels. This would potentially reduce the number of unnecessary referrals to secondary care and alleviate uncertainty for GPs as the referrers. Dr Mott would follow this up with the shared care pathology group and copy in Dr Henn.	**AM**
	A number of typographical errors were also highlighted and these would be checked and amended by Mr Dhadli. The amended guideline would be circulated to Dr Goddard, Dr Henn and Mrs Needham for reference.	**SD**
	Action: JAPC ratified the Primary Care Management of Irritable Bowel Syndrome guideline with the agreed amendments.	**SD**
d.	**<u>Liothyronine</u>** Mr Dhadli reported that the classification and evidence in detail of liothyronine (L-T3) had been discussed by JAPC at the June 2017 meeting. It had been agreed that levothyroxine (L-T4) was the treatment of choice for hypothyroidism as it was cost-effective, suitable for once daily dosing and provided stable and physiological quantities of thyroid hormone for patients who required replacement. A number of actions had been agreed and one of these had been for DHcFT to undertake a review of the use and place of liothyronine in the treatment for resistant depression. Ms Bassi advised that liothyronine for resistant depression was to be discussed by the DHcFT Drugs and Therapeutic Committee at the meeting to be held on 27th July. In addition, a review of usage over the last twelve months had revealed that only one patient had been given liothyronine (as an inpatient) but it was unclear whether this had been for treatment-resistant depression.	
	It was also noted that a provisional classification of BLACK had been given to liothyronine for use in endocrinology pending the production of a position statement at the June 2017 JAPC meeting. This position statement had now been produced and this highlighted that continued prescribing of liothyronine would only be supported in exceptional circumstances and only by recommendation from an NHS endocrinologist and supported by the individual funding request.	

Item		Action
	Mr Dhadli highlighted that this represented a significant change to the current traffic light classification of BLACK and would present a significant challenge to implement. In addition, references to the use of unlicensed preparations such as ArmourThyroid® had also been included and that patients who have been seen privately should be referred back to the private service for continued private prescription of liothyronine or an alternative thyroid treatment. Dr Goddard queried the reference in the position statement which indicated that support had been obtained from primary care clinicians and also the local endocrinologists from provider organisations. Dr Goddard stated that the local endocrinologists did support the significant cost savings to be achieved from the withdrawal of liothyronine for hypothyroidism but they would have to manage the adverse reactions from the patients who would be affected by this. Mr Dhadli reported that Dr F Game, DTHFT Consultant Endocrinologist, had advised that a traffic light classification of RED was not a realistic option. It had therefore been proposed that the traffic light classification of BLACK would be appropriate for new patients. For existing patients who had started before the traffic light change – Dr Game had suggested that these patients should be able to continue after review and without an IFR. Dr Game had also suggested that if, after discussion with a GP, a patient was willing to stop liothyronine then he/she could be referred back to the service which had originally initiated it. The patients might consequently be reviewed by the private sector, if this was initiated there. During discussion Dr Parkin highlighted that the JAPC traffic light classification of BLACK indicated that a drug would not be routinely recommended or commissioned and this should apply in the case of liothyronine for all patients. Dr Emslie commented that use of the IFR mechanism would not be sustainable and GPs would find it difficult to deal with this vociferous group of patients. The referral back to the service may also be difficult as some patients may have been started on liothyronine elsewhere in the country or by private practitioners who may no longer be in post. Dr Mott advised that the position statement was still in draft format and that a traffic light classification of BLACK was more difficult to deliver pragmatically without a basic guide to switch from LT-3 to LT-4 and a process for primary care follow up. However a classification of BLACK was appropriate and resources needed to be in place for primary care to support this classification. It was acknowledged that obtaining treatment for hypothyroidism by means of the IFR process would be extremely difficult but it had been retained as it was the process by which patients could potentially gain access to a drug if there were exceptional circumstances. **Action:** Further discussions would be held with the endocrinologists. The position statement would be amended and brought back to the August 2017 JAPC meeting.	**SD**
e.	**<u>Melatonin</u>** Mr Dhadli reported that there had been no changes to the melatonin guidance for the treatment of sleep disorders in children with neurodevelopment disorders. It was noted that Circadin® 2mg MR tablets (off-label) were the first line choice of melatonin in Derbyshire for new patients for the treatment of sleep disorders initiated by a specialist in children with neurodevelopment disorders.	

