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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 13th February 2018

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Inegy® (simvastatin+ ezetimibe combination)	BLACK
Darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza®)	RED as per NHS England commissioning intentions
Daptomycin (Cubicin®)	RED
Golimumab	RED (as per NICE TA 497)
Lenvatinib with everolimus	RED (as per NICE TA 498)
Glecaprevir - pibrentasvir	RED (as per NICE TA 499)
Ceritinib	RED (NHS England as per NICE TA 500)
Ibrutinib	RED (NHS England as per NICE TA 502)
Fulvestrant	BLACK (as per NICE TA 503)
Vilanterol + fluticasone + umeclidinium (Trelegy®)	BROWN (Triple therapy is reserved for exceptional use in severe disease in the presence of persistent exacerbations despite other treatments)

Clinical Guidelines

Management of Non-Malignant Chronic Pain in Primary Care
Referral guide for Allergic Rhinitis in Adults and Adolescents over 12 years of age
Menopause Management
Oxygen
Treatment of Severe Psoriasis in Adults (secondary care)

Patient Group Directions

Administration of Hepatitis B vaccine to individuals pre- and post-exposure to hepatitis
Administration of Hepatitis B vaccine to renal patients.
Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV)

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Professional Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management (also representing Erewash CCG)
Mrs S Qureshi	NICE Audit Pharmacist
North Derbyshire CCG	
Dr C Emslie	GP
Dr T Narula	GP
Mrs K Needham	Assistant Chief Quality Officer (Medicines Management) (also representing Hardwick CCG)
Hardwick CCG	
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 D Moore	HCD Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Ms B Thompson	Deputy Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Ms C Duffin	Principal Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Pharmacist
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Mr C Newman, Dr T Parkin, Ms M Simpson, Ms J Town and Dr M Watkins.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	Dr Mott reminded committee members of their obligation to declare any interest they may have on any issues arising at committee meetings which might conflict with the business of JAPC. No conflicts of interest were declared in relation to this agenda; in addition to the existing register of interests.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Esmya® (ulipristal acetate) – MHRA warning.	
4.	**MINUTES OF JAPC MEETING HELD ON 9 JANUARY 2018**	
	The minutes of the meeting held on 9th January 2018 were agreed as a correct record after the following amendment: Freestyle Libre® - Amend the second action to: 'The audit data results would be reviewed by JAPC, in conjunction with the diabetes service, in three, six and twelve months in order to gain assurance that the audit has been effective in its objectives.'	
5.	**MATTERS ARISING**	
a.	**Omega 3 and Liothyronine** The review of the two patients in Chesterfield who had been started on omega-3 fatty acids by DHcFT would be placed on the agenda for the next meeting of the Trust's Drugs and Therapeutic Committee.	**BT**
b.	**Levocarnitine** Dr Markus reported that examples when JAPC and other area prescribing committees had assigned different traffic light classifications for the same drug were currently being collated. Mr Dhadli added that Sheffield Area Prescribing Committee would discuss how levocarnitine would be commissioned in Sheffield at their next meeting.	
c.	**Nefopam** Dr Mott highlighted that the circulated trends for the prescribing of nefopam showed a significant reduction and this was largely attributable to the traffic light classification of BLACK assigned by JAPC.	
d.	**Omega 3** Mr Dhadli advised JAPC that NHS England had published a document concerning items which should not routinely be prescribed in primary care and one of the recommendations was that prescribers in primary care should not initiate omega-3 Fatty Acids for any new patient. JAPC had assigned a traffic light classification of BROWN after consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins. Dr R Stanworth, DTHFT Consultant Diabetologist, had been requested to submit evidence for the use of omega-3 fatty acids for this indication and three papers had subsequently been received:	

