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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 12 February 2019

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Hydrocortisone granules (Alkindi®)	BROWN specialist initiation
Olopatadine eye drops	GREEN
Ketotifen preservative free eye drops (Ketofall®)	BROWN
Levonorgestrel (Levosert®)	GREEN
Paravit™- CF	GREEN for use in patients with cystic fibrosis/BLACK for all other indications
Semaglutide	BROWN 2nd line if intolerant to Lixisenatide
VSL#3 probiotic	BLACK
Ganciclovir eye gel	GREEN consultant/specialist recommendation
Spironlactone	GREEN 1st line
Eplerenone	BROWN 2nd line mineralocorticoid receptor antagonist for HFREF if spironolactone not suitable (usually young men <50 years, due to gynaecomastia risk).
Enoxaparin biosimilar (Inhixa®)	GREEN consultant specialist initiation
Sodium deoxycholate (Belkyra®)	BLACK
Tisagenlecleucel	RED (as per NICE TA 554)
Regorafenib	RED (as per NICE TA 555)
Darvadstrocel	BLACK (as per NICE TA 556)
Pembrolizumab	RED (as per NICE TA 557)
Nivolumab	RED (as per NICE TA 558)
Axicabtagene ciloleucel	RED (as per NICE TA 559)

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Bumetanide	GREEN
Losartan	GREEN

Clinical Guidelines

Management of Heart Failure with Reduced Ejection Fraction (HFREF) - Subject to clarification of the echocardiogram diagnostic pathway and funding decision for sacubitril/valsartan (Funding agreed post meeting)

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Patient Group Directions
Derbyshire Health United (DHU) Patient Group Directions.
Administration of pneumococcal polysaccharide conjugate vaccine (Public Health England)

Shared Care Guidelines
Sacubitril/Valsartan for the treatment of symptomatic chronic heart failure with reduced ejection fracture subject to funding decision. (Funding agreed post meeting)
Vigabatrin for children with epilepsy

Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mrs S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Dr M Watkins	GP
North Derbyshire CCG	
Dr C Emslie	GP
Dr T Narula	GP
Mrs K Needham	Assistant Director of Medicine Optimisation and Delivery (also representing all four Derbyshire CCGs)
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	
University Hospitals of Derby and Burton NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr D Moore	HCD Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist (also representing DCHSFT)
Derbyshire Community Health Services NHS Foundation Trust	
Derby and Derbyshire Local Medical Committee	
Dr K Markus	Chief Executive Officer

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Derbyshire Health United	
Mr D Graham	Pharmacist
In Attendance:	
Mr G Griffith	Derby City Council Business Support
Ms S Horsley	Specialty Registrar in Public Health, Derby City Council
Mr A Thorpe	Derby City Council Business Support (minutes)

Item		Action
1.	**APOLOGIES**	
	Mr S Hulme.	
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 in relation to this agenda; in addition to the existing register of interests. It was noted that there was no representation from DHcFT so all recommendations and decisions made by JAPC would be subject to ratification outside the meeting.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	There were no declarations of any other business.	
4.	**MINUTES OF JAPC MEETING HELD ON 8 JANUARY 2019**	
	The minutes of the meeting held on 8th January 2019 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Amiodarone** Mr Moore would follow up the numbers of patients on amiodarone to be reviewed at UHDBFT.	**DM**
b.	**Specialist Infant Formulary** It was agreed that this would be discussed by the guideline group and placed on the action tracker with a report to a future JAPC meeting.	**SD**
6.	**JAPC ACTION SUMMARY**	
a.	**Freestyle Libre®** Dr Markus reported that some concern had been expressed by some GPs about the wording at the top of the flowchart which indicated that this must be strictly adhered to. It was noted that Freestyle Libre® would be discussed again in the next few months due to a change in national funding together with a review of the eligibility criteria – this could then be an opportunity to review the wording. It was highlighted that activity planning would still need to be carried out in the new financial year in the light of the publication of revised guidance from the RMOC. To be taken off the list.	**SD**