Item		Action
	Agreed: JAPC ratified the melatonin guidance for the treatment of sleep disorders in children with neurodevelopment disorders with a two year review date.	**SD**
f.	**<u>Management of UTIs in Children</u>** Dr D Harris, Lead Antimicrobial Pharmacist, had now included new details about the management of urinary tract infections (UTIs) in children to the Derbyshire Antimicrobial Treatment Guidelines. This mainly concerned the avoidance of use of nitrofurantoin suspension due to its high cost. Dr Emslie highlighted that the document was not particularly easy to follow and there was a lack of clarity about the use of nitrofurantoin tablets or suspension. **Action:** Mr Dhadli would contact Dr Harris about an amendment to the guideline. The amended guideline would be taken via the Guideline Group for ratification.	**SD**
8.	**SHARED CARE GUIDELINES**	
a.	**<u>Ciclosporin</u>** Mr Dhadli advised that the shared care guideline for patients with rheumatological disease prescribed Ciclosporin had been updated with the standard disease modifying antirheumatic drugs (DMARDs) template which had been previously discussed by JAPC. Mr Dhadli highlighted the additional changes specific to Ciclosporin: • Monthly monitoring for twelve months had now been included in line with the British Society for Rheumatology (BSR) guidance. • The adverse effect with management section has been replaced with a list of adverse effects only from the BNF and SPC for consistency with other shared care guidelines. • The BSR recommended the monitoring of therapeutic drug levels for patients receiving ciclosporin treatment with low level evidence so this was not included. • The BSR guidance referred to glucose monitoring and HBA1c had been added as opposed to fasting. It was highlighted however that HBA1c testing should only be done every three months and not with each visit. • The monitoring section vii included a table to outline the actions to be taken in line with BSR guidance. Previously creatinine had specific levels and advice for >30% and >50%. This now included the guidance for just >30% to contact specialists. • Potassium and lipid levels rising have been removed. JAPC was informed that other amendments to the template had been proposed by the DTHFT dermatology and rheumatology consultants: • Dermatology - maximum treatment twelve months to eighteen months (this was a further change suggested by Dr Shum, DTHFT Consultant Dermatologist). • Monitoring requirements – The recording of patient height, weight and blood pressure would only be carried out for new patients and only if clinically indicated. • Viral hepatitis B and C and HIV screening in patients at increased risk of infection to be routinely undertaken.	

Item		Action
	• GP responsibility and monitoring schedule - Blood pressure ≥140/90mmHg on two consecutive occasions two weeks apart – Contact rheumatology urgently and consider was suggested in the action boxes but was unclear if this advice cuts across all specialties. **Action:** The shared care guideline for Ciclosporin would be brought back to the next JAPC meeting for further consideration.	**SD**
9.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, licence extensions and drug discontinuations: New drug launches in the UK: Daclizumab (Zinbryta®) – Already classified as **RED** Follitropin delta (Rekovelle®) – **RED** Rolapitant (Varuby®) – NHS England. Classified as **RED** Licence extensions: Daratumumab (Darzalex®) - NHS England. Already classified as **RED** Nivolumab (Opdivo®) – already **RED** Epoetin alfa (Eprex®) – NHS England. Already classified as **RED** Eslicarbazepine (Zebinix®) – NHS England. Already classified as **RED** Pembrolizumab (Keytruda®) – Already classified as **RED** Drug discontinuations: Cleosensa® (ethinylestradiol/drospirenone) Daylette® (ethinylestradiol/drospirenone) Luvinsta XL® (fluvastatin) Trobalt® (retigabine) Orgaran® (danaparoid sodium) Panoxyl Aquagel® (benzoyl peroxide)	
10.	**MISCELLANEOUS**	
a.	**<u>Conflict of Interest</u>** It was noted that the JAPC conflict of interest declarations would now be undertaken on an annual basis and the next date for this would therefore be January 2018.	