Item		Action
	• Endocrine Society's Clinical Practice Guideline on the Evaluation and Treatment of Hypertriglyceridemia – This had highlighted that severe and very severe hypertriglyceridemia increased the risk for pancreatitis. Recommendations and key points in this document included: ➢ Lifestyle therapy, including dietary counselling to achieve appropriate diet composition, physical activity and weight reduction. ➢ For severe and very severe hypertriglyceridemia reduction of dietary fat and simple carbohydrate intake with drug treatment to reduce the risk of pancreatitis. ➢ Fibrates should be used as a first-line agent for reduction of triglycerides in patients at risk for hypertriglyceridemia induced pancreatitis and three drug classes (fibrates, niacin, n-3 fatty acids) alone or in combination with statins should be considered as treatment options in patients with moderate to severe hypertriglyceridemia levels. ➢ The evidence came from observational and epidemiological studies and there was a systematic review meta-analysis of observational studies commissioned by the Endocrine society. This had revealed that hypertriglyceridemia was associated with an increased risk of cardiovascular events and pancreatitis. The primary goal was to reduce triglycerides and the evidence suggested that fibrates and Omega-3 were most effective. To date there were no studies which demonstrated beneficial effects to show a reduction in cardiovascular events with the use of high-dose n-3 fatty acids in patients with moderate to severe hypertriglyceridemia levels. ➢ Reference had been made to over the counter preparations of omega-3 fatty acids which had variable quantities of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) ranging from 20 - 50%. Omega- 3 acid ethyl esters were available by prescription in capsules which contained 80% EPA and DHA. • The Association of Hypertriglyceridemia with Cardiovascular Events and Pancreatitis: a Systematic Review and Meta-analysis – This had used observational studies and control arms of RCT and had documented an association between fasting hypertriglyceridemia and the risk of several cardiovascular adverse events and also with acute pancreatitis. It had been highlighted that the main limitation of association studies was the observational nature of the existing evidence. Other limitations related to the heterogeneity of the meta-analytic estimates, publication bias and reporting bias. • Omega-3 carboxylic acids in patients with severe hypertriglyceridemia: EVOLVE II, a randomized, placebo-controlled trial. This had demonstrated that Omega-3 reduced triglycerides as a primary outcome if these were >10mmol/L and the treatment was well tolerated. Mr Dhadli advised that the evidence submitted by Dr Stanworth indicated that hypertriglyceridaemia was a cause of pancreatitis and the standard treatment for the prevention of recurrent pancreatitis was to reduce triglyceride levels with lipid medications, including Omega-3, which has been shown to reduce triglyceride levels. Fibrates were the first line treatment and this aligned with the available evidence.	

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	During discussion Mrs Needham queried whether the NHS England commissioners should be informed about the exceptional use of Omega-3 for the small cohort of patients with hypertriglyceridaema as this had not been indicated in their consultation report. Mr Dhadli would contact the NHS England/NHS Clinical Commissioners about this.	**SD**
	Agreed: The existing exceptionality for use of Omega-3 after consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins to continue.	**SD**
e.	**Suspected Deep Vein Thrombosis** Ms Braithwaite reported that that the Minor Injury Units (MIUs) within DCHSFT were leading the work, in association with a GP, on a revised pathway for suspected deep vein thrombosis (DVT). A pathway would be developed for use when patients presented with a suspected DVT at MIU and they would then be given a first dose of anticoagulant medicine before being sent for a scan at the Acute Trust. It was anticipated that the pathway would be developed by May/June 2018 and GPs would be able to access this. Ms Braithwaite added that it would be important to ensure that MIU staff were trained to check for D-Dimers and calculate the Wells DVT score. It was agreed that it would be preferable for a single pathway to be in use across the system including those patients who presented to general practice - this would be considered by the group.	
	The suspected DVT pathway would be placed on the action tracker for an update in three months.	**SD**
6.	**JAPC ACTION SUMMARY**	
	Use of NOAC for suspected DVT – To be brought to the May or June 2018 JAPC meeting.	**SD**
	Rosuvastatin – Pending DT price drop and launch of generics.	
	Hydroxychloroquine – Guidance from the Royal College of Ophthalmologists was still awaited on optical coherence tomography (OCT) testing and would be brought to a JAPC meeting when available.	**SD**
	Dosulepin – To be brought to the March 2018 JAPC meeting.	**SD**
	Freestyle Libre® - This had now been discussed by JAPC.	**SD**
	Shared care principles – The updated document on shared care principles was awaited from the Department of Health and would be brought to a JAPC meeting when available.	**SD**
7.	**NEW DRUG ASSESSMENTS**	
a.	**Inegy®** Mr Dhadli reported that Inegy®, a simvastatin + ezetimibe combination preparation, had been discussed by the Guideline Group who had recommended that the current traffic light classification of BROWN be changed to BLACK as it was more expensive than the separate products.	