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Item		Action
b.	**Hydroxychloroquine** Dr Mott advised that a decision about eye screening was still awaited from the CCG Clinical and Lay Commissioning Committee (CLCC). An update would be brought to the May JAPC meeting.	**SD**
c.	**Clostridium difficile** Mrs Qureshi reported that Ms D Holland was still in the process of liaising with Ms S Bestwick, Lead Nurse – infection Prevention and Control, Erewash and Southern Derbyshire CCGs. To be brought to the March JAPC meeting.	**SD**
d.	**Infant Feeding** To be taken off the list and Guideline Group to follow up.	**SD**
e.	**Budesonide** To be brought to the April JAPC meeting.	**SD**
f.	**Rosuvastatin** It was noted that the available data indicated that the use of rosuvastatin had not unexpectedly increased since the lipid guidance had been updated. To be taken off the list.	**SD**
g.	**Homely Remedies** This would be kept on the action tracker in the light of the concerns expressed about the requirement for GPs to sign off a list of homely remedies and check for possible interactions.	**SD**
h.	**Liothyronine** Mr Moore advised that feedback had been requested from all of the UHDBFT consultant endocrinologists on progress concerning the reviews of patients who were taking liothyronine. Comments received to date indicated that some of the patients had been stopped but others had not attended for review or had continued usage. The position therefore would need to be reviewed in a few months' time and brought back to a future JAPC meeting.	**SD**
7.	**NEW DRUG ASSESSMENTS**	
a.	**Hydrocortisone Granules (Alkindi®)** Mr Moore reported that Alkindi®, available as capsules containing granules of hydrocortisone, was now licensed for administration to children under the age of eighteen years for adrenal insufficiency. It had been assigned a traffic light classification of RED by JAPC in November 2018 as implied per NHS England commissioning intentions. However the East Midlands Specialised Commissioning team had stated that adrenal insufficiency in children was commissioned by NHS England but the drug itself was in tariff. The use of Alkindi® was now being considered in the light of the December 2018 MHRA alert concerning the risk of insufficient cortisol absorption and life-threatening adrenal crisis if muco-adhesive buccal tablets were used as adrenal replacement therapy. Currently approximately ten patients were receiving the buccal tablets for the treatment of adrenal insufficiency and these would need to be reviewed and then transferred to another product. Alkindi® had been discussed as a possible alternative choice by the UHDBFT Drugs and	

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	Therapeutic Committee and, although slightly more expensive, was considered to be a safer alternative to other preparations of hydrocortisone which must be individually prepared by compounding/crushing or by production of special solutions in order to produce age-appropriate doses. Mr Dhadli reminded JAPC that a licensed preparation should preferably be used where one was available as per MHRA advice. It had also been agreed by the UHDBFT that Alkindi® 5mg would not be routinely used as, once the patients were on measurable dosages of 5mg or above, then they could be transferred over to the standard tablets. For those younger children on smaller and variable dose, then Alkindi® would be used as the licensed product. Dr T Tinklin, UHDBFT Consultant Paediatrician, would co-ordinate the switching and had contacted the patients concerned to alert them to this. It was planned that the first prescription of Alkindi® would be supplied in secondary care and then transferred to primary care for continuation. Mr Shepherd advised that CRHFT used the oral suspension product so no difficulties were anticipated. **Agreed:** Alkindi® hydrocortisone tablets classified as **BROWN** specialist initiation for exceptional use in the cohort of patients identified.	**SD**
b.	**<u>Ketotifen Eye Drops</u>** Mr Moore reported that the December 2018 meeting of the UDBHFT Drugs and Therapeutic Committee had considered a request from a consultant ophthalmologist for the use of ketotifen eye drops for allergic conjunctivitis for adults and children. Ketotifen was available as two formulations, one of which contained a preservative and the other preservative free. The current first line drug was olopatadine which was not preservative free and there had been recent problems concerning the supply chain. The preservative containing formulation (Zaditen®) would be used when olopatadine was unavailable and the preservative free formulation (Ketofall®) would be used when a product containing a preservative was contra-indicated. It was noted that the evidence from two studies had not revealed significant differences in efficacy between olopatadine and ketotifen for the symptoms found with allergic conjunctivitis. Mr Dhadli informed JAPC that the current formulary choice of lodoxomide should be replaced with the cost effective olopatadine eye drops and that the supply issue had been resolved after contacting the manufacturer. Ketotifen was a reasonable cost effective option over Opticrom (sodium cromoglycate) preservative free formulation. The evidence being similar for eye treatments for treating allergic conjunctivitis. Following discussion it was agreed that the formulary choices in primary care for allergic conjunctivitis would be updated to include Otrivine Antistin (self-care) together with olopatadine and ketotifen to replace lodoxamide. Ketofall® to be used when a preservative free product was required. **Agreed:** Olopatadine eye drops classified as a **GREEN** drug as suitable for	

