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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 10th January 2017

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Tadalafil daily formulation	BROWN 2nd line to sildenafil (given up to daily)
Trimipramine	BLACK
Bazedoxifene + conjugated oestrogens (Duavive®)	BLACK
Deferasirox (Exjade®)	RED (NHS England)
Lidocaine + prilocaine (Fortacin®)	BLACK
Arsenic (Trisenox®)	RED (NHS England)
Budesonide MR	BROWN specialist initiation
Ticagrelor 60mg dose	BROWN specialist initiation as per NICE TA 420
Everolimus with exemestane	RED as per NICE TA 421(NHS England)
Crizotinib	RED as per NICE TA 422 (NHS England)
Eribulin	RED as per NICE TA 423 (NHS England)
Pertuzumab	RED as per NICE TA 424 (NHS England)
Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia	RED as per NICE TA 425 (NHS England)
Dasatinib, nilotinib and imatinib for untreated chronic myeloid leukaemia	RED as per NICE TA 426 (NHS England)

Clinical Guidelines

Antipsychotic Physical Health Monitoring
Management of Chronic Rhinosinusitis

Shared Care Guidelines

Lanreotide and octreotide somatostatin analogues
Vigabatrin shared care agreement for children with epilepsy

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Mrs L Hunter	Assistant Chief Finance Officer
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
Mr R Coates	Management Accountant
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 W Goddard	Chair - Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Ms B Thompson	Deputy Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Head Pharmacist
In Attendance:	
Mr S Ahmed	Pharmacist, Southern Derbyshire CCG
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	No apologies were received.	
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.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	Dicycloverine and doxepin.	
4.	**MINUTES OF JAPC MEETING HELD ON 13 DECEMBER 2016**	
	The minutes of the meeting were agreed as a correct record after the following amendment: Prescribing Specification Point 8 - Amend to: 'A GP has the right to refuse to enter into a shared care agreement, but to refuse on the grounds of drug cost alone is unacceptable. CCGs must proactively support implementation of agreed shared care protocols to maximise uptake.'	
5.	**MATTERS ARISING**	
a.	**Sayana Press** Mr Dhadli reported that the protocol for Sayana Press® would be discussed by the MOST group on 7th February and then brought to the March 2017 JAPC meeting.	**SD**
b.	**Oxygen** Mr Dhadli reported that advice on the use of oxygen in palliative care was due to be received from a new consultant who had recently taken up post.	
c.	**Osteoporosis** A meeting had been arranged between Dr Masters and Dr Stanworth on 26th January to look at the osteoporosis guidance, and also the lipid guidance, and this would include the use of PCSK9 inhibitors.	
d.	**Bowel Cleansing** Mr Dhadli reported that comments from Dr Cole (Consultant Gastroenterologist DTHFT) were awaited on whether barium enema should be removed from the guideline and replaced with CT colonography.	
e.	**Clozapine** Mr Dhadli advised that the anti-emetic cyclizine with advice had now been added to the guideline for patients who suffered from nausea and vomiting.	
f.	**Prescribing Specification** Mr Dhadli reported that the prescribing specification had now been agreed outside the meeting and circulated to medicines management and the contracting teams.	

