

## DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on  
13<sup>th</sup> May 2014

### CONFIRMED MINUTES

#### Summary Points

##### **Traffic lights**

<b>Drug</b>	<b>Decision</b>
Metoclopramide	<b>BROWN</b> for long term use in gastroparesis (on specialist initiation)
Brimonidine Gel	<b>RED</b> (moderate/ severe rosacea causing significant impact on quality of life)
Dapsone	<b>RED</b>
Diazoxide	<b>RED</b>
Fentanyl ( immediate release i.e.non-transdermal preparations)	<b>BROWN</b> (after specialist palliative care initiation only)
Indacaterol & glycopyrronium inhaler (Ultibro)	<b>BLACK</b>
Lubiprostone	<b>BLACK</b> (Chronic idiopathic constipation)
Mexiletine	<b>RED</b> (life-threatening ventricular arrhythmias)
Pregabalin	<b>GREEN</b> (specialist initiation for GAD)
GLP1 agonist (lixisenatide, liraglutide, exenatide)	<b>GREEN</b>
Pioglitazone	<b>BROWN</b> (reclassified from Green, based on on-going safety concerns)
Buccal midazolam (Buccolam for children and adults)	<b>GREEN</b> (after specialist initiation)
Buccal midazolam (Epistatus for adults)	<b>BROWN</b> (after specialist initiation)
Aripiprazole (depot)	<b>RED</b>
Sildenafil	<b>GREEN</b> (preferred drug choice to treat erectile dysfunction as per SLS criteria)
Tadalafil, Vardenafil and Avanafil,	<b>BROWN</b> (sildenafil is drug of choice for erectile dysfunction. 2 <sup>nd</sup> line options should be chosen on cost)
Macitentan	<b>RED</b> (PBR excluded high cost drugs)
Riociguat	<b>RED</b> (PBR excluded high cost drugs)
Sofosbuvir + daclatasvir/ledipasvir+/- ribivirin	<b>RED</b> (Hepatitis C treatment- PBR excluded NHSE)
Permetrexed	<b>BLACK</b> (as per NICE TA309)
Afatinab	<b>RED</b> (as per NICE TA310)
Bortezomib	<b>RED</b> (as per NICE TA311)
<b>Medical device</b>	<b>Decision</b>
Vacuum Pumps	<b>RED</b> (Requires assessment of condition and training on use of device)
Penile constrictor rings (replacement rings for use with vacuum pumps)	<b>GREEN</b> (after specialist initiation)
Vibropulse (disposable covers)	<b>BLACK</b>

## Clinical Guideline

Managing behaviour problems in patients with dementia (BPSD) policy -updated

Cellulitis class II treatment pathway for CRH- updated

Guidance on the management of Recurrent UTI's in adult females (non-pregnant women)- new

## Patient group direction

Levonorgestrel (Agreed for DCHS use)

<b>Present:</b>	
<b>Southern Derbyshire CCG</b>	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Dr I Tooley	GP
<b>North Derbyshire CCG</b>	
Dr D Fitzsimons	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG) from item 9 of the agenda
<b>Hardwick CCG</b>	
Dr T Parkin	GP
<b>Erewash CCG</b>	
Mrs H Murch	Lead Pharmacist
<b>Derbyshire County Council</b>	
Mrs S Qureshi	NICE Audit Pharmacist
<b>Derby Hospitals NHS Foundation Trust</b>	
Dr W Goddard	Chair – Drugs and Therapeutics Committee
<b>Derbyshire Healthcare NHS Foundation Trust</b>	
Dr S Taylor	Chair – Drugs and Therapeutic Committee
<b>Chesterfield Royal Hospital NHS Foundation Trust</b>	
Mr M Shepherd	Chief Pharmacist
<b>Derbyshire Community Health Services NHS Trust</b>	
Mr M Steward	Chief Pharmacist
<b>Healthwatch Derbyshire</b>	
Dr C Shearer	Healthwatch
<b>In attendance</b>	
Miss S Darby Dr M Watkins	Clinical Effectiveness Team SDCCG GP Vernon Street Medical Centre