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	primary care prescribing.	**SD**
	Agreed: Ketotifen eye drops (Ketofall®) classified as a **BROWN** drug if a preservative free product was needed.	**SD**
c.	**Levosert®** Mr Moore reported that Levosert® Intrauterine Delivery System (Levonorgestrel 52mg) was indicated for contraception and treatment of heavy menstrual bleeding. It had been licensed for three year use since its launch in 2015 but had now been approved in the UK for five year use. The licence extension meant that an additional five year treatment option could be offered to women seeking long-acting reversible contraception (LARC) for women under the age of 45 years. Levosert® had been assigned a traffic light classification of BLACK by JAPC in 2015 as it was comparable, but more expensive than Mirena®, and at the time only had a three year licence. Following the extension to five years it was now a cheaper alternative to Mirena® but was not yet licensed for endometrial protection during oestrogen replacement therapy. It was highlighted that Levosert® had a slightly different insertion technique than Mirena® which requires training in primary care.	
	Agreed: Levosert® classified as **GREEN** as suitable for primary care prescribing.	**SD**
	Action: A link to guidance about the fitting technique would be included.	**SD**
d.	**Paravit™- CF Liquid and Capsule** Mr Dhadli reported that some requests had been received from GPs to prescribe Paravit™-CF which was a fat-soluble vitamin supplement specifically designed for patients with cystic fibrosis in liquid and softgel capsule form. Paravit™-CF was classified as a Food for Special Medical Purposes (FSMP) and was a multivitamin containing the four fat-soluble vitamins A, D, E and K. This had the advantage of reducing the number of alternative tablets and/or capsules which otherwise would be required. Mr Dhadli added that the NHS England cystic fibrosis commissioning document referred to the long term use of vitamin supplements as being under the remit of the CCGs. GPs currently prescribed individual vitamin supplementation separately so Paravit™-CF would enable vitamin supplementation to be given to cystic fibrosis patients at doses which were in line with the Cystic Fibrosis Trust recommendations and at a reduced cost. It was noted that Nottingham, South Staffordshire and Greater Manchester Area Prescribing Committees had included Paravit™-CF into their formularies. The guideline group had proposed a traffic light classification of BROWN with exceptionality for cystic fibrosis patients only.	
	Agreed: Paravit™-CF classified as **GREEN** only for use in patients with cystic fibrosis and **BLACK** for all other indications.	**SD**
e.	**Semaglutide** Mr Moore reported that semaglutide (Ozempic®) was a glucagon-like peptide	

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	1 receptor agonist (GLP-1RA) indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise. Semaglutide could be used in conjunction with other drugs for the treatment of diabetes, or as monotherapy, in patients who could not tolerate metformin. Semaglutide had been the subject of an RDTC review which had demonstrated greater reductions in HbA1c than any of the other comparators together with significant weight loss of 3.5 - 6.4 kg. The reductions in fasting plasma glucose had been greater in patients treated with semaglutide than with most of the other comparators. The exceptions had been insulin glargine and dulaglutide 0.75 mg which were associated with reductions of similar magnitude to semaglutide 0.5 mg. Semaglutide was associated with good cardiovascular outcomes, similar to liraglutide, and had reduced the number of non-fatal strokes. The UHDBFT diabetologists had defined the potential cohort of patients who could benefit from the use of semaglutide as those who were unable to undergo bariatric surgery and those who had experienced a previous cardiovascular event or were at high risk of an event. Patients unable to tolerate semaglutide would be switched to liraglutide. Mr Dhadli advised that the cost of semaglutide was comparable to the other GLP-1s but the preferred local choice was lixisenatide which was significantly cheaper. However there was a lack of current information about the incremental costs and benefits. In addition, there could be a large number of patients who had experienced a previous cardiovascular event or were at high risk of an event and this could result in a potential additional cost pressure. Mr Dhadli reminded JAPC of the limited place in the treatment pathway for the treatment of type 2 diabetes. NICE were waiting for the outcome of a number of further diabetes clinical trials, which included GLP-1receptor agonists, to conclude before publication of a TA which was currently under consultation. It was also highlighted that the administration of semaglutide was once-weekly compared to lixisenatide which was daily. Dr Mott referred to the previous discussions at RMOC Midlands and the East of England on the GLP-1 receptor agonists. Semaglutide was known to be a superior drug but the cost effectiveness of this against the use of the other GLP-1s had yet to be determined. It was comparable to liraglutide daily dose although the side effects were potentially greater. However semaglutide was regarded as a potentially useful agent and could become the first line choice once the cost analysis had been done. The RMOC would be producing a position statement on semaglutide. Dr Henn queried whether there could be a QIPP opportunity to review all the current GLP-1 expenditure of £1.3 million in order to achieve cost savings. **Agreed:** Semaglutide classified as a **BROWN** drug for exceptional use defined as intolerance to the first line choice of lixisenatide or restricted by its licensing. **Action:** The agreed traffic light classification would be reviewed by the guideline group following the publication of the NICE TA.	**SD** **SD**