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g.	**Compression Hosiery** Further feedback had now been received and a reference to skin necrosis as a result of incorrectly worn stockings had now been included. Further advice had been added that elastic graduated compression stockings should not be offered to prevent post-thrombotic syndrome or VTE recurrence after a proximal DVT. The recommended duration for wearing the stockings post DVT was two years.	
h.	**High Cost Drug Pathways** Mrs Qureshi reported that no comments had been received from CRHFT clinicians and it was therefore agreed that the ankylosing spondylitis pathway and rheumatoid arthritis algorithms should now be ratified.	
6.	**NEW DRUG ASSESSMENTS**	
a.	**Tadalafil Daily** Mrs Needham reported that a number of requests had been received in North Derbyshire to prescribe tadalafil post prostatectomy once daily, where many such patients had not already received sildenafil. Mrs Needham highlighted that there was limited evidence for the use of daily tadalafil and a very significant difference in price due to the cost of tadalafil once daily being £714.87 per patient per year compared to the maximum annual cost of sildenafil of £89.43 per patient per year (if 100mg was taken daily). The annual spend per year in Derbyshire for tadalafil was £473,455 and it is expected to go off patent in November 2017 with a consequent decrease in price. JAPC had previously assigned a traffic light classification of BROWN for the 10mg and 20mg tablets of tadalafil as PDE5 inhibitors had been considered to be equivalent and the once daily preparations had not been recommended by JAPC. It was noted that DTHFT had sildenafil and tadalafil and CRHFT had sildenafil and avanafil on their formularies respectively. Sildenafil was licensed for use up to a maximum of once daily but not for this indication. Mr Dhadli advised JAPC that erectile dysfunction (ED) was a common complication following prostatectomy due to cavernosal nerve damage, causing hypoxia, apoptosis, venous leak and fibrosis of the corpora cavernosa. The use of the phosphodiesterase-5 (PDE5) inhibitors, avanafil, sildenafil, tadalafil and vardenafil following prostatectomy could reverse or minimise these adverse effects. They have been used as supportive therapy to rehabilitate erectile function successfully post-radical prostatectomy and with greater efficacy following nerve sparing radical prostatectomy. The UKMI review on the use of the PDE5 inhibitors had highlighted shortfalls in the studies: • It was unclear which regime, daily or on demand, offered the best treatment. • There were no direct head to head studies of one PDE5 inhibitor versus another; 75% of the patients treated in the studies were caucasian. • The treatment length had varied from twelve weeks to one year patients. • Some of the studies had been versus placebo or non-placebo. • There had been no clear distinction between unilateral or bilateral surgeries.	

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	Mr Dhadli added that the PrescQIPP bulletin on tadalafil once-daily had referred to the half-life of 17.5 hours for tadalafil which was approximately four times longer than sildenafil or vardenafil. It had been found to be suitable for once daily administration with steady state being reached after approximately five days. It was noted that, due to their different pharmacokinetic characteristics, neither sildenafil, vardenafil nor avanafil may reach steady state even if taken on a daily basis. The NICE guidelines had not recommended a particular PDE5 inhibitor but had only stated that the choice should be the one with the lowest acquisition cost. Dr Goddard commented that feedback from DTHFT consultant urologists had indicated that there was a role for tadalafil but only following radical prostatectomy or rehabilitation. Dr Mott advised that there were two possible traffic light classifications of BLACK or BROWN specialist initiation after the unsuccessful use of sildenafil as first line. **Agreed:** Tadalafil once daily formulation classified as a **BROWN** specialist initiation drug after the use of sildenafil first line as a small cohort of patients could benefit from prescribing.	**SD**
b.	**<u>Trimipramine</u>** Mr Dhadli reported that, due to a very significant increase in the price of the antidepressant drug trimipramine, it had been queried whether it should be de-commissioned and existing patients should be switched to another drug. Trimipramine was not listed on the DTHFT formulary and had restricted use within CRHFT and not included in the Derbyshire anti-depressant guidance. Ms Thompson stated that trimipramine was not currently used by DHcFT but it was likely that there were some patients who had been on it for some time and these would need to be carefully reviewed before being switched to an alternative drug. However it was noted that the numbers of patients concerned was small and therefore a BLACK classification for all new patients would be appropriate. Existing patients should be reviewed in line with local guidance. **Agreed:** Trimipramine classified as a **BLACK** drug as less cost-effective than current standard therapy.	**SD**
c.	**<u>Conjugated Oestrogens and Bazedoxifene Acetate (Duavive®)</u>** Mr Dhadli stated that bazedoxifene + conjugated oestrogens (Duavive®) had been highlighted in the horizon scan at the September 2016 JAPC meeting when it had been decided to leave as unclassified and await clinician request or a review. A NICE New Medicine Review on oestrogen deficiency symptoms in postmenopausal women: conjugated oestrogen and bazedoxifene acetate had now been produced and this had indicated that many women experienced a range of symptoms during the menopause and perimenopause and that these symptoms were often short lived and lessened or disappeared over time. A new drug Duavive® had now been launched which contained bazedoxifene and conjugated oestrogens. Oestrogens promoted the growth of the endometrium when used alone without progestogen in women with a intact uterus increased the risk of endometrial hyperplasia and cancer.	

