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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 9th August 2016

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
EyeBag	BLACK
Sayana Press	To remain RED
Pioglitazone	BROWN
Blinatumomab	RED
Daratumumab	RED
Elotuzumab	RED
Ferric Maltol	RED
Human Coagulation Factor X	RED
Ixekizumab	BLACK
Ibandonate 50mg	BROWN for off-licence use in post-menopausal women in breast cancer with Sheffield Teaching Hospitals Foundation Trust only as per guidance to improve breast cancer survival. Note dual traffic light classification - RED for all other use
Emticitabine/Tenofovir	RED
Levofloxacin nebuliser solution	RED
Ataluren	RED as per NICE HST3
Lumacaftor/Ivacaftor	BLACK as per NICE TA 398
Azacitinide	BLACK as per NICE TA 399
Nivolumab/ipilmumab	RED as per NICE TA 400

Clinical Guidelines
Management of Type 2 Diabetes in Adults
Management of Pregnant Women and Neonates in Contact with Chickenpox and Shingles

Patient Group Guidelines
Live attenuated influenza vaccine (LAIV) nasal spray suspension (Fluenz Tetra®▼) by currently registered nurses, pharmacists or paramedics

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Present:	
Southern Derbyshire CCG	
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
Dr C Emslie	North Derbyshire CCG- GP (Chair)
Dr T Narula	GP
Ms M North	Pharmacist, Medicines Management North (also representing Hardwick CCG)
Ms J Town	Head of Finance
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Dr R Dewis	Consultant in Public Health Medicine
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair - Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Ms S Bassi	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms J Shaw	Principal Pharmacist
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Dr A Mott and Mrs K Needham.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	No declarations of any other business were made.	
4.	**MINUTES OF JAPC MEETING HELD ON 9 AUGUST 2016**	
	The minutes of the meeting held on 9th August 2016 were agreed as a correct record after the following amendments: Page 3 – amendment to spelling of tamoxifen. Management of Type 2 Diabetes in Adults – Amend to: Empagliflozin – JAPC agreed to amend to GREEN 1st line SGLT2 inhibitor and Repaglinide – BROWN (limited for use in early diabetes).	
5.	**MATTERS ARISING**	
a.	**Osteoporosis Guideline** Mr Dhadli reported that the osteoporosis guideline had been updated based on the SIGN guidance and sent to Dr R Stanworth and Dr P Masters for comment. Comments from both consultants had been received to recommend the use of the FRAX assessment tool for patients at risk of osteoporosis. Those patients who were deemed to be at absolute risk of suffering a fracture should have a BMD and then re-assessed using both FRAX and BMD and those at absolute risk would then be treated for their osteoporosis. Mr Dhadli advised that the osteoporosis guidance would need to be re-written in the light of these recommendations and would then be brought to a future JAPC meeting for further consideration.	**SD**
b.	**Sacubitril Valsartan** Mr Dhadli advised that the consultant cardiologists at DTHFT and CRHFT had been requested to determine the place for sacubitril valsartan, for the treatment of symptomatic chronic heart failure with reduced ejection fraction, in the heart failure guidance. Some comments had been received from a cardiologist at DTHFT which had proposed slight changes to the guidance and also to the communication referral documents between primary and secondary care. Further work was to undertaken on the guidance by Mr Dhadli.	**SD**
c.	**PCSK9 Inhibitors.** Mr Dhadli reported that Dr R Stanworth would be liaising with Dr P Masters to re-draft the familial hypercholesterolaemia and lipid guidance in the light of the introduction of the first two PCSK9 inhibitors, evolocumab and alirocumab, which were a new class of drugs that had been shown to lower LDL cholesterol levels. The home care model would also be scoped due to the two different drug choices.	