Item		Action
1.	<b>APOLOGIES</b>	
	Mr C Newman, Dr C Emslie, Dr M Henn, Dr E Rutter	
2.	<b>DECLARATIONS OF CONFLICT OF INTEREST</b>	
	No declarations of conflict of interest were made.	
3.	<b>DECLARATIONS OF ANY OTHER BUSINESS</b>	
	Website Business Case for Anti TNF's.	
4.	<b>MINUTES OF JAPC MEETING HELD ON</b>	
	<p>The following amendments were made to the minutes of the meeting held on Tuesday 8<sup>th</sup> April 2014.</p> <p><b>Page 1</b> Include branded drug names to Dapagliflozin + Metformin (Xigduo) and Tamsulosin + Solifenacin. (Vesomni)</p> <p><b>Page 4</b> Amend: European Association of Urology guidance 2013 as an option <u>for patients</u> that have undergone..</p> <p><b>Page 5</b> Include branded drug name against Dapagliflozin + Metformin (Xigduo)</p> <p><b>Page 6</b> Include branded drug name Tamsulosin + Solifenacin. (Vesomni) Amend: Agreed Blephaclean <u>and similar related products</u> classified as <b>BLACK</b></p> <p><b>Page 7</b> Amend: potential for GPs <u>to initiate</u>.</p> <p><b>Page 8</b> Amend: Proportion of patients <u>on antipsychotic drugs</u></p> <p><b>Page 10</b> <u>Would</u> spelt incorrectly</p> <p><b>Page 12</b> <u>Oxaliplatin</u> spelt incorrectly</p>	
5.	<b>MATTERS ARISING</b>	
	<p><b><u>Acamprosate and disulfiram shared care agreement</u></b> It was highlighted that the shared care agreements for both acamprosate and disulfiram were sent to the Mental Health Trust for consultation and that it was taking longer than anticipated. Dr Mott stated the action tracker will need to be updated to reflect this.</p> <p><b><u>Metoclopramide use for long term conditions</u></b> Mr Mott asked if JAPC had any comments on Dr Goddard's paper written from Derby's perspective on the use of metoclopramide in gastroparesis.</p> <p>Mr Dhadli commented there were a few items that came out of the domperidone review which he thought Dr Goddard might like to include in the metoclopramide</p>	

<p>guidance, these included possible PRN dosing, restricting to those under age 60 (which is less than the 75 in the paper submitted), suggesting assessing nutritional status and glycaemic control in diabetics and reviewing drugs that might cause interactions. Dr Goddard commented that the domperidone paper is more complicated and Dr Goddard confirmed he would be producing a separate document for domperidone, which he has already drafted and will bring back to JAPC in July.</p> <p>Dr Parkin asked if the group could reach a consensus on what GPs should do for patients on the drug long term, commenting that GPs can't just stop without an alternative. Mr Dhadli added for JAPC to endorse the position statement undermined the MHRA contraindication for gastroparesis and queried if a GP carries on prescribing where would the liability sit. Dr Mott advised the liability, as always, sits with the prescriber.</p>	WG
<p>Dr Mott went on to say there is a cohort of patients who will be under specialist care for gastroparesis, and there will be a lot of responsibility upon the specialist to make the decisions with regard to prescribing.</p>	
<p>The group discussed whether the statement should be published on the website and the consensus was that it should, acknowledging that it is a contentious issue but felt if the position statement is being agreed then JAPC need to stand by it. Mr Hulme queried if something would also be included in the formulary as a note, Mr Dhadli confirmed it would.</p>	SD
<p><b>Agreed: Metoclopramide - Brown after specialist initiation for gastroparesis and other gastric outlet physiological impairment</b></p>	SD
<p><b><u>NOACs safety from the MHRA</u></b></p> <p>Mr Dhadli advised this is the information JAPC requested, in terms of the kind of adverse drug reactions (ADR) and fatal ADRs available through MHRA and UK data for the NOACs and warfarin. Mr Dhadli acknowledged the data has limitations and should be interpreted with caution. Referring to the first table Mr Dhadli informed the group that his interpretation of the data is warfarin has been around for 50 years, with many scripts issued over that period and to note 396 fatal ADRs, whereas apixaban, dabigatran, and rivaroxaban have only been introduced in the last few years but we have already seen above 150 fatal ADRs, in the context of limited prescribing. Mr Dhadli added that most GPs will be using them cautiously, bearing in mind they are new drugs and there are a lot of fatal and general ADRs.</p> <p>Mr Hulme queried if it was possible to get annualised rates. Mr Dhadli stated this is the only format of data available on the MRHA database. Dr Mott asked if Mr Dhadli could email MRHA to ask if the information is available in the annualised format.</p>	
<p><b>Agreed:</b> Mr Dhadli to see if annualised ADR rates are available through the MHRA.</p>	SD
<p><b><u>Vacuum pumps</u></b></p> <p>Dr Goddard had not received feedback from the urologists at RDH. Dr Mott informed the group this item came from the medical devices spend and was one of the more costly areas. Dr Mott stated that there is currently is no defined pathway for patients going onto this treatment.</p>	