Item		Action
	Bazedoxifene was a selective oestrogen receptor modulator and acted as an oestrogen receptor antagonist in the uterus to reduce the oestrogen-induced risk of endometrial hyperplasia in non-hysterectomised women. Duavive® was proposed as a second line treatment where progesterone therapy was not appropriate and was an oestrogen receptor modulator. The evidence came derived from 5 phase III RCT SMART studies SMART 2 had demonstrated a significant reduction in the average daily number of moderate and severe hot flushes compared to placebo. However the studies had highlighted significant safety concerns versus placebo due to lack of clarity on its positioning versus other progesterone containing HRT preparation. Without an active comparator it was unknown to what extent bazedoxifene reduced the effectiveness of conjugated oestrogens. SMART 1 (to assess endometrial safety) and 4 (to assess endometrial hyperplasia) had been excluded because EPAR considered studies to be flawed. SMART 5 had indicated that four women had endometrial thickness and eight of at least 4 mm did not have a biopsy and eight did not have a biopsy or trans-vaginal ultrasound undertaken. The short duration of all the studies had also been highlighted together with a lack of data about older women. **Agreed:** Conjugated Oestrogens and Bazedoxifene Acetate (Duavive®) classified as a **BLACK** drug due to lack of data on safety and comparison to an active comparator.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**<u>Antipsychotic Physical Monitoring</u>** Ms Thompson stated that a twelve month extension to the current guideline had been requested to allow time for the LESTER framework to be fully introduced within DHcFT. **Agreed:** JAPC ratified a twelve month extension to the existing guideline for Antipsychotic Physical Monitoring.	**SD**
b.	**<u>Management of Chronic Rhinosinusitis</u>** Mr Dhadli reported that the guideline for the management of chronic rhinosinusitis had been sent out for review to ENT consultants and no changes had been made. The guidance recommends a step up/down approach and primary care management. **Agreed:** JAPC ratified the guideline for the management of chronic rhinosinusitis with a two year review date.	**SD**
8.	**SHARED CARE GUIDELINES**	
a.	**<u>Somatostatin</u>** Mr Dhadli reported that the shared care guideline for lanreotide and ocreotide somatostatin analogues had been sent out for review to Dr Vijayan, DTHFT Consultant Oncologist, and Mr James Kerr, DTHFT pharmacist, and no changes had been made. It was noted that CRHFT did not initiate patients on this treatment.	

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Item		Action
	Agreed: JAPC ratified the shared care agreement for lanreotide and ocreotide somatostatin analogues with a two year review date.	**SD**
b.	**Vigabatrin** Mr Dhadli reported that the vigabatrin shared care agreement for children with epilepsy had been developed by Dr W Carroll, DTHFT Consultant Paediatrician. The shared care agreement had been sent out for review and no changes made. **Agreed:** JAPC ratified the vigabatrin shared care agreement for children with epilepsy with a two year review date.	**SD**
9.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New formulation launches in the UK: Deferasirox (Exjade®) – NHS England. Classified as **RED.** Desmopressin (Noqdirna®) – No change to current GREEN classification for nocturnal enuresis after consultation/specialist recommendation. Hydromorphone (Palladone®) – Intravenous or subcutaneous injection or infusion. It was agreed that the opinion of the pain consultants and palliative care should be obtained on its place in therapy. This will include the oral as well as injectable forms, and to be brought to future JAPC. Lidocaine + prilocaine (Fortacin®) – Classified as **BLACK** due to a lack of information to determine its place in therapy. Licence extensions: Arsenic (Trisenox®) – NHS England. Classified as **RED.** Nivolumab (Opdivo®) – Already classified as **RED.** Secukinumab (Cosentyx®) – Already classified as **RED**. Ustekinumab (Stelara®) – Already classified as **RED.** Drug Discontinuation: SMA Gold Prem 2, Premique, Tegretol suppositories, Respontin and calcium 500.	**SD** **SD** **SD** **SD**
10.	**MISCELLANEOUS**	
a.	**Budesonide MR** Mr Dhadli reported that the Guideline Group had received requests from some practice pharmacists for two forms of budesonide preparations for colitis, Entocort® 3mg EC MR and Budenofalk® 3mg EC which were currently unclassified, to be assigned a traffic light classification of RED. A traffic light classification of RED had been assigned to Cortiment® 9mg EC MR by JAPC in July 2015 given its short duration of treatment and likely place of UC diagnosis. It had been proposed that, in view of the licensed dosage for up to eight weeks, all the budesonide drugs should be given by specialists only and therefore should be classified as RED. However it was noted that there was a cohort of patients who were on budesonide outside the licence but under specialist supervision. A traffic light classification of BROWN specialist initiation could therefore be assigned on the grounds of exceptionality.	