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Item		Action
6.	**NEW DRUG ASSESSMENTS**	
a.	**EyeBag** Mr Dhadli reported that many requests had been received for GPs to prescribe eye bags which were listed in the drug tariff as MGDRx® EyeBag® The MGDRx® EyeBag® had been developed in 2004 by British consultant ophthalmologist, after fifteen years experience of treating patients with Meibomian Gland Dysfunction (MGD), and comprised a reusable warm compress which was heated in a microwave. The MHRA listed this as a class 1 medical device and the evidence came from a low evidence study conducted by Aston University involving twenty-five patients. This had concluded that the MGDRx® EyeBag® was a safe and effective treatment for MGD dry-eye with a subjective benefit of six months aided by occasional re-treatment. Mr Dhadli advised that the Guideline Group had discussed the use of the MGDRx® EyeBag® and recommended that a traffic light classification of BLACK be assigned due to cost effectiveness compared to conventional management. **Agreed:** MGDRx® EyeBag® classified as a **BLACK** drug as less cost-effective than current standard therapy. **Action:** The DTHFT and CRHFT consultant ophthalmologists would be contacted to advise them about the JAPC traffic light decision. Optometrists will be informed by the Local Area Team	**SD** **KN**
b.	**Sayana Press** Mr Dhadli reported that Sayana Press® (sub-cutaneous depot medroxyprogesterone acetate) was the sub-cutaneous formulation of Depo-Provera (DMPA-SC). Its licence had been extended in 2015 to include patient self-administration since it had been discussed by JAPC in June 2013 when a traffic light classification of RED had been assigned as it was not licensed at the time for self-administration. The Faculty of Sexual and Reproductive Health had advised that Sayana Press® had the ability to offer women greater choice and more autonomy over their contraception and fertility as they would not have to attend a clinic for an intra-muscular injection. The manufacturers of Sayana Press® had produced resources to support health care professionals and women who chose to use it - this included guides and text reminders. Mr Dhadli stated that Dr J Abrahams, Lead Doctor Integrated Sexual Health Services, had supported the use of Sayana Press® in primary care and had highlighted the following information arising from its use in the integrated sexual health service: • Some nurses had received training. • There had been no reported negative feedback from patients, although those who were using it may have been given a supply for one year. • There was a report from the Integrated Sexual Health Service that many patients overlooked their follow up appointments. • Some anecdotal evidence that cycle control was not as good. • Some reports about skin changes at injection sites but these were minimised by rotation.	

Item		Action
	A recommendation had been received from a Senior Public Health Manager about a protocol for self-administration to include the competency and maturity of the women who self-administered together with advice about home sharp bins and to highlight potential safeguarding concerns about home storage. In connection with the sharps bin it was suggested that the provision of a lidded purple bin should be highlighted. During discussion Dr Dewis queried whether it would be desirable to develop a single protocol for use in primary care with the integrated sexual health service in order to ensure that self-administration was used by appropriate women. Dr Henn, who declared a conflict of interest as a GP provider in a dispensing practice, supported the use of a protocol in primary care due to the need for user education and the desirability of using products which enabled people to take more responsibility for their own health. Dr Emslie highlighted the need for robust patient education in the use of self-administration and for practices to clarify whether they wished to give it themselves. **Agreed:** The current traffic light classification of **RED** for sub-cutaneous Depo-Provera (DMPA-SC) to remain unchanged. **Action:** Dr Dewis would follow up the production of a protocol for the self-administration of sub-cutaneous Depo-Provera (DMPA-SC).	**SD** **RD**
7.	**CLINICAL GUIDELINES**	
a.	**Management of Type 2 Diabetes in Adults** Mr Dhadli referred to previous discussion by JAPC about the current traffic light classification of pioglitazone and the recommendation from the DTHFT consultants that it should remain classified as BROWN due to the small increased risk of bladder cancer and the consequent need for caution with its use. A paper was tabled which outlined the reports made to the MHRA about reactions to pioglitazone from time of launch to 2016. Mr Dhadli highlighted the numbers and types of cardiac disorders, eye disorders, injuries leading to fractures and neoplasms. Dr Narula stated that the use of another type 2 diabetes drug rosiglitazone, which had been associated with severe adverse reactions, had been re-considered in the U.S. when diabetes could not be controlled using either of the first-choice medications, metformin and sulphonylurea. Dr Narula highlighted that the majority of type 2 diabetes care was undertaken in primary care rather than secondary care and that sulphonylureas could cause hypoglycemias which were a common cause of hospital admissions. There should therefore be an option to use pioglitazone in certain cases when patients would benefit. Mr Hulme commented that the risk of bladder cancer with pioglitazone was unclear and queried why NICE had decided to include it in their recommendations. Mr Dhadli stated that NICE associates had been contacted about the safety issue and cost effective choice but no reply had yet been received. Dr Narula highlighted that an incorrect traffic light classification had been given for empagliflozin on page 46 of the guidance and this should be corrected to GREEN as per NICE TA336 and NICE TA 390.	**SQ**