b.	**<u>Early Access to Medicines</u>** Mr Dhadli reported that Idebenone for the slowing of the decline of respiratory function in patients with Duchenne Muscular Dystrophy (DMD) from the age of ten years who were currently not taking glucocorticoids had been approved as part of the NHS England Early Access to Medicines Scheme (EAMS). Idebenone was classified as a **RED** drug.	**SD**
c.	**<u>High Risk Drug Prescribing</u>** Mr Dhadli reported that PrescQIPP had produced a report on the tariff excluded high cost drugs and cytotoxic agents from sections 8.1 and 8.2 of the British National Formulary. An exercise had been undertaken by the Clinical Effectiveness Team to determine if these were appropriately classified by JAPC or risk considered where prescribed: • Classify all of the drugs indicated in the table 1 in the background paper from Aztreonam to Tretinoin as RED. There had been a query about folinic acid which was used in cases of methotrexate rescue.	

Item		Action
	• The Guideline Group considered in table 2 azathioprine, ciclosporin, lanthanum carbonate, mercaptopurine and methotrexate were appropriately classified in terms of safety. It was noted that all these drugs were covered by shared care agreements and lanthanum carbonate had been re-classified from Amber to GREEN after specialist initiation as it was supported by a clinical guideline. • The list of high risk drugs had already been classified as RED or BLACK so therefore no further action was required (table 3). **Action:** The ePACT data would be looked at in connection with folinic acid and, once clarification had been obtained, all the drugs in the table would be classified as RED.	**SD**
d.	**<u>Pregabalin</u>** Mr Dhadli advised that NHS England had previously issued guidance in March 2015 on the prescribing and dispensing of pregabalin. JAPC was reminded that the general patent for Lyrica®, of which pregabalin was the active ingredient, had expired but the manufacturer had retained the product's patent for the treatment of pain until July 2017. NHS England had now issued a letter to indicate that generic pregabalin for all conditions could be dispensed in accordance with normal practice with effect from 17th July 2017.	
e.	**<u>Strontium Discontinuation</u>** Mr Dhadli reported that notice had been received that strontium ranelate, licensed for the treatment of severe osteoporosis, would be discontinued at the end of August 2017 and no longer be manufactured. It had been estimated that thirty-six patients would be affected in Derbyshire and the specialists had advised that these should be re-assessed and their original diagnoses looked at. There was also a National Osteoporosis Society patient helpline which could provide advice. Strontium had been removed from the osteoporosis guidance and its discontinuation highlighted in the traffic light classifications. Information and advice concerning the discontinuation of strontium would be conveyed to all GP practices in Derbyshire.	**SD**
f.	**<u>Hepatitis A</u>** Dr Dewis advised that there had been an outbreak of hepatitis A in Europe that appeared to follow on from the Gay Pride event held in Madrid in 2016 and more recently following the same event in 2017. There had been a number of cases in Southern Derbyshire over the Autumn period 2016 and these appeared to be related to that community. This had coincided with a shortage of vaccine supply and a recommendation had been made to change some of the travel advice for other countries and to highlight that men who have sex with men (MSM) should be vaccinated. Public Health England had recommended that all MSM attending GUM and HIV clinics should be opportunistically offered a single dose of adult monovalent hepatitis A vaccine where available. There had been a consequent focus on vaccination of this group by the Derbyshire Sexual Health Service but, due to an ongoing global shortage of hepatitis A vaccines, the paediatric monovalent hepatitis A vaccine had been administered instead as advised by Public Health England. Dr Dewis added that the main message was that there may be cases of hepatitis A and these should be reported to the local Health Protection Team. It was agreed that key messages about hepatitis A should be included in the JAPC bulletin and newsletter in view of the queries which were being received by GP practices.	**SD**

Item		Action
g.	**Traffic Light Definition – Specialist** Mr Dhadli queried whether there was a need to clarify the term specialist in the JAPC traffic light classification and suggested that the term could refer to a nurse specialist within a service; a General Practitioner with special interest (GPwSI) or a practice nurse working in primary care who had undergone training with high level of competency. Following discussion it was agreed that a definition of specialist was not required.	