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f.	**VSL#3** Mr Dhadli reported that the pharmaceutical company who manufactured VSL#3 poly-biotic food supplement had notified GPs that this product was no longer approved by the Advisory Committee for Borderline Substances (ACBS). VSL#3 had accordingly been taken off the local formulary but could still be dispensed and reimbursed on FP10 prescriptions. In addition, it was noted that patients could still purchase the product over the counter. The guideline group and Clinical Effectiveness Team had therefore recommended that VSL#3 should no longer be promoted. This was in line with advice provided by PrescQIPP and NHS England concerning the lack of sufficient clinical evidence to support the prescribing of probiotics. Mr Dhadli added that, due to the recommendation to no longer make this product available to patients and the lack of an alternative on prescription, an Equality Impact Assessment (EIA) and Quality Impact Assessment (QIA) had been completed. **Agreed:** VSL#3 classified as a **BLACK** drug as not recommended or commissioned as the ACBS had withdrawn their approval. **Action:** The EIA and QIA forms would be circulated to JAPC members to ensure that all members were sighted on any issues arising and ensure due process has been completed.	**SD** **SD**
g.	**Zovirax (Aciclovir) Eye Ointment Discontinuation/Ganciclovir Eye Gel** Mr Dhadli reported that notification had been received from GlaxoSmithKline that Zovirax® (aciclovir) eye ointment had now been discontinued with stock expected to continue to be available in the UK until the end of June 2019. There was no other branded or generic acyclovir eye ointment available and the only alternative product was ganciclovir (Virgan®) eye gel. This would result in an increased incremental spend of approximately £3k. **Agreed:** Ganciclovir eye gel classified as a **GREEN** consultant/specialist recommendation drug for herpes simplex eye infections.	**SD**
8.	**CLINICAL GUIDELINES**	
a.	**Clozapine** This item was deferred to the next JAPC meeting as there was no representative from DHcFT present.	**SD**
b.	**Heart Failure** Mr Dhadli reported that the heart failure guideline had been reviewed by UHDBFT and CRHFT consultant cardiologists, DCHSFT heart failure specialist nurse and GP lead for shared care pathology and updated in line with NICE NG106 'Chronic heart failure in adults: diagnosis and management.' The following changes had been made: • The definition of heart failure had been updated. • NT-proB-type Natriuretic Peptide (NTPro BNP) blood test was the recommended test for choice but not for brain natriuretic peptide (BNP) • The diagnostic section now included a link to the shared care	