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	Mr Dhadli advised that an Equality Impact Assessment (EIA) would not be required as there were suitable alternative treatments. **Agreed:** Inegy® classified as a **BLACK** drug as not routinely recommended or commissioned.	**SD**
8.	**CLINICAL GUIDELINES**	
a.	**Chronic Non-Cancer Pain** Mr Dhadli reported that the guideline had been updated in collaboration with Dr R Faleiro, DTHFT Consultant in Anaesthesia and Pain Medicine, and Dr Ian Makkison, CRHFT Consultant in Pain Medicine. Main changes were: • Addition of reference to the increased risk of harm/mortality from oral morphine at doses exceeding 120mg/day with no increase in benefit. • Topical capsaicin 0.025% could be considered as an adjunct after NSAIDs (topical or oral) with or without paracetamol in osteoarthritis. This was in line with the September 2017 JAPC decision to classify topical capsaicin cream as BROWN for this indication. • A table of 24 hour doses of codeine/tramadol/morphine, which were considered to be approximately equivalent to the buprenorphine patches, had been included. It had been highlighted that when switching there was a need to reduce the calculated equivalent dose of the new opioid by one-quarter to one-half to avoid possible opioid induced hyperalgesia. • Addition of North Derbyshire pain management programme referral form as appendix 5. **Agreed:** JAPC approved the Management of Non-Malignant Chronic Pain in Primary Care guideline with the approved amendments with a review date of two years.	**SD**
b.	**Dymista®** Mr Dhadli advised that the guideline had been updated in collaboration with Mr S Mortimore, DTHFT ENT Consultant, and Mr C de Casso, CRHFT Consultant Otolaryngologist, Head, Neck and Thyroid Surgeon. The guideline included referrals in for those patients who had been optimally treated in primary care before referral to secondary care and the appropriate restricted use of Dymista® which had been previously re-classified from BLACK to BROWN after consultant/specialist initiation. Main changes were: • Addition of the need to encourage self-care in mild and intermittent (seasonal) allergic rhinitis. • Tabulation of the dose and cost of Dymista® in a similar way as the nasal steroid sprays. There was no new evidence in relation to Dymista® so its position in the pathway would be unchanged. **Agreed:** JAPC approved the referral guide for Allergic Rhinitis in adults and adolescents over 12 years of age with the agreed amendments with a review date of two years.	**SD**

