

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 8th October 2019

CONFIRMED MINUTES

Summary Points

Traffic lights

| Drug | Decision |
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| Adapalene cream/gel | GREEN for the treatment of mild to moderate comedonal acne |
| Liothyronine (in combination with levothyroxine) | AMBER for EXISTING patients who have been reviewed by a specialist and the treatment dose has been stabilised for 3 months. |
| Liothyronine | BLACK for NEW patients. Liothyronine is in the black section of the traffic light drug list in Derbyshire and should not be initiated in new patients. If there is an exceptional clinical need, such as difficulty in tolerating or absorbing levothyroxine, then a request to prescribe must be made via the IFR process by an NHS endocrinology specialist. |
| Liothyronine | RED when used as monotherapy, resistant depression and in doses exceeding 60mcg per day |
| Lorlatinib (Lorviqua) | RED (as per NHS England commissioning intentions) |
| Teriparatide biosimilar (Terrosa) | RED |
| Sodium zirconium cyclosilicate | RED (as per NICE TA599) |
| Pembrolizumab with carboplatin and paclitaxel | RED (NHS England Cancer Drugs Fund as per NICE TA600) |
| Bezlotoxumab | BLACK (as per NICE TA601) |
| Pomalidomide with bortezomib and dexamethasone | BLACK (as per NICE TA602) |
| Lenalidomide with bortezomib and dexamethasone | BLACK (as per NICE TA603) |

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

| Drug | Decision |
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| Vacuum Pumps (existing/clarification) | RED for out of area requests, GPs can accept initial prescribing after assessment or on-going prescribing for replacement pumps if the specialist provides an APC approved shared care protocol or evidence the device is approved by another APC. |
| Triamcinolone acetone injection | GREEN 10mg/1ml ampoules; 40mg/1ml vials. Cost effective alternative to methylprednisolone acetate injection. |
| Fexofenadine | BROWN alternative option when other antihistamines on formulary are not effective |

Clinical Guidelines

Managing Acne Vulgaris

Primary Care management of Overactive Bladder

Requesting prescriptions for and managing patients using varenicline

Liothyronine Position Statement

Patient Group Directions (Children's continence service – DHcFT)

Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride 13.8g sachets

Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride 6.9g sachets

Sodium picosulfate 5mg/5ml elixir

Desmopressin 120 microgram sublingual tablets

Oxybutynin hydrochloride 2.5mg tablets

Shared Care Guidelines

Acamprosate Calcium (Campral EC) for alcohol abstinence

Disulfiram (Antabuse) for maintenance of alcohol abstinence

Riluzole for the treatment of the Amyotrophic Lateral Sclerosis (ALS) form of Motor Neurone Disease (MND)

ADHD in children over 5 years and adults

Liothyronine in combination with levothyroxine *(Existing patients only)

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| Present: | |
| Derby and Derbyshire CCG | |
| Dr C Emslie | GP (Chair) |
| Mr S Dhadli | Assistant Director of Clinical Policies and Decisions (Professional Secretary) |
| Dr H Hill | GP Prescribing Lead |
| Mr S Hulme | Director of Medicines Management and Clinical Policies |
| Mrs K Needham | Assistant Director of Medicine Optimisation and Delivery |
| Mrs S Qureshi | Head of Medicines Management, Clinical Policies and High Cost Interventions |
| Mr R Coates | Finance Manager |
| 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 R Sutton | Pharmacist |
| Derbyshire Healthcare NHS Foundation Trust | |
| Dr S Taylor | Consultant and Chair to Drugs and Therapeutic Committee |
| Chesterfield Royal Hospital NHS Foundation Trust | |
| Ms C Duffin | Principal Pharmacist |
| Derbyshire Community Health Services NHS Foundation Trust | |
| Derby and Derbyshire Local Medical Committee | |
| Derbyshire Health United | |
| Staffordshire CCG's | |
| Ms S Bamford | Senior Medicines Optimisation Pharmacist |
| In Attendance: | |
| Ms J Butterfield | Senior Medicines Optimisation Pharmacist |
| Ms M Hill | Derby and Derbyshire CCG High Cost Interventions Pharmacy Technician |