Item		Action
	During discussion Dr Goddard advised that budesonide MR was used by consultants off-licence for selected patients who could not tolerate standard oral steroids. However advice had been received from other secondary care clinicians that low dose maintenance budesonide had proved to be beneficial for some elderly patients who were intolerant to other drugs; those patients with microscopic and collagenous colitis and some patients with autoimmune hepatitis who experienced side effects with prednisolone. **Agreed:** Budesonide MR oral preparations classified as a BROWN specialist initiation drug due to exceptionality where a small cohort of patients may benefit from prescribing.	**SD**
11.	**JAPC BULLETIN**	
	The bulletin was ratified by JAPC.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for December 2016 was noted. Mr Dhadli highlighted the following MHRA advice: • Cobicistat, ritonavir and co-administration with a steroid: risk of systemic corticosteroid adverse effects. If co-administration was considered to be necessary then the use of beclomethasone should be considered where possible; particularly for long-term use. • Spironolactone and renin-angiotensin system drugs in heart failure: risk of potentially fatal hyperkalaemia. • In November 2016 letters had been sent to relevant healthcare professionals concerning apremilast (Otezla▼), which had a risk of suicidal ideation and behaviour, and lenalidomide (Revlimid▼) with new advice about viral reactivation. Mr Dhadli highlighted again the risk of RED drugs not being recorded on GP clinical systems.	
13.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in December 2016: TA 420 Ticagrelor for preventing atherothrombotic events after myocardial Infarction – A dual classification had been assigned by JAPC of GREEN after specialist/consultant initiation as per NICE TA236 for cardiologist initiation only, with the discharge to indicate the stop date. For acute coronary syndromes (ACS) a loading dose of 180mg should be given to be followed by 90mg twice daily for up to twelve months. A traffic light classification of BLACK had been assigned for the prevention of atherothrombotic events after myocardial infarction. TA 420 now recommended the use of 60mg ticagrelor with aspirin as extended therapy for up to three years after the initial twelve month treatment with dual anti-platelet therapy. It was highlighted that there would be cost implications for the CCGs associated with the implementation of NICE TA 420.	

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Item		Action
	Mr Dhadli added that advice had been received from DTHFT consultant cardiologists that the numbers of patients would be very small and the TA was due to be discussed by DTHFT Drugs and Therapeutic Committee. The ACS guidance would need to be updated accordingly and the place in therapy for the use of ticagrelor for this indication determined before it could be used in primary care. There was an issue about the action which would need to be taken concerning the historic MI patients and stop dates were also needed. Classified as a **BROWN** consultant/specialist initiation drug due to the exceptional use determined within the TA.	**SD**
	TA421 Everolimus with exemestane for treating advanced breast cancer after endocrine therapy. This guidance replaced TA295 Everolimus in combination with Exemestane, which was recommended within its marketing authorisation as an option for the treatment of advanced human epidermal growth factor receptor 2 (HER2)-negative, hormone-receptor-positive breast cancer in postmenopausal women without symptomatic visceral disease that had recurred or progressed after a non-steroidal aromatase inhibitor. Classified as a **RED** drug.	**SD**
	TA422 Crizotinib for previously treated anaplastic lymphoma kinasepositive advanced non-small-cell lung cancer. This guidance replaced TA296 Crizotinib which was recommended, within its marketing authorisation, as an option for previously treated anaplastic lymphoma kinase-positive advanced non-small cell lung cancer in adults. Classified as a **RED** drug.	**SD**
	TA423 Eribulin for treating locally advanced or metastatic breast cancer after two or more chemotherapy regimens. This guidance replaced TA250 Erbulin which was recommended as an option for treating locally advanced or metastatic breast cancer in adults. Classified as a **RED** drug.	**SD**
	TA424 Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer. Classified as a **RED** drug (NHS England).	**SD**
	TA425 Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia. This guidance replaced TA241 and partially replaced TA70 Dasatinib and Nilotinib which were recommended as options for treating only chronicor accelerated-phase Philadelphia chromosome-positive chronic myeloid leukaemia in adults if they could not have imatinib or their disease was imatinib-resistant. Classified as a **RED** drug.	**SD**
	TA426 Dasatinib, nilotinib and imatinib for untreated chronic myeloid leukaemia. This guidance replaced TA251 and partially replaced TA70 Imatinib which was recommended as an option for untreated, chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults. Dasatinib and nilotinib were recommended, within their marketing authorisations, as options for the treatment of untreated chronic-phase Philadelphia chromosome-positive chronic myeloid leukaemia in adults. Classified as a **RED** drug.	**SD**