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c.	**Menopause** Mr Dhadli reported that the menopause guideline had been discussed at the January 2018 JAPC meeting and some amendments requested. The guideline had therefore been amended in collaboration with Dr A Smith, Associate Specialist with the Derbyshire Integrated Sexual Health Service, to include: • Addition of definitions of menopausal symptoms. • Inclusion of a new treatment flowchart to include formulary choices of hormone replacement therapy (HRT). • Addition of advice about the use of Mirena® and Tibolone®. • Addition of absolute risks of HRT taken from NICE CG 23 Menopause: diagnosis and management. • Clarification of the wording relating to blood test for diagnosis. • In the hormonal content of formulary HRT preparations table cyclo-progynova to be removed and Femoston® and Indivina® to be added. • Inclusion of advice about topical testosterone gel (Testogel®) dose and duration to follow specialist advice. **Agreed:** JAPC approved the Menopause Management guideline with the agreed amendments with a review date of two years.	**SD**
d.	**NSTEMI (South)** Mr Dhadli reported that the anti-platelet guideline for ACS (Acute Coronary Syndrome) NSTEMI (Non-ST-elevation myocardial infarction) in the south had been due for review in March 2017. Mr Dhadli advised that, at the time the guidance had first been produced, the routine use of ticagrelor had been considered to be unaffordable when the cheaper alternative products of clopidogrel and prasugrel were available. There were currently two versions of the NSTEMI/anti-platelet guidance for north and south. In the north version the open use of ticagrelor had been permitted but in the south version a restriction had been agreed for its use only in high risk patients while acute coronary syndrome (ACS) was confirmed with the thrombolysis in myocardial infarction (TIMI) score. It was highlighted that both ticagrelor and prasugrel had both received positive TAs from NICE: • Ticagrelor in combination with low-dose aspirin was recommended for up to twelve months as a treatment option in adults with acute coronary syndromes (ACS). • Ticagrelor 60mg BD, in combination with aspirin, was recommended as an option for the prevention of atherothrombotic events in adults who had a MI and who were at high risk of a further event. • Prasugrel 10 mg in combination with aspirin was recommended as an option for the prevention of atherothrombotic events in adults with acute coronary syndrome (UA, NSTEMI or STEMI). Mr Dhadli highlighted that, on an annual basis, approximately 330 patients underwent percutaneous coronary intervention (PCI) for NSTEMI at DTHFT and this was the target group for the use of ticagrelor. Assuming 220 patients were prescribed ticagrelor instead of clopidogrel for one year the additional cost would be £152,838. Mr Dhadli referred to the NICE document 'Achieving and Demonstrating Compliance with NICE TA and HST Guidance' and highlighted the following:	

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	• Commissioners had a statutory responsibility to make funding available for a drug or treatment recommended by a NICE TA or HST within the timeframe recommended in that guidance. • Providers and commissioners must not restrict access to NICE approved medicines by adding to or modifying the clinical eligibility criteria stated in the TA or HST. In terms of clinical effectiveness of ticagrelor versus clopidogrel it was noted that a Canadian Agency for Drugs and Technologies in Health (June 2012) and a MTRAC review (January 2011) had concluded that ticagrelor was more effective than clopidogrel for high risk patients but there was no direct comparison with prasugrel. It would be possible therefore for the south guidance to be aligned with the north which stated that, if a diagnosis of NSTEMI was confirmed, there would be a switch to ticagrelor from clopidogrel. If a diagnosis of unstable angina was confirmed clopidogrel would be continued. During discussion Mr Hulme highlighted the necessity for CCGs, in the light of the current challenging financial climate, to scrutinise all new and unplanned investment decisions, even if they were NICE mandated. It may be necessary therefore to disinvest in another area in order to release the necessary finance to fund this particular TA. Mr Hulme also advised that the CCG governance structures were about to change and all future new investments would be reviewed by a new clinical commissioning committee to cover all of the Derbyshire CCGs. Dr Mott commented that all TAs were mandated by NICE and would therefore need to be implemented within the stipulated timescale. However this presented a process issue for the CCGs and consequently there would be a need to determine how to mitigate for this. **Agreed:** JAPC approved the merger of the north and south NSTEMI guidelines into one document. **Agreed:** Mr Hulme would take to the appropriate Southern Derbyshire and Erewash CCG committees for agreement for the investment to change the pathway.	**SD** **SH**
e.	**<u>Oxygen</u>** Mr Dhadli advised that the oxygen guideline had been updated in collaboration with Ms S Smith, DTHFT Specialist Practitioner for Oxygen and Ms C Barnett, CRHFT Home Oxygen Nurse and the main change was: • Out of hours and emergency requests for oxygen would now be requested via an electronic portal. The Guideline Group had queried how this change had been communicated to GP practices. The Home Oxygen Order Form (HOOF) had been changed in November 2016 and at that time NHS England had notified CCGs and all GP practices accordingly. HOOF prescribers would be routed to the Air Liquid Portal to order the oxygen and this would be accessible without a log in. **Agreed:** JAPC approved the oxygen guideline with the agreed amendments with a review date of two years.	**SD**