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| 1. | APOLOGIES | |
| | Dr K Markus, Mr M Shepherd, Ms A Braithwaite, Dr R Gooch, Mr D Graham | |
| 2. | DECLARATIONS OF CONFLICTS OF INTEREST | |
| | <p>Dr Emslie 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.</p> <p>No conflicts of interest were declared in relation to this agenda; in addition to the existing register of interests.</p> | |
| 3. | DECLARATIONS OF ANY OTHER BUSINESS | |
| | There were no declarations of any other business. | |
| 4. | MINUTES OF JAPC MEETING HELD ON 10 SEPTEMBER 2019 | |
| | The minutes of the meeting held on 10 th September 2019 were agreed as a correct record after minor grammatical amendments. | |
| 5. | MATTERS ARISING | |
| a. | <p><u>Live vaccine query</u> Mr Dhadli reported that JAPC discussed the leflunomide shared care agreement in September 2019 and requested further clarification as to the evidence base for the recommendation to permit live vaccines in patients treated with leflunomide. Mr Dhadli contacted the local UK Medicines Information (UKMi) centre. UKMi have referred to the European League Against Rheumatism (EULAR) recommendations and guidelines published in Australia which suggests that live vaccines may be considered with caution in patients with disease-modifying antirheumatic drugs (DMARDs); however the reference that they have used is not specific to leflunomide so this needs to be interpreted with a degree of caution. The consultants also sent a paper to evidence their advice on the use of live vaccines; however this paper contains the same cross referencing that EULAR refer to.</p> <p>Mr Dhadli suggested that where there is evidence that a live vaccine can be used with defined doses this can be included into the shared care guidelines; where defined doses are not available the GP's are advised to liaise directly with the consultant to get specific advice on a case by case basis. Dr Emslie asked if Mrs Qureshi could contact the consultants to see if they would be happy with this arrangement.</p> | SQ |
| b. | <p><u>Sayana Press</u> Mr Dhadli stated that Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) were to communicate to the sexual health service that there is a supply shortage of sayana press, therefore it should not be recommended to new patients during this time.</p> <p>Mr Dhadli has received confirmation from Ms J Shaw Principal Pharmacist DCHSFT that this action has been done.</p> | |
| c. | <p><u>Hepatitis B vaccine in Chronic Kidney Disease (CKD)</u> Mrs Qureshi advised that she has contacted Sheffield and Nottingham providers to ask how they have ensured a smooth transition for at risk renal</p> | |