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	pathology heart failure guideline. • Increased access to spironolactone/eplerenone for patients who remained symptomatic. Spironolactone, currently classified as a BROWN drug, was now the preferred first line choice for heart failure with a reduced ejection fraction (HFREF). Eplerenone, currently classified as a BROWN drug needed to be amended with a defined cohort for only to be used for young males less than fifty years of age due to the risk of gynaecomastia. • NICE recommended that, once the target/maximum tolerated dose of ACE inhibitor was reached renal function should be monitored monthly for three months; then at least every six months. Local guidance referred to that, if the target/maximum tolerated dose was reached, renal function should be checked after one month then every six months or more frequently if the status of the patient changed. • An update to the diagnosis flow chart which removed reference to previous MI • The use of licensed beta blockers for HF was recommended by NICE. • Information about sacubitril/valsartan included subject to approval of the shared care guideline. • Lifestyle advice updated. • Changes to the monitoring of the ACE inhibitors. During discussion it was highlighted that clarification was required concerning the diagnostic pathway for an echocardiogram and specialist advice. Dr Markus suggested that the reference to faxing in the GP Referral Criteria and Contact Details section should be removed. **Action:** JAPC ratified the Management of Heart Failure with Reduced Ejection Fraction (HFREF) guidance subject to clarification of the echocardiogram diagnostic pathway with a review date of two years. **Agreed:** Spironolactone classified as **GREEN** 1st line mineralocorticoid receptor antagonist for Heart Failure with reduced ejection fraction. **Agreed:** Eplerenone classified as **BROWN** 2nd line mineralocorticoid receptor antagonist for Heart Failure with reduced ejection fraction.	**SD** **SD** **SD** **SD**
9.	**PATIENT GROUP DIRECTIONS**	
a.	**Derbyshire Health United (DHU) Patient Group Directions** Mr Graham reported that the PGDs for DHU Health Care CIC had now been scrutinised and amended where necessary by the DHU PGD Board and subsequently by a sub-committee of the Clinical Effectiveness Group. The PGDs were noted as follows: • Amoxicillin 500mg Capsules and 125mg/5ml and 250mg/5ml SF suspension • Chlorphenamine maleate 2mg/5ml solution • Chlorphenamine maleate 4 mg tablets • Clarithromycin 250mg/500mg tablets 125mg/ml and 250mg/5ml suspension.	

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	• Codeine phosphate 30mg and15mg tablets • Doxycycline 100mg capsules • Erythromycin 250mg tablets & 125mg/5ml, 250mg/5ml suspension • Flucloxacillin 250mg & 500mg capsules, 125mg/5ml and 250mg/5ml suspension • Ibuprofen 100mg/5ml suspension • Ibuprofen tablets 400mg tablets • Nitrofurantoin 100mg MR capsules • Paracetamol 120mg/5ml and 250mg/5ml SF suspension • Prednisolone 5 mg tablets • Paracetamol 500mg tablets • Salbutamol 100 microgram metered dose inhaler • Salbutamol nebulising solution • Clarithromycin 500mg tablets 250mg/5ml suspension • Clarithromycin 250mg/500mg tablets clarithromycin 125mg/ml suspension, clarithromycin 250mg/5ml suspension Mr Graham highlighted that the analgesic PGDs remained the same and there were two new inclusions for clarithromycin in line with national guidance. In addition, erythromycin had been maintained due to the supply issues previously experienced with clarithromycin. Mr Graham confirmed that self-care would be actively promoted and monitored by DHU. Mr Dhadli queried the necessity of obtaining antimicrobial sign off for the antimicrobial PGDs in order to ensure that they were legally compliant. Mrs Needham would check this with Dr D Harris. Dr S Lloyd, Derbyshire CCGs Medical Director, would then be requested to provide final sign-off.	**KN**
b.	**<u>PHE Pneumococcal Polysaccharide Conjugate Vaccine</u>** The following PGD from Public Health England was noted by JAPC: Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals from 6 weeks (routinely from 8 weeks) to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease and to individuals from 6 weeks of age recommended PCV13 in response to an outbreak of pneumococcal disease.	
10.	**SHARED CARE GUIDELINES**	
a.	**<u>Attention Deficit Hyperactivity Disorder (ADHD)</u>** This item was deferred to the next JAPC meeting as there was no representative from DHcFT present.	**SD**
b.	**<u>Sacubitril/Valsartan (Entresto®)</u>** Mr Dhadli reported that sacubitril/valsartan for the treatment of symptomatic chronic heart failure with reduced ejection fracture use across both secondary and primary care had been classified as RED by JAPC in May 2016 due to a difference of opinion amongst cardiologists about its efficacy and to gain experience of use across both secondary care trusts and specialist community services. NICE had published TA 388 ‘Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction’ in	