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Item		Action
	Agreed: Piloglitazone classified as a **BROWN** drug due to known excess of significant adverse effects compared with standard therapy.	**SD**
	Action: The position of pioglitazone in the flowchart to be amended in the light of the traffic light classification.	**SQ**
	Mr Dhadli highlighted the inclusion in the local guidance of GLP1s with insulin and the NICE recommendation that these should only be considered with specialist care advice and on-going support from a consultant-led multidisciplinary team (MDT). Mr Dhadli stated that the place of GLP1s in local guidance, and by NICE was limited, and it would therefore be important to obtain assurance about the level of communication between secondary and primary care and confirm the definition of a MDT. Dr Emslie commented that the prescribing could be done in primary care but patients would need to have ongoing specialist supervision. Mr Dhadli referred to the inclusion in the local guidance that GLP1s should only be offered in combination with insulin with specialist care advice and with on-going support from a consultant-led multidisciplinary team. Dr Henn stated that there were a number of GPs who were highly skilled in diabetes care and worked closely with both diabetes nurses and consultant diabetologists. The statement in the local guidance covered the use of GLP1s but provided sufficient flexibility for highly skilled and trained GPs to work with the community diabetic team, including consultants, and determine which patients would benefit from the use of GLP1s with insulin. It was agreed that the reference on page 29 of the local guidance which referred to licenced and NICE approved insulin combinations be amended to read 'Only on advice of specialist and with ongoing support from a consultant-led service.'	**SQ**
	Agreed: JAPC ratified the Guideline for the Management of Type 2 Diabetes in Adults with the agreed amendments.	**SD**
b.	**<u>Bath Emollients/Shower Gels Prescribing</u>** Mr Dhadli reported that the use of bath emollients/shower gels had been discussed at a recent Guideline Group meeting as a potential area for QIPP savings. It was noted that the current spend on bath emollients/shower gels across the four Derbyshire CCGs was approximately £300,000 annually. Mr Dhadli highlighted that there was a lack of strong evidence as to the effectiveness of bath emollients/shower gels and a lack of published RCTs. There was a section on the use of emollients for daily washing and bathing in NICE CG 57 Atopic eczema in under 12s: diagnosis and management from 2007. The PrescQIPP document on cost effective prescribing of emollients did recommend emollients for a cohort of patients as an alternative to soap and this contained a list of suggested emollient lotions and creams. The consultant dermatologists at DTHFT and CRHFT had been contacted in order to ascertain their views on emollients and a reply had been received from Dr C Greenfield at CRHFT who advised that they should be an option as a skin cleansing product but the choices limited to one simple soap substitute and an antimicrobial product such as Dermol®.	

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Item		Action
	During discussion Dr Parkin highlighted that there was a place for soap substitutes but not bath emollients, for which there was little evidence as to effectiveness, and that the JAPC traffic light classifications gave a clear indication of the products which could be prescribed in primary care. Dr Watkins referred to a recent patient request for a new product, MooGoo® skin cream, to be prescribed and queried whether this should be assigned a traffic light classification to aid GP prescribing. There was broad consensus by JAPC that, due to lack of evidence on effectiveness, the bath emollients should all be classified as BLACK but there was exceptionality in the cases when patients could benefit from the short-term use of emollients with antimicrobials - these should therefore be classified as BROWN. However, it would be necessary to obtain the views of the consultant dermatologists at DTHFT and CRHFT before any traffic light classifications were agreed. **Agreed:** Mr Dhadli would contact the DTHFT and CRHFT consultant dermatologists to obtain their views and bring back to the next JAPC meeting.	**SD**
c.	**<u>Oral Nutrition Support Guidelines</u>** Mr Dhadli reported that the following amendments to the Oral Nutrition Support (ONS) guidelines had been made by pharmacists at a recent educational event; • Clarification of MUST scoring on page 3. • Replacing 'stop ONS' with 'tapering dose'. • Change of MUST score from ≥2 to >2 when considering referral to dietician on page 3. • Addition of re-feeding syndrome (new at the request of practice pharmacists) on page 4. • Message about use of repeat prescriptions with a care plan on page 6. Mr Dhadli stated that Ms Melanie Coy from CRHFT had indicated that there were no major concerns with these amendments but had highlighted that the local MUST scoring now varied from that included in the NICE guidance and current practice. It had originally intended to attach a referral form to the local ONS guidance but Ms J Barratt had advised that this was not necessary and an email address should be used instead. In response to a query concerning the use of a county-wide referral form in the ONS guidance Ms F Moore, DTHFT Dietetic Manager, had indicated that this form was for use in Southern Derbyshire as the service in the north had its own referral form. Ms Moore had added that the purpose of the communication exercise with GP practices, referred to at the educational event, had been to request that GPs and other practice staff email the form to the generic email address for community dietetics rather than send paper referrals via the postal service. The referral form therefore did not need to be included in the local ONS guidance. In connection with the change to the MUST score Dr Emslie and Mr Hulme highlighted a potential issue concerning the proposed change from ≥2 to >2 when a referral to a dietician was being considered. Ms North advised that there had been discussion at the educational event whether this should be two or more but it had been acknowledged that this could result in a lot of referrals and therefore should be >2.	