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| <p>d.</p> <p><u>Vacuum pumps</u></p> <p>Mr Dhadli reported that at the previous months JAPC meeting there was a query about how long a vacuum pump should last for; Mrs Qureshi has contacted a couple of suppliers and put this question to them. The response was that the life of a vacuum pump can vary as it will depend on how the patient uses the device. Mr Dhadli stated that ones looked into had a five year warranty but was unable to confirm if this applied to all of the devices. JAPC decided the traffic light classification should be updated to advise to check warranty with the manufacturer; the usual shelf life is around five years.</p> <p>e.</p> <p><u>GlucoRx safety needles</u></p> <p>Mr Dhadli informed the committee that he has received feedback from DCHSFT that the training materials for GlucoRx safety needles needs some improvement before their nursing teams are advised to start using these. Ms Duffin will liaise with Ms Braithwaite to ensure this information is communicated to the pharmaceutical company so that they can look to provide something more suitable.</p> | <p>patients to be vaccinated against Hepatitis B in secondary care; however, she has currently had no response. Mr Dhadli advised that there needs to be an assumption that the renal services will vaccinate these patients going forward and that any requests received in primary care should be refused.</p> | <p>SQ</p> <p>CD/AB</p> |
| 6. | JAPC ACTION SUMMARY | |
| <p>a.</p> <p><u>Hydroxychloroquine</u></p> <p>Dr Dewis advised that there is a small working group for this which has met with ophthalmology Clinical Interest Group's (CIGs) in the North and South of Derbyshire. Discussions have taken place in regard to where there are areas of flexibility in the pathway and the working group are currently awaiting numbers and costings from the services before they can look at this further.</p> <p>b.</p> <p><u>Ibandronic acid</u></p> <p>Mr Dhadli advised there is a paper that has been drafted for the Clinical and Lay Commissioning Committee (CLCC) meeting. Mrs Qureshi had been to an Equality Impact Assessment/Quality Impact Assessment (EIA/QIA) panel where it was agreed. The paper will raise awareness of the risks; however, a supporting paper is still needed from University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) in regards to patient numbers, the patient pathway, likelihood of treatment etc. Mr Sutton advised that he has produced a business case and is currently awaiting comments on this; it should be ready to submit next month.</p> <p>c.</p> <p><u>Amiodarone</u></p> <p>Mr Dhadli reported that a draft shared care has been produced; however, at a previous meeting there were some queries from the committee in regards to ECG monitoring and primary care responsibilities. These queries have been forwarded onto the Cardiovascular Right Care Group and Mr Dhadli is awaiting a response following their next meeting.</p> | <p>Dr Dewis advised that there is a small working group for this which has met with ophthalmology Clinical Interest Group's (CIGs) in the North and South of Derbyshire. Discussions have taken place in regard to where there are areas of flexibility in the pathway and the working group are currently awaiting numbers and costings from the services before they can look at this further.</p> | <p>RS</p> <p>SD</p> |

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| d. | <p><u>GlucoRx safety needles</u> Mrs Needham reported that the action summary still advised that Mylife Clickfine safety needles will be reclassified as BROWN once DCHSFT nurses switch to using GlucoRx safety needles. However it was agreed at the September 2019 JAPC meeting that all safety needles priced less than or equal to £20 per 100 would become GREEN 2nd line, this will include Mylife safety needles. Mr Dhadli would update this on the action summary.</p> | SD |
| 7. | CLINICAL GUIDELINES | |
| a. | <p><u>Acne Guideline</u> Mr Dhadli advised that a new acne guideline has been produced by the dermatology CIG and they would like this to be adopted across Derbyshire. The guideline has had representation from Consultant Dermatologists at Chesterfield Royal Hospital NHS Foundation Trust (CRHFT), UHDBFT, and GPwSI's in the North of Derbyshire. Information and reference sources used include NICE Clinical Knowledge Summaries (CKS), British Association of Dermatologists (BAD), and Primary Care Dermatology Society. Mr Dhadli reported that the Derbyshire Medicines Management Shared Care and Guideline Group (MMSCGG) had recommended amendments to the original submission that included self-care first line for mild acne as per NHS England and NICE/PHE primary care antimicrobial prescribing guidance. Doxycycline is 1st line as per NICE and Public Health England (PHE) advice. Adapalene (Differin) cream/gel was also added to the primary care formulary. Mr Hulme queried whether microbiology has been consulted with. Mr Dhadli responded to say that he had contacted both Ms J Lacey Antimicrobial Pharmacist at UHDBFT and U Quinn Lead Antimicrobial Pharmacist CRHFT, neither had any objections or further comments to add. Dr Emslie advised that adapalene will need to be given a traffic light classification.</p> <p>Agreed: Adapalene classified as GREEN for treatment of mild to moderate comedonal acne.</p> <p>Agreed: JAPC ratified the clinical guideline for Managing Acne Vulgaris with a review date of 3 years.</p> | SD SD |
| b. | <p><u>Overactive Bladder</u> Mr Dhadli reported that the Management of Over Active Bladder guideline was due for its periodic review. This was sent to specialists for comment. Where the guideline previously mentioned frailty this has now been changed to say 'older women who may be at higher risk of a sudden deterioration in their physical or mental health'. Previously oxybutynin and tolterodine were the same cost however, tolterodine is now a slightly lower price therefore it will become 1st line. Solifenacin patent has now expired so its position in the pathway has been moved to reflect this.</p> <p>Agreed: JAPC ratified the clinical guideline for Primary Care management of Overactive Bladder with a review date of 3 years.</p> | SD |