h.	**Key Therapeutic Topics** Mr Dhadli reported that NICE were running a consultation on key therapeutic topics to be retained, retired or added for the January 2018 update and comments on the proposals were invited before the deadline of 14th July 2017. It was highlighted that standardisation of chemotherapy doses and products had now been added to the list.	
11.	**JAPC BULLETIN**	
	The bulletin was noted for information and ratified by JAPC.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for June 2017 was noted. Mr Dhadli highlighted the following MHRA advice: • Denosumab (Prolia®, Xgeva▼): reports of osteonecrosis of the external auditory canal. Cases of osteonecrosis of any bone suspected to be associated with denosumab or any other medicine to be reported via the Yellow Card system. • Brimonidine gel (Mirvaso®): risk of systemic cardiovascular effects; not to be applied to damaged skin and including after laser therapy to the skin. It was noted that brimonidine gel had received a traffic light classification of RED by JAPC in May 2014. • Pseudoephedrine and ephedrine: regular review of minimising the risk of misuse in the UK. • Electronic cigarettes and refill containers (e-liquids): suspected side effects and safety concerns to be reported via the Yellow Card system.	
13.	**NICE SUMMARY**	
	Mr Dhadli informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in June 2017. HST5 Eliglustat for treating type 1 Gaucher disease – Classified as a **RED** drug (NHS England). TA 446 Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma - Already classified as a **RED** drug (NHS England). TA 447 Pembrolizumab for untreated PDL1-positive metastatic non-small-cell lung cancer – Classified as a **RED** drug (NHS England). TA 448 Etelcalcetide for treating secondary hyperparathyroidism – Classified as a **RED** drug. CCG commissioned drug.	

Item		Action
	TA 449 Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease – Classified as a **RED** drug (NHS England). TA 450 Blinatumomab for previously treated Philadelphiachromosome-negative acute lymphoblastic leukaemia – Classified as a **RED** drug (NHS England). TA 451 Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia – Classified as a **RED** (NHS England).	
14.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in June 2017 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Dupilumab classified as RED and awarded EAMS status for severe atopic dermatitis. A NICE TA was expected in 2018. • Insulin aspart (Fiasp®) – Classified as GREEN after specialist recommendation. Chapter Updates: • Chapter 7 Obstetrics, gynaecology and urinary tract disorders updated with the following: ➢ Oral CHC choice. ➢ Wording of medroxyprogesterone advice amended to reflect FSRH guidance. ➢ Quick starting contraception section updated in line with FSRH guidance. ➢ SLS criteria for PDE-5 inhibitors updated to include specialist centre use. ➢ Caverject out of stock information removed as now back in stock. Guidelines: • Amiodarone guideline updated to include liver function tests and thyroid function tests monitoring post amiodarone. Miscellaneous: • Quetiapine licensed liquid preparation was now available and included in the A-Z special guide. • Optive fusion included in the BNF eye chapter (appendix 1). • Diabetes guideline updated to remove 'NICE do not recommend liraglutide 1.8mg'. • Ralvo® was the preferred cost-effective brand for lidocaine 5% plasters. • Relevtec® was the preferred cost-effective brand for buprenorphine high strength patches.	