Item		Action
	However this would be at variance with the remainder of the guideline and there would therefore be a difference in practice between the two dietetic services in the north and south of the county. **Action:** Mr Dhadli would contact Ms M Coy and request that the MUST score issue be further discussed with the dietitians and that any changes were agreed Derbyshire wide.	**SD**
d.	**Management of Pregnant Women and Neonates in Contact with Chickenpox and Shingles** Mr Dhadli advised JAPC that the guidance provided advice on the management of pregnant women and neonates in contact with chickenpox and shingles, highlighted that the GP/midwife should contact microbiology at their local hospital without delay in order to discuss a case and receive advice on management. The guidance had been updated in August 2014 following consultation with the microbiologists at DTHFT, CRHFT and Sheffield Hospital. A further update in June 2016 now included information that the laboratory at the Northern General Hospital in Sheffield would provide the testing for immunity and also advice during 'in hours'. The on-call microbiologist at Royal Derby Hospital would provide advice for 'out of hours'. **Agreed:** JAPC ratified the guidance on the Management of Pregnant Women and Neonates in Contact with Chickenpox and Shingles.	**SD**
8.	**PATIENT GROUP DIRECTIONS**	
	The Public Health England/NHS England Patient Group Direction for live attenuated influenza vaccine (LAIV) nasal spray suspension (Fluenz Tetra®▼) by currently registered nurses, pharmacists or paramedics was noted by JAPC. **Agreed:** JAPC agreed the PGD for live attenuated influenza vaccine (LAIV) nasal spray suspension (Fluenz Tetra®▼) by currently registered nurses, pharmacists or paramedics.	**SD**
9.	**MONTHLY HORIZON SCAN**	
a.	**Monthly Horizon Scan** Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New drug launches in the UK: Blinatumomab (Blincyto®) – NHS England. Classified as **RED.** Daratumumab (Darzalex®) – NHS England. Classified as **RED.** Elotuzumab (Empliciti®) – NHS England. Classified as **RED.** Ferric maltol (Feraccru®) - An oral formulation of a stable complex of ferric ion for iron deficiency anaemia in adults with inflammatory bowel disease. A review had been undertaken by the London Medicines Evaluation Network and this advised that Feraccru® was intended for use in patients who could not tolerate other iron preparations and for whom IV iron products were being considered. This could result in a reduction in the number of IV formulations currently used in secondary care.	

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	Dr Goddard commented that the demand for the use of Feraccru® was very limited and there was a lack of outcome data to prove that IV daycase use would be avoided. It was agreed to wait for requests for use to be received and to classify as **RED** as it was new to clinical practice. Human coagulation factor X – For the treatment of hereditary factor X deficiency – treatment and prophylaxis of bleeding episodes and perioperative management. Classified as **RED.** Ixekizumab (Taltz®) – For the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy. NICE TA expected in April 2017. Classified as **BLACK.** Lumacaftor + ivacaftor (Orkambi®) – Negative NICE TA 398. Classified as **BLACK.** New formulation launches in the UK: Emtricitabine + tenofovir alafenamide (Descovy®) – NHS England. Classified as **RED.** Levofloxacin (Quinsair®) nebuiliser solution – NHS England. Classified as **RED.** Paliperidone palmitate (Trevicta®) - Already **RED** for LA formulation in 2011. No action required. Licence extensions: Bevacizumab (Avastin®) – NHS England. Currently classified as **BLACK** for various TAs. Carfilzomib(Kyprolis®) – Already **RED.** Liraglutide (Victoza®) – CCG. Already **BROWN** by exceptionality defined as intolerance to the preferred 1st line choice or restricted by their licensing. Obinutuzumab (Gazyvaro®) – NHS England. Already classified as **RED.**	**SD**
b.	**<u>Quarterly NICE Updates</u>** Mr Dhadli highlighted the following relevant to CCGs: Clinical Guidelines: • Heavy menstrual bleeding (standing committee update). Expected August 2016. • Familial hypercholesterolaemia (standing committee update). Expected January 2017. • Glaucoma: diagnosis and management (update). Expected July 2017. • Macular degeneration. Expected August 2017. • Dementia – assessment, management and support for people living with dementia and their carers. Expected August 2017. NICE Technology Appraisals: • Macular oedema (branch retinal vein occlusion) – Alibercept. Expected publication in October 2016. • Ankylosing spondylitis – secukinumab (after NSAIDs or TNF-alpha inhibitors). Expected publication in October 2016. • Hyperuricaemia (chronic) in gout – lesinurad. Expected publication in November 2016.	