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	May 2016. It was reported that the cardiologists had now reached a consensus on its use in line with the recommendations from the SPC. A consultant or specialist would initiate treatment and then handover the patient to primary care according to the shared care agreement. Mr Dhadli referred to the changes which had been made to the actions required if patients experienced side effects concerning hypotension, hyperkalaemia and renal impairment. A reference had been included to the JAPC Heart Failure guidance on ACE inhibitors (ACEi) to include advice from the NICE Clinical Knowledge Summary (CKS) on chronic heart failure and also to the risk of hyperkalaemia following interaction with trimethoprim. Dr Watkins advised that the necessity of ensuring that a patient's repeat prescription for ACE inhibitors or ARBs was stopped before being commenced on sacubitril/valsartan should be highlighted in the guidance. Dr Markus requested the addition of the need for confirmation that the consultant or specialist had initiated a patient on sacubitril/valsartan and titrated up to achieve stabilisation before a transfer to primary care was made. Dr Mott highlighted that a re-classification of sacubitril/valsartan had the potential to increase prescribing and that it would be advantageous to ascertain the extent of any increase in activity in order to understand the financial implications. However sacubitril/valsartan had received a positive NICE TA and increased use of it in Derbyshire could have a positive impact on the outcomes of patients with heart failure. The adoption of the shared care guideline would result in a cost shift from secondary care to primary care of approximately £100k and a process would therefore be required within the CCGs to consider the investment required. **Action:** Dr Mott, Mrs Hunter and Mr Hulme would discuss the investment required for the cost shift from primary to secondary care and seek CCG approval of the increased spend. **Agreed:** JAPC approved the shared care agreement for sacubitril/valsartan for the treatment of symptomatic chronic heart failure with reduced ejection fracture subject to clarification of the initiation, titration and stabilisation section, and subject to CCG agreement for the additional cost in the primary care prescribing spend. (funding agreed post meeting)	**AM/LH/SH**
c.	**<u>Vigabatrin</u>** JAPC noted that the vigabatrin shared care guideline for children with epilepsy had been updated in January 2019 and subsequent changes had been made by Dr H Faza, UHDBFT Consultant Paediatrician, in association with Nottingham paediatric neurologists at Nottingham and a UHDBFT paediatric ophthalmologist. The changes were: • Paediatricians to make appropriate arrangements for visual field checks or where these are not practical, alternative arrangements for visual screening/monitoring. • Patients above the age of twelve should undergo, where appropriate, systematic screening examination when starting vigabatrin and at	**SD**

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	regular intervals for detection of visual field defects. • Screening for visual field deficits required specialist input for children with a cognitive age of nine years and above. Children with epilepsy should be under regular review by a paediatrician with expertise in epilepsy and where necessary a paediatric neurologist. Where required, the hospital team will seek ophthalmology assessment. These specialists should arrange visual screening for children (above the age of twelve) taking vigabatrin at the appropriate time. • Ensure that the patient has had planned visual field checks included in the GP responsibilities section. • Contact details had been updated. **Agreed:** JAPC approved the shared care agreement for vigabatrin for children with epilepsy with the agreed amendments with a review date of two years.	**SD**
11.	**MISCELLANEOUS**	
a.	**Enoxaparin** Mr Moore explained that it was planned within UHDBFT to switch as soon as possible from Clexane (enoxaparin) 40mg, 60mg and 80mg to Inhixa® (an enoxaparin biosimilar) partly due to stock availability issues. In addition, there would be a cost saving for both secondary care and primary care by the use of Inhixa® which was highly similar to Clexane in terms of structure, safety, purity and biological activity but needed a different administration technique with the use of a syringe needle guard. It was noted that only one needlestick injury had been experienced within the Trust from the use of Inhixa® and training videos were available to demonstrate the administration technique. Mr Moore added that two further strengths of Inhixa® 120mg and 150mg were to be launched in March 2019. Mr Dhadli advised that another biosimilar Arovi® was available at a lower unit cost. However an exercise had been undertaken to look at the net benefit for the Derbyshire health economy based on usage and procurement prices and this concluded that Inhixa® was a reasonable choice. Some shortages of tinzaparin, which was used by CRHFT, were also anticipated and some Trusts had been requested to move to alternative products. However CRHFT would continue to use tinzaparin. **Agreed:** Inhixa® enoxaparin biosimilar classified as **GREEN** consultant/specialist initiation. **Action:** Mrs Needham would discuss with Ms K Lindley, Head of Medicines Management, Clinical Intelligence and Standards, the process for switching to Inhixa® within primary care. An update would be given to the March JAPC meeting.	**SD** **KN**
b.	**Management of Opioid Medications** A recent briefing statement to healthcare professionals on the management of opioid medications issued by the Faculty of Pain Management was noted by JAPC. The current commissioning gap in primary care for the	