	<p>Feedback from CRH urologists is that they don't supply the pumps or refer patients to GPs directly, but advise their patients to discuss with their GP or consider purchasing a pump directly. Derby has a loaning process for initial assessment and then pass prescribing out to general practice if required.</p> <p>Dr Mott queried how JAPC were going to move forward with this issue, commenting that it is a patient pathway issue and medicines/devices should be delivered at the most appropriate setting. However, Mr Shepherd felt that it was a commissioning issue, adding that it appears to be more about money than efficacy and feels previous attempts to engage with commissioners needs to be revisited.</p> <p>Dr Mott asked if it was for JAPC to state how the service should be and how it ought to be commissioned. Mr Hulme felt it wasn't just about cost, it's about where is it appropriate to provide these - is it in a specialist setting, or can it be done in primary care and this is a question JAPC needs to consider to determine who prescribes it.</p> <p>Mr Dhadli advised the training needs to be considered and the adverse reactions were discussed previously in terms of the constrictor rings. Dr Mott asked what GPs would do in their practice and both Dr Fitzsimons and Dr Parkin didn't feel they had the experience to prescribe and would refer into secondary care, but would be happy to follow up with the constrictor rings.</p> <p>Dr Mott agreed it's better to refer for a specialist opinion and for the patient to get the device and once they've been trained, the disposables can be picked up in primary care. Dr Mott suggested making the device red and constrictor rings for follow up green after specialist initiation; adding that he didn't think it would increase the number of referrals into secondary care as none are currently initiated in primary care. To pick up with the commissioners for the North and South and bring it back to JAPC when there was a clear outcome. Dr Mott suggested the north and southern CCGs pick up the pathway with their local trust.</p> <p><b>Agreed: Devices Red and constrictor rings Green after specialist initiation</b></p>	<p>AM/TP</p> <p>SD</p>
9.	<b>NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS</b>	
	<p><b><u>Brimonidine Gel</u></b> (Mirvaso)</p> <p>Mr Dhadli informed the group that brimonidine gel is used for the symptomatic treatment of facial erythema of rosacea in adults. It acts by attaching to receptors called alpha2-adrenergic receptors on the cells of blood vessels of the skin and activating them - vasoconstriction effect. Mr Dhadli stated the background to rosacea is that it is a poorly understood long-term chronic relapsing condition, with no cure and the treatments are to control symptoms. Advising there are several risk factors that make the condition worse and these should be avoided. The efficacy for the gel comes from 2 main studies, with 553 patients (with mod/severe facial redness) compared to placebo. The reduction in redness is measured at 3, 6, 9, 12 hours on days 1, 15 and 28 after start of treatment and it does show there is a beneficial effect. There is a reduction in redness on day 29, after 3 hours. There are further on-going studies including one vs azelaic acid. In terms of pharmacological treatments, Mr Dhadli advised there's no national or authoritative guidance. Small studies and expert opinion exist. Mild/moderate papulopustular rosacea can be treated with</p>	

topical metronidazole (rozex 0.75% = £7.40 30g) and topical azelaic acid (20g = £3.74), and for severe /moderate papulopustular rosacea there's oral tetracycline/erythromycin. (Course of 6-12 weeks oxytetracycline 500mg bd = £13.19). Brimonidine gel 30g NHS list price = £33.69.

Mr Dhadli stated the company have developed a rosacea screening tool/risk management plan to answer safety concerns. He went on to say there is an open label study of 449 patients after one year, which shows it is safe and effective and there's no loss of efficacy over time and if patients are going to experience side effects these usually occur in the first 29 days of use. Mr Dhadli advised it is not licensed in the under 18's, it's contraindicated in the under 2s, pregnancy, breast-feeding and experience in the under 65s is limited. In terms of treatment affordability it is a common condition affecting 1 in 10 people, it's not life threatening but it does affect a patients social life and is linked to depression, it's not curative and the condition is relapsing and so it is accumulative prescribing. The only people referred into secondary care would be those with flushing, persistent erythema and other signs causing psychological or social distress and to a plastic surgeon for those with severe phymatous disease, and an ophthalmologist for ocular symptoms. There is a NICE review due in July 2014. Feedback from the dermatologists at RDH is that there is an interest in using the treatment, citing the improvement in the quality of life and it may reduce referrals for cosmetic camouflage, however they too shared concerns over the safety of the drug.

Mr Shepherd stated that there is an interest from his dermatologists, but as yet had received no formal application to use.

Dr Fitzsimons commented that it seemed to be more of a cosmetic treatment and therefore should be classified as Black, Mr Hulme also agreed. However, Dr Goddard commented that there is a place for this drug and it is an alternative to expensive camouflage or laser treatment. Dr Mott suggested that it is classified Red to give the dermatologists chance to use it with the most appropriate group of patients and define where the most appropriate use is.

**Agreed: Brimonidine gel classified as Red** for use in adults by dermatologists where quality of life is severely impaired by rosacea and alternative treatments are not suitable.

SD

#### **Dapsone**

Dr Mott advised this was an old drug. Its main use is for dermatitis herpetiformis with other indications under close supervision. It isn't currently classified, but prior communication had confirmed that both dermatology departments were happy to both prescribe and ensure the necessary monitoring of this drug.