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Item		Action
10.	**MISCELLANEOUS**	
a.	**Adrenaline Statement** Mr Dhadli reported that work had been undertaken by practice pharmacists and technicians to rationalise the existing formulary for adrenaline injections and the quantities used in practices. The formulary listed Jext 150 micrograms, 300 micrograms; Epipen auto-injector 0.3mg; Epipen Jr auto-injector 0.15mg; Emerade auto-injector 150 micrograms, 300 micrograms and 500 micrograms and it had been queried when patients should use the 500 micrograms ahead of the 300 micrograms. Mr Dhadli advised that the Resuscitation Council guidelines for the emergency treatment of anaphylactic reactions recommended the following: • Adult 500 micrograms IM (0.5 mL) • Child more than 12 years: 500 micrograms IM (0.5 mL) • Child 6 to12 years: 300 micrograms IM (0.3 mL) • Child less than 6 years: 150 micrograms IM (0.15 mL) It was highlighted that the dose recommendations for adrenaline in this guideline were intended for healthcare providers treating an anaphylactic reaction and that the Summary of Product Characteristics for Jext referred to weight based treatment. Mr Dhadli added that a Leicestershire-based Consultant Allergist had advised that adrenaline had a narrow therapeutic index so there would be a lower risk of toxicity if the 300mg dose was used. It was therefore proposed the following advice should be included in chapter 3 of the BNF: Epipen - Weight range between 7.5 to 25kg: 150micrograms (junior auto injector) and >25kg: 300microgram (adult auto injector). Jext and Emerade – Weight range between 15-30kg: 150microgram and >30kg 300microgram. In addition the 500mcg adrenaline dose (Emerade pre-filled pen) should only be prescribed for self-administration on the advice of a specialist, for example where a repeated second dose of adrenaline (300mcg) was necessary or in obese patients where a larger dose is necessary. **Agreed:** JAPC ratified the agreed amendment to the local BNF chapter.	**SD**
b.	**Annual Report** The final draft of the JAPC Annual Report April 2015 to March 2016 was noted for information. The report would be widely circulated to the CCG Governing Bodies and other relevant committees.	
c.	**Domperidone** Mr Dhadli advised that domperidone was currently listed as a BROWN drug for off-licence use for gastroparesis and other gastric outlet physiological impairment, babies and children (normally prescribed by specialists) and nursing mothers to promote lactation with a maximum treatment dose of one week as recommended by UKMi. However, it had now been queried whether the maximum treatment dose could be extended beyond one week to promote lactation in breastfeeding women, following advice from an Infant Feeding Adviser, it was now proposed that a maternal dose of 30mg (10mg three times daily) should be used which was a commonly accepted dosing regimen.	