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	management of patients who were addicted to prescription opioids would be discussed by the CCG Clinical and Lay Commissioning Committee (CLCC). It was agreed that a reference be included in the bulletin that JAPC supported the reduction of the use of opioid based medications.	**SD**
c.	**<u>Brexit</u>** The letter from the Department of Health and Social Care concerning the continuity of supply of medicines as part of the Government's contingency preparations for a 'no deal' exit from the European Union was noted by JAPC.	
12.	**REGIONAL MEDICINES OPTIMISATION COMMITTEE (RMOC)**	
	JAPC noted the following: • RMOC Midlands and East Update 2019 – There had been discussion on sodium oxybate and further discussions would be held with NHS England specialised commissioning. A position statement would be issued on GLP-1 mimetics.	
13.	**JAPC BULLETIN**	
	The January 2019 bulletin was ratified.	
14.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for January 2019 was noted. Mr Dhadli highlighted the following MHRA advice: • Tapentadol (Palexia®): risk of seizures and reports of serotonin syndrome when co-administered with other medicines. • Ipilimumab (Yervoy®): reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation. • Yellow Card App: The updated app can be downloaded to receive the latest MHRA safety news and report suspected side effects, including in pregnancy.	
15.	**HORIZON SCAN**	
	<u>Monthly Horizon Scan</u> Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New drug launches in the UK: • Adalimumab biosimilar (Imraldi®) – Previously classified as **RED**. • Infliximab biosimilar (Zessly®) – Previously classified as **RED**. • Semaglutide (Ozempic®) – Classfied as **BROWN**. • Sodium deoxycholate (Belkyra®) – Classified as **BLACK**. New formulation launches in the UK: • Guselkumab (Tremfya®) – Previously classified as **RED**. • Tenofovir alafenamide (Vemlidy®) – Previously classified as **BLACK** (NHS England). • Tocilizumab (RoActemra®) – Previously classified as **RED**. Licence extensions:	

Item		Action
	• Canagliflozin (Invokana®) – Previously classified as **BROWN**. • Dulaglutide (Trulicity®) – Previously classified as **BROWN**. • Exenatide (Bydureon®) – Previously classified as **BROWN**. • Fingolimod (Gilenya®) - Previously classified as **RED** (NHS England). • Pembrolizumab (Keytruda®) – Previously classified as **BLACK** for NICE TA 540 and **RED** for all other TAs (NHS England). **NICE Horizon Scan** Mr Dhadli highlighted the following clinical guidelines which may be of relevance to JAPC: • Epilepsies in children: diagnosis and management - February 2019. • Epilepsies in adults: diagnosis and management update – February 2019. • Urinary incontinence (update) and pelvic organ prolapse in women: management – April 2019. • Depression in children and young people: identification and management – April 2019. • Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (update) - May 2019. • Ulcerative Colitis (update) (CG166) - May 2019. • Cohn's Disease Management (update CG152) – May 2019. • Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2019 update) in relation to triple therapy of LABA+LAMA+ICS– July 2019. • Hypertension in adults: diagnosis and management – August 2019. • Venous thromboembolic diseases: diagnosis, management and thrombophilia testing (2019) - November 2019. • Thyroid disease: assessment and management - November 2019. • Depression in adults: treatment and management – December 2019. • Acute coronary syndromes - May 2020. • Chronic pain: assessment and management – August 2020. • Atrial fibrillation: management – September 2020. • Acne Vulgaris: Management - January 2021. • Epilepsies in children: diagnosis and management - April 2021. **NICE Technology Appraisals** Tildrakizumab for treating moderate to severe plaque psoriasis - April 2019 Certolizumab pegol for treating moderate to severe plaque psoriasis – April 2019. Ertugliflozin as monotherapy and in dual therapy for treating type 2 diabetes - June 2019. Ertugliflozin in a triple therapy regimen for treating type 2 diabetes – June 2019. Clostridium botulinum neurotoxin type A for treating hypersalivation associated with neurological conditions – December 2019.	
16.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance in January 2019:	