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| c. | <p><u>Smoking cessation (varenicline)</u> Mr Dhadli stated that the varenicline prescribing advice guideline was due for its periodic review and had been sent for comment to Dr R Dewis and Ms H Gleeson Smoking Cessation Service Manager, Derbyshire City Council. There was only a minor amendment, varenicline is no longer a black triangle drug so all details that related to this have been removed.</p> <p>Agreed: JAPC ratified the clinical guideline Requesting prescriptions for and managing patients using varenicline with a review date of 3 years.</p> | SD |
| d. | <p><u>Liothyronine</u> Mrs Needham advised that the liothyronine working group met on 20th September 2019 to discuss a way forward with the classification of this drug which is currently listed as RED. Members of the meeting looked at audits and work done in primary care and across the trusts. The agreement in principle is that for existing patients who have had a review by an NHS endocrinology specialist, liothyronine should be classified as AMBER pending the approval of a shared care agreement. It was suggested BLACK for new patients, referring to the wording from Sheffield CCG and Sheffield Teaching Hospital's liothyronine Q&A as a guide, if JAPC members are in agreement with this. Further it was proposed to classify liothyronine as RED for monotherapy, any other indication except hypothyroidism and daily dose of 60mcg per day or more.</p> <p>A position statement has been developed; however since circulating the document to the committee there has been some amendments, therefore Mrs Needham asked if Mrs Qureshi would circulate the updated document to JAPC members following the meeting and this could be agreed via email.</p> <p>If liothyronine is classified as BLACK for new patients it would mean an Individual Funding Request (IFR) application via the specialist. GP's would be able to make a referral to an NHS endocrinology clinic if they felt that the patient needed further assessment of their condition or there were difficulties tolerating levothyroxine. Mr Dhadli expressed that it must be made clear on the shared care agreement that liothyronine in combination with levothyroxine is for hypothyroidism and not for other indications or as monotherapy.</p> <p>Mr Dhadli also stated that there's a possibility IFR requests which are received for new patients wanting to commence treatment on liothyronine may not be approved, therefore it has been suggested that a clinical criteria is developed and supported by the secondary care Drugs and Therapeutics committees. JAPC members recognised that the proposed traffic light classifications could be subject to change in the future pending a review of any issues that may arise. Mr Hulme commented that there may be concerns in regards to out of area patients re-locating and registering with a Derbyshire GP to gain access to this treatment and this should be considered in the wording used when assigning a traffic light classification for liothyronine. Mr Hulme also added that the definitions of IFR may need to be looked at in the future.</p> <p>Dr Taylor raised concerns that he felt there was an inconsistency in which patients who are taking liothyronine for hypothyroidism may have a review appointment and if appropriate be treated via a shared care agreement, however patients who are taking liothyronine for treatment resistant depression and where it is effective, may not be prescribed this under a</p> | SQ |