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	In exceptional circumstances, the feeding specialist may recommend a longer duration (never longer than three weeks) at a reduced dose of 10mg twice daily to 10mg daily. **Agreed:** JAPC ratified the agreed amendment to the off-licence position statement for the use of domperidone in nursing mothers to promote lactation.	**SD**
d.	**DTB Review on Empagliflozin** Mr Dhadli referred to the Drugs and Therapeutic Bulletin Review empagliflozin which was the third SGLT2 inhibitor licensed in the UK for the management of people with type 2 diabetes. All three SGLT2 inhibitors have been shown to reduce HbA1c by a similar amount. Mr Dhadli highlighted that the initial results with the use of empagliflozin had been positive for people with type 2 diabetes and cardiovascular disease who are at high risk of heart failure. However there was a lack of evidence of longer-term outcomes in people at lower risk of cardiovascular disease together with concerns about the safety of SGLT2 inhibitors.	
e.	**Ibandronate in Breast Cancer** Mr Dhadli reported that Sheffield Area Prescribing Committee (APC) had decided to re-classify ibandronate sodium 50mg, a type of bisphosphonate, for use in the management of post-menopausal women with breast cancer initiated on ibandronic acid 50mg by a secondary care specialist to improve breast cancer survival. It was noted that ibandronic acid or ibandronate sodium was unlicensed for this indication. This decision had been made in the light of research published in the Lancet on the risks and benefits of adjuvant bisphosphonate treatment in breast cancer which had concluded that adjuvant bisphosphonates reduced the rate of breast cancer recurrence in the bone and improved breast cancer survival, but only in women who were postmenopausal at the commencement of treatment. In the light of this study the South Yorkshire Cancer Strategy Group had developed a business case for bisphosphonates to improve breast cancer survival and had indicated that they should be included in the breast cancer CRG service specification. Sheffield APC had also developed prescribing guidance for Ibandronic Acid 50mg tablets in post-menopausal women with breast cancer and this included the responsibilities of hospital specialists and primary care. **Agreed:** Ibandronate 50mg tablets classified as a BROWN drug for off-licence use in post-menopausal women with breast cancer with Sheffield Teaching Hospitals Foundation Trust only as per guidance to improve breast cancer survival. **Action:** Mr Dhadli would obtain the link to the guidance developed by Sheffield Teaching Hospital Foundation Trust for inclusion in the website.	**SD** **SD**
f.	**Guidance on the Prevention, Diagnosis and Management of Vitamin D Deficiency in Primary Care** Dr Dewis reported that Public Health England had published new guidance on vitamin D supplementation following the document of the Scientific Advisory Committee on Nutrition (SACN) on vitamin D and health.	

Item		Action
	The section on prevention of vitamin D deficiency had been updated accordingly to include: • The recommendation for vitamin D supplementation for specific at risk groups of infants, pregnant women, people within residential care or use exclusive clothing which would prevent exposure to the sun. The only change concerned infants where vitamin D supplementation was now recommended from birth for those who were breast-fed. • The recommendation that these patients should be offered lifestyle advice and advised to purchase supplementation over the counter in the first instance. Patients who were unable to access over the counter supplements and were unable to modify lifestyle behaviour adequately should be prescribed the relevant supplement. • The SACN recommendation that everyone over one year of age, including pregnant women, breastfeeding women and those at risk of vitamin D deficiency (people with minimal exposure to sunshine and those from minority ethnic groups with dark skin), should get 10micrograms of vitamin D every day. Following discussion it was agreed that the paragraph in the section on prevention should be amended to read 'Most of these patients should be offered lifestyle advice as detailed in section 5 (p6) and advised to purchase supplementation over the counter (eligible patients can obtain free supplements through the Healthy Start scheme). More information on available products for supplementation and the Healthy Start scheme can be found in appendix 2.' Mr Dhadli highlighted that the Guideline Group had agreed that Thorens® (colecalciferol), a licensed liquid vitamin D3 preparations for children should be added to the guideline. Mr Dhadli also queried the use by the SACN of 25nmol/l as a cut-off point for diagnosis. Dr Dewis commented that the evidence was based on between 20 and 30 and there had been a lot of variation in the studies which had been used. The SACN had indicated that it had not been possible to identify a specific serum 25(OH)D threshold concentration between 20-30 nmol/l associated with increased risk of poor musculoskeletal health as various assay methods had been used in the studies considered. The current national threshold of 25 nmol/L, used to define the concentration below which the risk of vitamin D deficiency increased, had therefore been retained and local variation to this noted. **Agreed:** JAPC ratified the Guidance on the Prevention, Diagnosis and Management of Vitamin D Deficiency in Primary Care with the agreed amendments.	**SQ** **SD**
11.	**JAPC BULLETIN**	
	The bulletin was ratified by JAPC.	**SD**
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for July 2016 was noted. Mr Dhadli highlighted the following MHRA advice:	