Item		Action
	TA 554 Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years – Classified as **RED** (NHS England as per NICE TA 554). TA 555 Regorafenib for previously treated advanced hepatocellular carcinoma – Classified as **RED** (NHS England as per NICE TA 555). TA 556 Darvadstrocel for treating complex perianal fistulas in Crohn's disease – Classified as **BLACK**. TA 557 Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, nonsquamous nonsmall- cell lung cancer – Classified as **RED** (NHS England as per NICE TA 557). TA 558 Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease – Classified as **RED** (NHS England as per NICE TA 558). TA 559 Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies – Classified as **RED** (NHS England as per NICE TA 559).	
17.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in January 2019 was noted. Mr Dhadli highlighted the following: Traffic Lights: Bumetanide – Classified as GREEN. Losartan – Classified as GREEN. For Information: Formulary update (Chapter 2 – Cardiovascular System): Coracten SR or XL was the cost effective brand where slow release nifedipine was recommended. Clinical Guidelines: Menopause guideline - Contacts removed as the North Derbyshire NHS Specialist Menopause Service had been decommissioned. Antimicrobial Guidance – A review of all the guidelines was currently in process.	
18.	**JAPC SUB-GROUPS**	
	<u>Biosimilar and High Cost Drugs (HCD) Working Group</u> The paper of the top biosimilar medicines list which gave the target annual savings broken down to UHDBFT, CRHFT and Burton Hospitals NHS Foundation Trust was noted by JAPC. It was noted that the Biosimilar and HCD Working Group would no longer meet at present as there were no new biosimilar drugs on the horizon but monitoring of biosimilar uptake would continue virtually.	

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Item		Action
	Dr Mott highlighted the very successful uptake of adalimumab by all of the Trusts. However the etanercept biosimilar uptake in UHDBFT had not been as successful and action would be taken to address this. A joint letter to remaining patients from the DTC and APC Chairs would support this.	
19.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Hydrocortisone granules (Alkindi®) –BROWN specialist initiation Olopatadine eye drops - GREEN Ketotifen preservative free eye drops (Ketofall®) – BROWN Levonorgestrel (Levosert®) - GREEN Paravit™-CF – GREEN for use in patients with cystic fibrosis/BLACK for all other indications Semaglutide – BROWN 2nd line if intolerant to Lixisenatide VSL#3 probiotic - BLACK Ganciclovir eye gel- GREEN consultant/specialist recommendation Spironolactone – GREEN 1st line Eplerenone – BROWN 2nd line mineralocorticoid receptor antagonist for HFREF if spironolactone not suitable (usually in younger men <50yrs of age, due to gynaecomastia risk) Enoxaparin biosimilar (Inhixa®) – GREEN consultant specialist initiation Sodium deoxycholate (Belkyra®) - BLACK Tisagenlecleucel – RED (as per NICE TA 554) Regorafenib – RED (as per NICE TA 555) Darvadstrocel – BLACK (as per NICE TA 556) Pembrolizumab - RED (as per NICE TA 557) Nivolumab – RED (as per NICE TA 558) Axicabtagene ciloleucel – RED (as per NICE TA 559)	
20.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• DHcFT Medicines Management Committee 25/10/2018 • DHcFT Medicines Management Committee 22/11/2018 • Nottingham Area Prescribing Committee 15/11/2018 • UHDBFT Drugs and Therapeutic Committee 18/12/2018 • CRHFT Drugs and Therapeutic Committee 15/01/2019	
21.	**ANY OTHER BUSINESS**	
	Clinical Guideline/Shared Care Guidelines Expiry Date Mr Dhadli referred to the current two year review date for clinical guidelines and shared care guidelines and queried whether this could be extended to three years. This was agreed by JAPC.	**SD**
22.	**DATE OF NEXT MEETING**	
	Tuesday, 12th March 2019 at 1.30pm in the Coney Green Business Centre, Clay Cross.	