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Item		Action
f.	**Psoriasis** Mr Dhadli reported that the pathway for the treatment of severe psoriasis in adults was for use in secondary care where high cost drugs (out of tariff) were used and commissioned directly by the CCG. The drugs used in the pathway were all NICE TA compliant, with some locally agreed variations, based on the NICE CG Psoriasis: assessment and management to prevent further hospital admissions for those patients with severe psoriasis. It was highlighted that the high cost drugs could potentially present a significant financial challenge to the CCGs if commissioning intentions were unclear. Dr Mott added that the pathway had been discussed earlier by the JAPC Biosimilar/High Cost Drugs Working Group and the next phase would be to map the cost effectiveness of each of the agents. The adalimumab biosimilar was due to be released in late summer/early Autumn and this was likely to have some impact on choice. There was a plan in place to consider a switch to the biosimilar if there were sufficient numbers of patients and cost benefits to implement this. **Agreed:** JAPC approved the guidelines for the treatment of severe psoriasis in adults.	**SD**
9.	**PATIENT GROUP DIRECTIONS**	
	The following PGDs from Public Health England were noted and agreed by JAPC: • Administration of Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals considered at increased risk of exposure to hepatitis B virus, at increased risk of complications of hepatitis B disease, or post potential exposure to hepatitis B virus. • Administration of Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure that is likely to require haemodialysis or transplant. • Administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV) Individuals from 8 weeks to under 2 years of age in accordance with the national immunisation programme.	
10.	**MISCELLANEOUS**	
a.	**Gluten Free** Mr Dhadli referred to the national consultation on the prescribing availability of gluten-free (GF) foods on NHS prescriptions and the three options which had been included in this: • Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. • Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods in primary care. • Option 3: To only allow the prescribing of certain GF foods (e.g. bread and flour) in primary care by amending Schedule 1 of the above regulations. Mr Dhadli advised that the Secretary of State for Health and Social Care had decided to adopt option 3 and it was noted that this was a variation to the local decision that GF foods were not to be commissioned.	

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	A position statement had been produced by the four Derbyshire CCGs and this was tabled for information. Mr Dhadli highlighted the reference in the position statement that CCGs were allowed under the NHS Constitution to make their own decision making to best meet the needs of their populations and this had been referenced in the national consultation. Another query had been raised concerning exceptionality and JAPC had concluded that the exceptional group of patients who would benefit could not be identified and this was one of the reasons for the planned six month review. GPs were allowed to prescribe GF products in restricted cases and record the reasons. These would subsequently be reviewed in order to ascertain whether anyone had been missed via the consultation and Quality Impact Assessment (QIA). During discussion Mrs Needham commented on the low number of people who had responded to the national consultation. Dr Mott referred to increasing interest from the media but the decision made by the CCG governing bodies still stood subject to review. Dr Henn queried whether there was sufficient clarity on the difference between the individuality and exceptionality and added that there was likely to be pressure on some GPs in the light of their obligation under the primary care service contract to provide patients with the appropriate medications for their clinical conditions. Mr Dhadli referred to the inclusion of Individual Funding Requests (IFRs) process in the local policy which was how a GP or consultant could request, on behalf of a patient, treatments that were not normally funded locally on the NHS. Dr Markus opined that certain conditions required medications only available on prescription but, for patients who were diagnosed with coeliac disease and needed a GF diet, then a prescription would not be needed as GF products could be purchased from a variety of sources. However, the difficulty for GPs would be how to explain this difference to the patients who presented at a surgery. Mrs Needham commented that it had been helpful that prescribers were able to convey queries to the Patient Advice and Liaison Service (PALS) as this would avoid them having to be involved in any discussions as to whether a prescription should be issued or not. It was noted that the information that had been provided did contain this reference to PALS. The four CCG Governing Bodies would receive a paper reflecting the outcome of the national consultation and subsequent decision in the next round of Governing Body meetings.	
b.	**<u>Flu Vaccination</u>** The letter from NHS England on vaccine ordering for the 2018 to 2019 influenza season was noted by JAPC.	
c.	**<u>Freestyle Libre®</u>** Mr Dhadli reported that a letter had been sent by NHS England to CCG Accountable Officers to say that CCGs should engage with GPs and diabetes secondary care clinicians locally to ensure that there was common understanding on the local approaches being taken in relation to Freestyle Libre®. An email had also been received from Dr M Atkin and Dr R Gregory, on behalf of the Association of British Clinical Diabetologists (ABCD) Type 1 Diabetes Clinical Collaborative UK /Association of British Clinical Diabetologists, which referred to the considerable variation in approach to Freestyle Libre® by CCGs.	