**Agreed: Red**

SD

#### **Diazoxide**

Dr Goddard informed the group this came up at Drugs and Therapeutics Committee earlier in the year and has been brought to JAPC for classification. The endocrinologists want to have it available to treat hypoglycaemia and those with neuroendocrine tumours and who are not chemo-sensitive or not suitable for surgery. Expected low numbers require long term treatment and RDH proposed these should remain under hospital supervision for safety reasons.

**Agreed: Red**

SD

**Fentanyl formulations (non-transdermal preparations)**

Mr Dhadli explained that JAPC previously classified fentanyl film tablets brown in line with all the other non-oral fentanyl products, but it has come back to JAPC following a query from a GP in the south regarding its potential for illicit use. After relooking at the SPCs for these particular products, Mr Dhadli suggested reclassifying this group of drugs to brown following palliative specialist initiation. The suggestion of red may have been more suitable but after discussions with GPs this restriction could be a problem with quick access to the drugs in primary care. The 'palliative care specialist restriction' is supported by the SPCs some of which state or indicate that treatment should be initiated and maintained under the guidance of a physician experienced in the management of opioid therapy in cancer pains.

Dr Parkin commented that he is concerned for these types of preparations being made widely available in the community. Dr Mott advised it is brown already but this further restricts use and in palliative use only. He stated it would be for a very low number of patients who are housebound and dying and may have difficulty to access from the hospital in timely manner.

**Agreed: Brown for palliative specialist initiation only.**

SD

**Indacaterol & glycopyrronium inhaler (Ultibro)**

Mr Dhadli explained this is a fixed dose combination inhaler licensed for maintenance bronchodilator symptoms in adults with COPD. It's a combination of LABA (indacaterol) and LAMA (glycopyrronium), Mr Dhadli referred to the flow chart in the current NICE COPD guidelines where a combination of a LABA and LAMA is indicated, noting on the left hand side that FEV1>50% is a trigger to consider and on the right hand side FEV1<50% it's an alternative - in both cases it's when ICS is declined or not tolerated. Mr Dhadli went on to explain why indacaterol was classified brown, advising there was a DTB review in June 2012 that showed it is effective in terms of measuring lung function, but given the cost and no major advantages in terms of patient orientated outcomes, the DTB couldn't recommend it over existing LABAs. Explaining the glycopyrronium-brown 2<sup>nd</sup> choice LAMA after tiotropium, the MTRAC review- suggested although similar in efficacy to tiotropium it lacked long term data and direct comparisons, although it is cheaper. Mr Dhadli went on to note the patent expiry of tiotropium in 2015.

There are two main published RCTs SPARK and BLAZE reporting exacerbations and dyspnoea as their primary outcome and lung functions as a secondary outcome. Mr Dhadli referred to the NICE summary evidence review which outlined the limited benefit of this combined inhaler.

SPARK showed reduction in exacerbations of 12% compared with glycopyrronium alone but NICE consider 20% reduction to be clinically relevant. Exacerbations in an open label arm versus tiotropium showed a 10% reduction which was not statistically significant. Health outcomes using the St George's respiratory questionnaire although favouring the combination inhaler, failed to meet the four point difference which is clinically important.

The SHINE study versus active comparators (indacaterol, glycopyrronium, open label tiotropium) showed improvements in FEV1 but these were less than the 100mls NICE considers clinically important

It was further noted that both SPARK and SHINE in the context of the COPD pathway is complicated and makes it difficult to interpret because 75% of SPARK and 57% of SHINE patients used inhaled corticosteroids. This means that many people in the indacaterol/glycopyrronium group received triple therapy LABA/LAMA/ICS compared with a LAMA treatment arm and a substantial number received dual therapy with a LAMA and ICS, with the latter not NICE recommend nor licensed.

Mr Dhadli recommended it is classified black

**Agreed: BLACK**

SD

### **Lubiprostone**

Mr Dhadli advised this was launched in the UK in November 2013. JAPC originally agreed to await a peer review before deciding its position locally. A DTB review which was published in April 2014 stated that it is licensed for the treatment of chronic idiopathic constipation and associated symptoms in adults when response to diet and other non-pharmacological measures are inappropriate, the recommended dose is one capsule twice a day and the treatment course is 2 weeks, however it doesn't say in the SPC how often this can be repeated and the container once opened has a shelf life of 4 weeks. The cost of 56 capsules is £59.36.