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Item		Action
	NG 59 Low back pain and sciatica in over 16s: assessment and management. Recommendation for the use of non-steroidal anti-inflammatory drugs (NSAIDs) at the lowest effective dose for the shortest period of time and for patients to be given gastro protection if needed. Weak opioids, with or without paracetamol, should be given if a NSAID was contraindicated, not tolerated or had been ineffective. It was noted that the local pain guidance would need to be updated in the light of this NICE guideline.	**SD**
14.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Tadalafil once daily preparation– **BROWN** 2nd line to sidenafil Trimipramine – **BLACK** Bazedoxifene + conjugated oestrogens (Duavive®) – **BLACK** Deferasirox (Exjade®) – **RED** (NHS England) Lidocaine + prilocaine (Fortacin®) – **BLACK** Arsenic (Trisenox®) – **RED** (NHS England) Budesonide MR – **BROWN** specialist initiation Ticagrelor – **BROWN** specialist initiation as per NICE TA 420 Everolimus with exemestane – **RED** as per NICE TA 421 Crizotinib - **RED** as per NICE TA 422 Eribulin – **RED** as per NICE TA 423 Pertuzumab – **RED** as per NICE TA 424 Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia – **RED** as per NICE TA 425 Dasatinib, nilotinib and imatinib for untreated chronic myeloid leukaemia – **RED** as per NICE TA 426	
15.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: PCSK9 inhibitors and Lipid/Familial Hypercholesterolaemia guidance – a meeting had been arranged between Dr Masters and Dr Stanworth to look at the osteoporosis guidance and also the lipid guidance to include PCSK9 inhibitors. This would then be brought to a JAPC meeting when finalised. Guanfacine - to be taken off the list and left with DHcFT to request reclassification in due course if they wish. Osteoporosis - guidance to be re-drafted with consultant feedback. Sacubitril/valsartan – to be brought to the March 2017 JAPC meeting.	**SD** **SD** **SD** **MS/CN**
16.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in November 2016 was noted. Mr Dhadli highlighted the following: • Advice included concerning the use of lower doses of paracetamol in oral treatment in patients with low body weight and risk factors. • Movicol 'ready to take' assigned a traffic light classification of BLACK as not cost-effective.	

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	• Nicotine replacement therapy guidance almost completed. • Phosphate binders guidance almost completed but further information awaited about the generic version of sevelamer. • Comments had now been received from Ms Thompson on the vitamin supplementation in alcohol misuse and this would be further discussed by the Guideline Group.	**SD**
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Sheffield Area Prescribing Group 15/09/16 • Sheffield Area Prescribing Group 20/10/16 • Chesterfield Drugs and Therapeutic Committee 15/11/16 • Clinical Commissioning Policy Advisory Group 10/11/16 • DTHFT Drugs and Therapeutic Committee 15/11/16 Mr Dhadli highlighted the following: • Sheffield Area Prescribing Group - a traffic light classification of AMBER had been assigned for guanfacine. • Chesterfield Drugs and Therapeutic Committee - an incident had occurred in the CRHFT emergency department where a patient under the care of the rheumatology service and receiving treatment with etanercept had presented with signs of sepsis and there had been a subsequent failure to recognise that the patient was being treated with etanercept and the association between this, its immunosuppression effects and the patient's presentation.	
18.	**ANY OTHER BUSINESS**	
	Mr Dhadli referred to dicycloverine and doxepin where the drug tariff prices had very significantly increased and queried the extent of usage of these two high cost drugs and whether the prescribing of these should be stopped and action taken to switch historic patients to an alternative. For doxepin Ms Thompson advised that it would be necessary to discuss this on a patient by patient basis. It was agreed that it would be advantageous if the prescribing groups could discuss the practice level data on the level of prescribing of the two drugs before any decision on action was made.	**SH/KN**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 14th February 2017 at 1.30pm in the Post Mill Centre, South Normanton.	