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	In addition, an amendment to the position statement had been made to state that Freestyle Libre® was permitted for NHS patients started outside of Derbyshire that complied with Regional Medicines Optimisation Committee (RMOC) criteria and undertook the national audit or following an APC shared care agreement.	
d.	**NICE Osteoporosis** Mr Dhadli explained that NICE TA 464 'Bisphosphonate for Treating Osteoporosis' had indicated that an oral bisphosphonate was cost effective for treating osteoporosis in adults if the person was eligible for risk assessment on osteoporosis and the ten year probability of osteoporotic fragility fracture was at least 1%. The purpose of the TA had been to determine at what level of absolute fracture risk bisphosphonates were cost effective. There had been a cost reduction for oral bisphosphonates and the absolute risk level at which they were cost effective was now very low. Dr R Stanworth, DTHFT Consultant Endocrinologist, had sent an article from 'The Lancet ' published in November 2017 to Medicines Management which referred to concern that the strict application of cost-effectiveness thresholds for inexpensive drugs could lead to counterintuitive and potentially harmful guidance. Clinicians from Birmingham had highlighted that the 1% threshold included in the NICE TA was not a treatment intervention threshold but a cost effectiveness threshold. Their default position was therefore that a clinically assured service was provided which addressed the cost effectiveness threshold by NICE of 1%. The information provided by Dr Stanworth was noted for information by JAPC. Dr Markus referred to those patients who had osteopenia diagnosed via a DEXA scan who were attending the Falls Clinic. It was noted that practices were being requested to prescribe bisphosphonates and it had been queried whether this was a relevant indication.	
11.	**JAPC BULLETIN**	
	Mrs Needham advised that it should be highlighted in the text of the Freestyle Libre® section that this should only be started after diabetic consultant/specialist initiation within a Derbyshire Diabetes Service – this was agreed. The amended bulletin was ratified by JAPC.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for January 2018 was noted. Mr Dhadli highlighted the following MHRA advice: • Daclizumab (Zinbryta▼) and risk of severe liver injury: new restrictions to use and strengthened liver monitoring. • Recombinant human erythropoietins: very rare risk of severe cutaneous adverse reactions (SCARs). • Drug-name confusion: reminder to be vigilant for potential errors. • Co-dydramol: prescribe and dispense by strength to minimise risk of medication error. Previously co-dydramol (dihydrocodeine/paracetamol) had been available only in the ratio 1:50 (co-dydramol 10/500 mg).	