To summarise, the DTB review states constipation is a very common condition, usually treatable with bulk forming laxatives, osmotic laxatives or stimulant laxatives as recommended in national guidance. Mr Dhadli went on to say the evidence comes from 2 fully published double blind RCTs with identical design and a third study published as an extract only. Compared to placebo for a 4 week period there is improvement in bowel movement with improvements in secondary outcomes that included abdominal bloating and discomfort. The DTB also mentions a systematic review on laxatives that included the 3 lubiprostone American studies (total of 610 pts). They note that 90% of patients in trials were women and they are less likely to fail to respond to lubiprostone - 45% vs 67% placebo)...giving an NNT of 4, so it appears to be effective. Safety concerns were considered minor. Mr Dhadli advised the DTB concluded that they couldn't see its place in the treatment pathway because there are no comparisons to standard treatment and the trial following other treatment failure has not been established. Mr Dhadli recommended it is classified Black.

Dr Goddard commented that this is very early data and at the moment there is prucalopride, he agreed with Mr Dhadli that it should be classified black at the moment. Mr Dhadli commented that the DTB review mentioned prucalopride and its positive NICE appraisal but still went on to quote their 2011 review where they did not recommend it. Dr Goddard pointed out that the evidence for it prucalopride was better than for lubiprostone.

**Agreed: Black**

SD

### **Mexiletine**

Mr Dhadli explained, although this is an old drug, he has received a query from a GP which is the 2<sup>nd</sup> in the last 12 months. The GP requested JAPC to traffic light classify this, after receiving a request from a Consultant Neurologist at RDH for a patient with a diagnosis of myotonia congenita with Becker's subtype. Mr Dhadli advised it is not listed in the BNF as a listed drug but is stated in the text as a "special order" for life-threatening ventricular arrhythmias. Use of the drug in national guidelines is limited; it is mentioned in a CAST study for life



	<p>threatening ventricular arrhythmias and also in an American guideline “for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death”.</p> <p>Mr Dhadli queried if this is appropriate for primary care use. The committee felt it was not. Dr Mott confirmed it would be classified red, so the hospital can use it if they want to.</p> <p><b>Agreed: Red</b></p> <p><b><u>Pregabalin for generalised anxiety disorder (GAD)</u></b></p> <p>Pregabalin is currently listed in the formulary for epilepsy and neuropathic pain and DHcFT request it be added for GAD. Dr Taylor and Mr Dhadli both commented that evidence for the use in GAD is supported by NICE CG 113 and a DTB review (February 2010) when other options have been tried. Dr Mott suggested that green specialist initiation for GAD as 3<sup>rd</sup> line treatment.</p> <p><b>Agreed: Green (3<sup>rd</sup> line) after specialist initiation where SSRIs or venlafaxine are ineffective, poorly tolerated or clinically considered inappropriate.</b></p> <p><b><u>Vibropulse medical device</u></b></p> <p>Mr Dhadli summarised by stating the disposable covers are available on the NHS. He informed JAPC that UKMI have done a review - it’s used for lots of indications and works by 3 dimensional oscillating vibrations. The clinical effectiveness evidence is limited from a small number of patients from non-blinded or retrospective studies. A Cochrane review of cycloidal vibration was not endorsing it.</p> <p>Mr Dhadli recommended it is classified black.</p> <p><b>Agreed: Black</b></p>	<p>SD</p> <p>SD</p> <p>SD</p>
7.	<p><b>CLINICAL GUIDELINES</b></p>	
	<p><b><u>BPSD</u></b></p> <p>Dr Taylor referred to the paper by Rachel Walsh who has outlined the various questions that were asked. She has sent an additional email about the antidepressants along the lines that the evidence hasn’t particularly changed but the better evidence is for citalopram. Dr Mott covered the queries Mr Dhadli put to DHcFT and was happy with the response.</p> <p>Dr Mott stated the citalopram had moved to 1<sup>st</sup> line use over sertraline to treat depression in Alzheimer’s disease, and expressed concern with its known effects on the QT interval. It was noted in the response from Rachel in the field of use in this area there is not a lot of high level evidence for any SSRI (one over another) but citalopram had less negative evidence than sertraline. Mr Dhadli advised there has been a recent HTA SADD study supporting this view</p> <p>Mr Dhadli questioned the inclusion of temazepam to treat poor sleep and suggested that given the cost zopiclone should only be listed and is the preferred choice</p> <p><b>Agreed: JAPC agreed to adopt the guidance and removal of temazepam</b></p> <p><b><u>Cellulitis</u></b></p> <p>Dr Mott highlighted that it was an update to the cellulitis pathway in Chesterfield. Mr Dhadli advised it had gone through Guideline Group, pointing out the front sheet states the recommendations Jayne Booth has added, including MRSA screening when commencing treatment, inclusion of oral doxycycline in stage 1</p>	<p>SD</p>

cellulitis for MRSA+ve patients or high risk of MRSA, advice with regard to IV to oral switch to follow guidelines for class 1 treatment and culture and sensitivity results for MRSA+ve patients, advising this was developed in consultation with Wijitha Weerakoon – microbiologist consultant from RDH.