Item		Action
	• Warfarin: reports of calciphylaxis. • Citalopram: suspected drug interaction with cocaine. The health professional must have, or take, an adequate history, which considered the recent use of other medicines including non-prescription medicines, herbal medicines, illegal drugs, and medicines purchased online. • N-acetylcysteine: risk of false-low biochemistry test results due to interference with Siemens assays.	
13.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in July 2016. HST3 Ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene – Classified as a **RED** drug (NHS England). TA259 Updated (from June 2012) Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen – Already classified as a **RED** drug. TA387 Updated Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated – Already classified as a **RED** drug. TA398 Lumacaftor– ivacaftor for treating cystic fibrosis homozygous for the F508del mutation - Not recommended, within its marketing authorisation, for the treatment of cystic fibrosis in people 12 years and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Classified as a **BLACK** drug. TA399 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts - Not recommended, within its marketing authorisation, for the treatment of acute myeloid leukaemia with more than 30% bone marrow blasts in people of 65 years or older who are not eligible for haematopoietic stem cell transplant. Classified as a **BLACK** drug. TA400 Nivolumab in combination with ipilimumab for treating advanced Melanoma – Classified as a **RED** drug (NHS England).	**SD** **SD** **SD** **SD** **SD** **SD**
14.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	<u>Classifications</u> EyeBag – **BLACK** Sayana Press – To remain **RED** Pioglitazone – **BROWN** Blinatumomab – **RED** Daratumumab – **RED** Elotuzumab – **RED** Ferric Maltol – **RED** Human Coagulation Factor X – **RED** Ixekizumab – **BLACK** Ibandonate – **BROWN** for off-licence use in post-menopausal women in	

Item		Action
	breast cancer with Sheffield Teaching Hospitals Foundation Trust only as per guidance to improve breast cancer survival. Emticitabine/Tenofovir and Levoflxacin - **RED** Ataluren HST3 – **RED** as per NICE HST3 Lumacaftor/Ivacaftor – **BLACK** as per NICE TA 398 Azacitinide – **BLACK** as per NICE TA 399 Nivolumab – **RED** as per NICE TA 400	
15.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Management of Type 2 diabetes in Adults – To be taken off the list. PCSK9 Inhibitors – Draft to be brought to the October 2016 JAPC meeting. Osteoporosis Guidance – To be brought to the October 2016 JAPC meeting. Diagnosis and Management of Lower UTIs – To be taken off the list.	**SD** **SD** **SD** **SD**
16.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in July 2016 was noted. It was agreed to add: • Sayana Press • Bath Emollients Mr Dhadli highlighted the following: • Obstretics, Gynaecology and Urinary Tract – Chapter 7 updated with CHC table with cost-effective options as per MIMS. • Binosto effervescent tablets included as a cost-effective alternative to alendronic acid oral solution for patients with swallowing difficulties. • Nicotine replacement therapy to be reviewed in August 2016 – Dr Dewis to contact Michelle Halfpenny in the Derbyshire Public Health Team to check on progress. • Antipsychotics: recommended physical monitoring – Ms Bassi reported that this was due to be discussed by the DHcFT Physical Healthcare Committee.	**SD** **RD**
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• DHcFT Drugs and Therapeutic Committee 26/05/16 • DTHFT Drugs and Therapeutic Committee 21/06/16 Mr Dhadli highlighted that a number of shared care agreements had been extended at the DHcFT Drugs and Therapeutic meeting and these would need to be discussed by JAPC in due course.	

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Item		Action
18.	**ANY OTHER BUSINESS**	
	Dr Narula queried whether there was any Derbyshire wide guidance concerning the prevention of diabetes and whether this should include references to the use of metformin and orlistat in the pre-diabetes stage as indicated in the NICE Type 2 diabetes: prevention in people at high risk published in July 2012. Mr Dhadli stated that the Guideline Group had discussed the use of metformin at the pre-diabetes stage where it had been suggested that this could be done on an individual patient basis. However it would be necessary to determine a definition of pre-diabetes. Mrs Qureshi advised that NICE was due to issue guidance on prevention of diabetes in March 2017 and Dr Dewis referred to the lifestyle and education programme. Dr Narula referred to guidance which had been produced by Nottinghamshire Area Prescribing Committee on pre-diabetes and the prescribing of metformin. Mr Dhadli would contact Nottinghamshire APC about this.	**SD**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 13th September 2016 at 1.30pm in the Post Mill Centre, South Normanton.	