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	<u>Classifications</u> Fiasp Insulin – **GREEN** after specialist recommendation only Liraglutide (Saxenda®) – **BLACK**	

Item		Action
	Linaclotide **– BROWN** after specialist initiation and stabilisation Daclizumab (Zinbryta®) **– RED** Follitropin delta (Rekovelle®) **– RED** Rolapitant (Varuby®) **– RED** (NHS England) Daratumumab (Darzalex®) **– RED** (NHS England) Nivolumab (Opdivo®) – **RED** Epoetin alfa (Eprex®) **– RED** (NHS England) Eslicarbazepine (Zebinix®) **– RED** (NHS England) Pembrolizumab (Keytruda®**) – RED** Idebenone – **RED** Eliglustat **– RED** as per HST 5 (NHS England) Brentuximab vedotin **– RED** (as per NICE TA 446) Pembrolizumab – **RED** (as per NICE TA 447) Etelcalcetide **– RED** (as per NICE TA 448) Everolimus and sunitinib **– RED** (as per NICE TA 449) Blinatumomab **– RED (**as per NICE TA 450) (NHS England) Ponatinib **– RED (**as per NICE TA 451) (NHS England) Mrs Needham queried whether the vitamin D preparations would need to be re-classified due to the new vitamin D guidance which only recommended prescribing of treatment dose vitamin D. It was agreed that it would be discussed at the next guidelines group to agree the classification of vitamin D products.	**SD**
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: DMARDS/Immunomodulating Shared Care – This was a rolling programme and ciclosporin had now been discussed by JAPC but would require further discussion. Juxta Cures – To be discussed by DTHFT Drugs and Therapeutic Committee and by JAPC in September 2017. Suspected DVT - NOAC/D-dimer – To be brought to the September 2017 JAPC meeting. NRT and service provision – To be brought to the October 2017 JAPC meeting. Rosuvastatin – To be brought to the December JAPC meeting. Etanercept 'Lifmior' biosimilar/Rituximab biosimilar – Awaiting contract agreement. ADHD monitoring in adults – To be brought to the October 2017 JAPC meeting.	**SD** **SD** **SD** **SD** **SD** **SD** **SD**
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Sheffield Area Prescribing Group 16/03/17 • Sheffield Area Prescribing Group 20/04/17 • Derbyshire JAPC Working Group 11/05/17 • DTHFT Drug and Therapeutics Committee 16/05/17	

Item		Action
	• Chesterfield Drug and Therapeutics Committee 16/05/17 • Medical Optimisation Safety Team 01/06/17 Mr Dhadli highlighted the following: Sheffield Area Prescribing Group 16/03/17 – The Area Prescribing Group had noted the item on Voke®, the e-cigarette device, and that this device had an MHRA licence but was not yet commercially available. It had been noted that the document from the East of England recommended that GPs should not prescribe this or other novel nicotine containing devices.	
18.	**ANY OTHER BUSINESS**	
	Mr Dhadli reported that Hypurin® Bovine insulin was being discontinued at the end of 2017 and therefore patients currently using this form of insulin would need to have their insulin prescription changed. It had been recommended that the alternative beef insulin was porcine insulin. This would be further discussed by the prescribing groups. Mr Dhadli reported that there had been a shortage of Clexane® (enoxaparin sodium) injections, but that the national situation had now been resolved but was being monitored. Dr Henn referred to the private service offered by the Boots company which allowed women access to prescription-only medicines in order that their periods could be delayed. There had been internal discussions about the safety of norethisterone which was the drug used. This had been discussed by JAPC in 2015 and Dr Henn queried whether there was any current up to date guidance as to the safety issue and the safest products to prescribe. Dr Mott reported that the first meeting of the Midlands Regional Medicines Optimisation Committee (RMOC) would be held at the end of August 2017. Dr Mott and Mr Dhadli had both been selected to represent commissioners on the group. Ms Bassi advised of the discontinuation of Modecate® (fluphenazine decanoate) by the end of 2018. This would be discussed by the DHcFT Drugs and Therapeutic Committee and brought back to JAPC for discussion about alternative therapies.	**SD** **SD**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 8th August 2017 at 1.30pm in the Post Mill Centre, South Normanton.	