**Agreed: Guideline accepted**

### **Diabetes**

Mrs Qureshi advised this is the updated version of the diabetes guideline which has been to the guideline group several times, adding that it has also been to the diabetologists Dr Robinson and Dr Game and wider consultation with their colleagues.

Referring to the document, Mrs Qureshi pointed out all changes clarifying alignment to NICE guidance. Some key messages have remained unchanged. HBA1c targets had largely been removed with widespread support stating that these should be individualised. The algorithm is in line with NICE and has been moved to the front of the document, the 9 key tests in section 2 have been included, and these were recommended by Dr Game. Some preconception advice has also been added.

Further comments from Mrs Qureshi included renal function measurements for metformin, appendices that included GLP1 agonists, DVLA advice and blood glucose testing and diabetes.

Mrs Qureshi commented there are quite a few points for discussion and these are as follows:

1. The Diabetes hand should it be kept in or removed?

The general consensus was to keep the hand. The GPs on the group found the hand useful, especially when explaining the course of treatment to patients. It was also felt that the hand was useful for practice nurses who look after diabetic patients.

2. Traffic light classification of gliptins?

It was suggested on the advice of Dr Robinson to classify two gliptins (linagliptin and sitagliptin) as green and the remaining three as brown. However the group felt a definitive decision could not be made without Dr Game's views.

Mr Hulme observed that the flowchart seemed to place gliptins much higher in the treatment pathway than in the past. He suggested the flowchart be reformatted if possible.

3. Reclassification of pioglitazone to brown (Recommendation from the guideline group (GG))

The Derbyshire GG felt that the traffic light classification of pioglitazone as green (and gliptins as brown) sent out the wrong message to primary care, and so in light of the safety concerns around pioglitazone (bladder cancer, fracture and heart failure) suggested it should be reclassified as brown. This was approved by the committee.

4. Dual classification of GLP1 agonists

The GLP1 agonists currently have a dual classification of amber and green depending on whether the clinician has undertaken specific training or not. The question was raised if this training was still pertinent and if a register was kept of GPs who undertook this training. The committee felt that a single classification of Green is now more appropriate, as long as GPs who did not feel competent

SD

	<p>to initiate them retained the right to refer in to specialist services accordingly.</p> <p>5. Insulin with GLP1 and gliptins The gliptins are licensed to be given with insulin, but there is no NICE guidance on this. With the GLP1 agonists some have a licence to be used with insulin and some don't; some are covered by NICE guidance and some are not. The Derbyshire type 2 diabetes guidance has not mentioned the use of insulin with these drugs. It was felt that if insulin is required for use with either class of drugs then a further proposal would be needed for JAPC. Therefore JAPC has not approved the combined use of GLP1 or gliptin with insulin.</p> <p>Mrs Qureshi to re-draft with changes.</p> <p><b>Agreed: SQ should reflect changes discussed and return to JAPC in June</b></p> <p><b><u>Recurrent UTIs</u></b> Mr Hulme presented this guidance on behalf of Diane Harris.</p> <p>Mr Dhadli informed JAPC that this was new guidance on the request of some GPs asking about recurrent UTIs, informing the group there isn't any national guidance. This is taken from papers, peer reviews and consultations that Dr Harris has had with the microbiologists and the urologists, and added that it had gone out for wide consultation.</p> <p>Dr Fitzsimons commented that it's very useful to have the guideline to advise that antibiotic prophylaxis should only be initiated by a specialist and to explain to all our GPs that they need to review all their patient on long term antibiotics for UTIs because quite a few may have been on them for more than 6 months. She suggested that this should be highlighted in the bulletin.</p> <p><b>Agreed: Guideline accepted</b></p>	<p>SQ</p> <p>SD</p>
8.	<b>PGDs</b>	
	<p><b><u>Levonorgestrol</u></b> Dr Mott informed the group this is an existing PGD but is complicated by the governance of authorisation.</p> <p>Mr Dhadli advised there is an updated version with the clinical contents of which are virtually the same, but it has been rebadged for DCHS because of the issue around the governance with regards to who owns the PGD.</p> <p>Mr Steward advised this is owned by DCHS and agreed through their governance structure. DCHS manage the sexual health service who regularly review the PGD. Mr Steward added DCHS also have the minor injury units which are also mentioned in this PGD but are aware this PGD can be used wider.</p> <p>Mr Steward commented that local authority could adopt this for their public health services allowing use by community pharmacists. In terms of authorisation it was identified that Dr Abrahams/Dr Searle are the senior doctors within the sexual health services, Mr Steward the lead pharmacist and the directors of public health from City and County could sign</p> <p><b>Agreed: PGD accepted</b></p>	<p>SD</p>