Item		Action
	Two products were now available with a higher strength of dihydrocodeine (co-dydramol 20/500 mg and 30/500 mg tablets). Dr Mott suggested that Guideline Group should consider whether the two new strengths of co-dydramol should be given a traffic light classification.	**SD**
13.	**HORIZON SCAN**	
	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: Darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza®) - Classified as **RED** as per NHS England commissioning intentions. Licence extensions: Daptomycin (Cubicin®) – Classified as **RED** pending review by the Drug and Therapeutic Committees. **Quarterly NICE Updates** Mr Dhadli referred JAPC to the NICE horizon scan and highlighted the following: Clinical Guidelines: • Dementia – assessment, management and support for people living with dementia and their carers. • Attention deficit hyperactivity disorder (update). • Hearing loss in adults: assessment and management. • Chronic heart failure in adults: diagnosis and management. • Chronic obstructive pulmonary disease in over 16s: diagnosis and management (update). • Lyme disease.	
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in January 2018: TA 497 Golimumab for treating nonradiographic axial spondyloarthritis – Classified as **RED** (as per NICE TA 497). TA 498 Lenvatinib with everolimus for previously treated advanced renal cell Carcinoma – Classified as **RED** (NHS England as per NICE TA 498). TA 499 Glecaprevir – pibrentasvir for treating chronic hepatitis C – Re-classified as **RED** (as per NICE TA 499). TA 500 Ceritinib for untreated ALK positive non-small-cell lung cancer – Classified as **RED** (NHS England as per NICE TA 500). TA 502 Ibrutinib for treating relapsed or refractory mantle cell lymphoma – Classified as **RED** (NHS England as per NICE TA 502). TA 503 Fulvestrant for untreated locally advanced or metastatic oestrogenreceptor positive breast cancer – Classified as **BLACK** (as per NICE TA 503).	

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Item		Action
	NG 82 Age-related macular degeneration - The use of ranbizumab and aflibercept was recommended but the guidance stated 'be aware that no clinically significant differences in effectiveness and safety between the different anti-VEGF treatments have been seen in the trials considered by the guideline committee.' NICE anticipated a small resource impact as a result of this guideline which would occur gradually over the next five years (Southern Derbyshire CCG £169k; North Derbyshire CCG £91k; Hardwick CCG £36k and Erewash CCG £31k) and a large proportion of cases would mean people would be treated earlier than they would have been previously. The costs were queried and it was agreed that the local ophthalmologists would be asked whether they were following the NG and whether this would represent a change in practice. NG84 Sore throat (acute): antimicrobial prescribing – This was in line with the Public Health England 'Antimicrobial prescribing and stewardship competencies'. Sore throats were mainly a self-limiting condition and the general advice was to use self-care but, if antibiotics were needed, recommendations for adults and children were included. Dr Markus and Dr Narula requested clarity about the stated course length of antibiotics of five to ten days for adults. It was agreed that the NICE Guidance should be sent to Dr D Harris, Lead Antimicrobial Pharmacist, with a request for clarification.	**SQ** **SD**
15.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group (SCaGG) meeting held in January 2018 was noted. Mr Dhadli highlighted the following: Traffic Light: Vilanterol and fluticasone and umeclidinium (Trelegy®) – Classified as **BROWN**. Guidelines: Glaucoma - Intraocular pressure (IOP) treatment updated in line with NICE NG81 and the new IOP treatment threshold was 24mmHg; generic topical prostaglandin first line. Low-molecular-weight heparin (LMWH) (enoxaparin and tinzaparin) – the enoxaparin dose had been updated in line with the SPC. 1.5mg/kg OD for uncomplicated patients with low risk of venous thromboembolism (VTE) recurrence; 1mg/kg BD in all other patients such as obesity, symptomatic PE, cancer and recurrent VTE orproximal (vena iliaca) thrombosis. This should be prescribed by brand. Shared Care Guidelines: DMARDS – A new Disease-modifying antirheumatic drugs (DMARDs) quick reference guide has been produced which summarised the monitoring requirements. Lithium – Addition of 'avoid abrupt discontinuation unless indicated by toxicity or severe side effects' in the GP responsibilities section.	