9.	<b>SHARED CARE GUIDELINES</b>	
	<p><b>Buccal Midazolam</b></p> <p>Mr Dhadli informed JAPC that currently there are 2 shared care agreements for buccal midazolam in status epilepticus across Derbyshire. Epistatus is an unlicensed product for use in adults and the licensed Buccolam product for children. The MRHA states if a licensed product is available then it should be used. Dr Dhadli added the previous barrier for JAPC in not agreeing to use one preferred product was around the training and resource to implement the change and the anticipation that Epistatus had applied for licensing. Mr Dhadli stated that the use of Epistatus was getting more difficult to defend in terms of cost (for the special formulations) and patient safety as children move to adult services. As Epistatus is an unlicensed preparation, prescriptions written for Epistatus could have equivalent special dispensed against the prescription. Mr Dhadli queried also the rationale for a shared care agreement and proposed these patients would be equally managed well through an individual care management plan.</p> <p>Dr Mott suggested that Buccolam be reclassified from amber to green and Epistatus would be reclassified to brown.</p> <p>Dr Mott pointed out DCHS previously had issues with this classification. Mr Steward advised DCHS had been contacted by the council with concerns that carers working with people with learning disabilities and the elderly spent a lot of time training their staff on Epistatus</p> <p>Mr Shepherd highlighted that the Sheffield Neurology Service who see adults in Chesterfield still use Epistatus as their preferred choice at the moment, but that would be OK if the classification stayed brown.</p> <p><b>Agreed: Epistatus – Brown after specialist initiation for adults, Buccolam green after specialist initiation for adults and children</b></p>	SD
9.	<b>MONTHLY HORIZON SCAN</b>	
	<p>Aripiprazole which is a once a month intramuscular treatment for schizophrenia Action – classify RED..</p> <p>Mr Dhadli discussed Avanafil for erectile dysfunction, which prompted him to look at all the classifications for all the PDE-5 inhibitors and stated inconsistencies in their classification. For clarity Mr Dhadli proposed only sildenafil be classified as green for erectile dysfunction following SLS criteria and all others as brown</p> <p>Mr Dhadli stated that PDE5 inhibitors are generally considered equivalent with only subtle differences in their response, so the choice should be based on cost.</p> <p><b>Agreed Sildenafil Green and other PD5 inhibitors Brown</b></p> <p>Golimumab license extension has already been classified red  Omalizumab is a high cost drug and is classified red.  Macitentan and Riociguat are outside PBR - red</p>	SD

<b>10.</b>	<b>MISCELLANEOUS</b>	
	<p><u>Miscellaneous</u> For information Mr Dhadli informed JAPC of new Hep C drugs and the likely impact, they are a major advance but are very expensive drugs, Mr Dhadli stated they are expensive – estimated cost is £35,000 pa for treatment but with a high success rate. <b>Agreed: RED</b></p>	SD
<b>11.</b>	<b>JAPC BULLETIN</b>	
	<p><u>Bulletin</u> Agreed</p>	SD
<b>12.</b>	<b>MHRA DRUG SAFETY UPDATE</b>	
	<p>Mr Dhadli raised two items</p> <ul style="list-style-type: none"> <li>• Anti-TNFs screening for TB prior, during and after treatment.</li> <li>• Increased requirement to reporting pregnancy / last menstrual cycle and expected delivery date for the yellow card system</li> </ul>	
<b>13.</b>	<b>NICE SUMMARY</b>	
	<p><u>NICE template</u> Mrs Qureshi commented on the following drugs TA309 Pemetrexed is a NHS England drug, it's not recommended for use, so recommended it is classified black. <b>Agreed: BLACK</b></p> <p>TA310 Afatinib a NHS England drug, but it is recommended, so suggested it is red. <b>Agreed: RED</b></p> <p>TA311 Bortezomib a NHS England drug. <b>Agreed:RED</b></p> <p>Mr Dhadli commented on CG179 which is about pressure ulcers, it gives a negative assessment of topical negative pressure therapy which we do use locally. Mr Dhadli informed the group he has been in touch with the tissue viability nurses and there is a small group of patients they manage through their service though strict referral criteria. The use by the TVNs goes wider than the pressure ulcers appraised by NICE i.e. in surgical patients to free up beds and improve speed of discharge. No change in existing JAPC guidance was felt to be needed.</p>	SD  SD  SD
<b>14.</b>	<b>TRAFFIC LIGHTS – ANY CHANGES?</b>	
	<p>Metoclopramide - <b>Brown (for long term use in gastroparesis on specialist initiation)</b> Brimonidine Gel - <b>RED</b> Dapsone - <b>RED</b> Diazoxide - <b>RED</b> Fentanyl non transdermal preparations - <b>BROWN (palliative care initiation only)</b> (lozenges/tablets/ buccal film and sublingual tablets)</p>	SD

	<p>Indacaterol &amp; glycopyrronium (Ultibro) inhaler - <b>BLACK</b>  Lubiprostone - <b>BLACK</b>  Mexiletine - <b>RED</b>  Pregabalin - <b>GREEN for GAD</b> (Specialist initiation where SSRIs or venlafaxine are ineffective, poorly tolerated or considered clinically inappropriate)  GLP1 agonists - <b>GREEN</b> (Lixisenatide/liraglutide/exenatide)  Buccolam -<b>GREEN (specialist initiation)</b>  Epistatus - <b>BROWN (specialist initiation)</b>  Aripiprazole depot- <b>RED</b>  Sildenafil - <b>GREEN</b> for Erectile dysfunction as per SLS criteria  Avanafil, Vardenafil and Tadalafil – <b>BROWN</b>  Golimumab – <b>RED</b>  Omalizumab – <b>RED</b>  Macitentan – <b>RED</b>  Riociguat – <b>RED</b>  Sofosbuvir + daclatasvir/ledipasvir+/- ribavirin – <b>RED</b>  Pemetrexed – <b>BLACK</b>  Afatinab – <b>RED</b>  Bortezomib – <b>RED</b></p> <p>Vacuum Pumps - <b>RED (GREEN for constrictor rings)</b>  Vibropulse medical device - <b>BLACK</b></p>	
<b>15.</b>	<b>JAPC ACTION SUMMARY</b>	
	<p><b><u>Shared care – Disulfiram</u></b>  <b>Agreed:</b> Shared Care to return to JAPC in June 2014</p> <p><b><u>Actinic Keratosis</u></b>  Dr Goddard advised Dr Bleiker was finding it difficult to get opinion from CRH, Dr Goddard will follow this up with Graham Colver.  <b>Agreed:</b> Guidance to be submitted to JAPC in June 2014</p> <p><b><u>Diabetes Guideline</u></b>  <b>Agreed:</b> Guidance to be submitted to JAPC in June 2014</p> <p><b><u>Anti-epileptics</u></b>  <b>Agreed:</b> Verbal feedback from Mr Hulme in June 2014</p> <p><b><u>Metoclopramide and gastroparesis</u></b>  <b>Agreed:</b> Domperidone advice to be submitted to JAPC in July 2014</p> <p><b><u>ADHD shared care</u></b>  There was a query around adults and whether they can accept 6 monthly monitoring. Dr Taylor unable to find where NICE found the evidence for 3 monthly monitoring. Mr Dhadli stated if JAPC happy with 6 monthly monitoring he could bring it back to JAPC next month. Mrs Needham suggested emailing Deborah O’Callaghan from NICE to query the monitoring evidence.  <b>Agreed:</b> Shared Care to be submitted to JAPC in June</p> <p><b><u>Medical Devices</u></b>  <b>Lymphoedema garments</b>  Mr Dhadli stated there hadn’t been much engagement in terms of developing the guidance. Dr Mott suggested this was removed from the summary and</p>	<p>SD</p> <p>WG</p> <p>SQ</p> <p>SH</p> <p>WG</p> <p>SD</p>

	<p>taken to guideline groups action plan and for it to come back to JAPC when they have some guidance</p> <p><b>Agreed: Return to Guideline Group</b></p> <p><b>Compression hosiery</b></p> <p><b>Agreed:</b> Return to JAPC in June 2014</p> <p><b><u>NOACs</u></b></p> <p><b>Agreed:</b> Return to JAPC in July 2014</p> <p><b><u>Substance misuse – shared care agreement</u></b></p> <p>Mr Dhadli advised they should be in the work plan from DHcFT, suggesting removing it from the summary and taking it to the guideline group who are chasing up all the shared care agreements.</p> <p><b>Agreed:</b> To remove from the summary and take to guideline group.</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
<b>16.</b>	<b>GUIDELINE GROUP ACTION TRACKER</b>	
	The Guideline Group action tracker was ratified by JAPC.	
<b>17.</b>	<b>MINUTES OF OTHER PRESCRIBING GROUPS</b>	
	For information only	
<b>18.</b>	<b>ANY OTHER BUSINESS</b>	
	<p><b><u>Website</u></b></p> <p>Mrs Needham advised the website is much better, with better searching, facilities. Mrs Needham informed the group if anyone has any issues with website they should contact Miss Chera, Mr Dhadli or Miss Darby to resolve any issues.</p> <p>Dr Mott wished to thank Dr Tooley for his contribution to both JAPC and the Guideline Group over the previous 6 years and wished him well in his retirement.</p>	
<b>19.</b>	<b>DATE OF NEXT MEETING</b>	
	Tuesday 10 <sup>th</sup> June 2014 1.30pm – 4.00pm The Post Mill, South Normanton.	