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Item		Action
	Miscellaneous: Rivaroxaban – Rivaroxaban for the treatment and prevention of recurrent DVT/PE can be prescribed following specialist initiation as per the SPC. Following completion of at least six months therapy for DVT/PE 10mg or 20mg OD could be used. Self-care messages – These have been incorporated into various chapters in Derbyshire primary care formulary. Dry eye formulary in Chapter 11 appendix – This had been updated to include information on expiry once opened. Dr Markus queried whether optometrists had access to the dry eye formulary and subsequent updates. Mrs Needham advised that specific messages about items such as eye bags and eye vitamins were conveyed to optometrists but it would be advantageous if updated versions of the dry eye formulary were made available as well. Guideline Timetable for JAPC: Naltrexone Shared Care Guideline – Ms Thompson reported that there had been a delay in holding the meeting to discuss the shared care guideline and would follow this up. The summary of key messages from the Derbyshire Medicines Management Biosimilar and QIPP Working Group was noted. Mr Dhadli reported that all the ophthalmology pathways had now been agreed. However the IVD pathways were still awaited together with rheumatoid arthritis and psoriatic arthritis. The next stage would be to determine, in cases where there were several treatment options, the costs for second year treatments and promote the most cost effective ones via the clinicians.	**SD** **BT**
16.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Inegy® (simvastatin+ ezetimibe combination) – **BLACK** Darunavir + cobicistat + emtricitabine + tenofovir alafenamide (Symtuza®) – **RED** as per NHS England commissioning intentions Daptomycin (Cubicin®) – **RED** Golimumab – **RED** (as per NICE TA 497) Lenvatinib – **RED** (as per NICE TA 498) Glecaprevir – **RED** (as per NICE TA 499) Ceritinib – **RED** (NHS England as per NICE TA 500) Ibrutinib – **RED** (NHS England as per NICE TA 502) Fulvestrant – **BLACK** Vilanterol + fluticasone + umeclidinium (Trelegy®) - **BROWN**	
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• JAPC Working Group 8/08/2017 • Sheffield Area Prescribing Group 19/10/2017 • DTHFT Drugs and Therapeutic Committee 21/11/2017 • DTHFT Drugs and Therapeutic Committee 19/12/2017 • Clinical Policy Advisory Group 14/12/2017 • Medication Optimisation Safety Team 07/12/2017	

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Item		Action
18.	**ANY OTHER BUSINESS**	
a.	**<u>Ulipristal acetate (Esmya®)</u>** Mr Dhadli referred to the tabled paper which gave details of a MHRA warning issued on 9th February 2018 concerning Esmya® (ulipristal acetate 5mg tablets) and the need for new temporary measures following reports of serious liver injury in women who had used this drug for uterine fibroids. Derbyshire Medicines Management had a clinical pathway for Esmya® ulipristal acetate for the treatment of uterine fibroids which was commenced by the specialist and could then be taken over by GPs for three months up to four cycles. The MHRA warning had highlighted four reports of serious liver injury and the temporary safety measures which had been put in place while a European Union review of the evidence took place. The MHRA had recommended that liver function in current and recent users should be monitored and that treatment must not be initiated in new users or those between treatment courses. Mr Moore advised that a list had been compiled in DTHFT of all the patients who had been prescribed Esmya®. This had been prescribed to 144 patients, but only issued to 110, and the gynaecologists were in the process of developing a plan to deal with the affected patients. Ms Duffin reported that a similar list of patients had been compiled in CRHFT and these were being followed up. It was agreed that these lists should be shared with the Medicines Management Team. Dr Mott highlighted the need to maintain close contact with both acute trusts and ensure that a safe plan was in place for all the affected patients. **Agreed:** Emsya® (ulipristal acetate) re-classified as a **BLACK** drug. It was highlighted that this only applied to Emysa® ulipristal acetate and not ellaOne® ulipristal acetate.	**CD/DM**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 13th March at 1.30pm in the Coney Green Business Centre, Clay Cross.	