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| | <p>shared care agreement. Mr Dhadli stated that it was found there were only a small number of patients being treated with liothyronine for treatment resistant depression so it would not be consistent to develop a shared care for this. Dr Emslie also added that this was not in line with the NHS England guidance. The committee had no further comments to add to the draft shared care agreement. It was agreed that the new traffic light classifications for liothyronine along with the shared care agreement and position statement will take affect from the middle of November 2019 following final ratification at the November JAPC meeting.</p> <p>Agreed: Liothyronine (in combination with levothyroxine) to be classified as AMBER for existing patients who have been reviewed by a specialist and the dose has been stable for 3 months. Liothyronine to be classified as BLACK for new patients. Liothyronine to be classified as RED for monotherapy, resistant depression and in doses exceeding 60mcg per day.</p> | |
| 8. | PATIENT GROUP DIRECTIONS | |
| a. | <p><u>Children's continence service</u> Mr Dhadli reported that CRHFT are the lead providers commissioned for children's continence services, DCHSFT and Derbyshire Healthcare NHS Foundation Trust (DHcFT) are sub-contractors. DHcFT have proposed the use and approval of PGD's to enable initial provision of medication from nurse led clinics. Following initial supply of medications a clinic letter is sent to GP's to ask them to continue supply if indicated. These PGD's have been submitted to JAPC for review to ensure that the drugs and doses are compatible within the Derbyshire wide formulary. Mr Dhadli listed the following PGD's:</p> <ul style="list-style-type: none"> • Macrogol 13.8g to treat chronic constipation for age 12-17 years – doses as per BNF for children and recommended first line by CKS • Macrogol 6.9g to treat chronic constipation for age 2-11 years – doses as per BNF for children and recommended first line by CKS • Sodium picosulfate 5mg/5ml elixir to treat chronic constipation for age 4-17 – doses as per BNF for children • Desmopressin 120 microgram S/L tablet to treat nocturnal enuresis for age 5-17 – doses as per BNF for children • Oxybutynin 2.5mg tablet to treat day time and nocturnal enuresis for age 5-17) – doses as per BNF for children. <p>Dr Emslie questioned whether macrogol was listed as a brand within the Derbyshire formulary and Mrs Qureshi confirmed that Laxido paediatric is listed as the most cost effective choice.</p> <p>Action: Mr Dhadli to discuss with DHcFT the most cost effective options in line with formulary choices if macrogol is to be prescribed as maintenance treatment in primary care.</p> <p>Agreed: The PGD's were accepted for use by DHcFT children's continence service</p> | SD |

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| 9. | SHARED CARE | |
| a. | <p><u>Acamprosate and Disulfiram</u> Mr Dhadli reported that this is a scheduled review of existing shared care agreements, the guidelines have been reviewed by DHcFT Drugs and Therapeutics Committee and the Drug and Alcohol Advisory Group (DAAG). There were minor changes to the acamprosate shared care agreement. There was a query within the disulfiram shared care agreement under GP responsibility to check LFTs at six monthly intervals in order to inform six monthly specialist reviews. The current arrangement is that specialists already ask for this to be done as part of six monthly reviews. DAAG has raised issues of GPs refusing to take over prescribing responsibility due to some patients registered at group practices where the main site location is within Derbyshire City however the patient's GP practice is located in the County. No specific examples could be given, therefore Dr Emslie asked if the Medicines Management Team within Derby and Derbyshire CCG could look into this to see if it is an ongoing issue and address this within individual practices. Mr Dhadli advised that DAAG had proposed the removal of 'Alcohol dependence confirmed' from the referral criteria and 'to be satisfied the patient is alcohol dependent' from specialist responsibilities. A discussion took place and the committee agreed that this wording should remain within the disulfiram shared care agreement.</p> <p>Agreed: JAPC approved the shared care guidelines for Acamprosate Calcium (Campral EC) for alcohol abstinence and Disulfiram (Antabuse) for maintenance of alcohol abstinence, with a review date of 3 years.</p> | <p>KN</p> <p>SD</p> |
| b. | <p><u>Riluzole</u> Mr Dhadli advised that this is an update to an existing shared care, the contact details have been updated however no further comments were received from consultants at UHDBFT.</p> <p>Agreed: JAPC approved the shared care guideline for Riluzole for the treatment of the Amyotrophic Lateral Sclerosis (ALS) form of Motor Neurone Disease (MND), with a review date of 3 years.</p> | <p>SD</p> |
| c. | <p><u>Attention Deficit Hyperactivity Disorder (ADHD)</u> Mr Dhadli informed the committee that this is a partial update to the shared care agreement as NICE have updated their Attention deficit hyperactivity disorder: diagnosis and management' guideline in September 2019, in regards to ECG monitoring. It states that an electrocardiogram is not needed before starting stimulants, atomoxetine or guanfacine if cardiovascular history and examination are normal and the person is not on medicine that poses an increased cardiovascular risk. The ADHD shared care agreement now reflects the advice from NICE. Mr Dhadli stated that a proposal has been put forward by Derby and Derbyshire CCG's Medicines Management Team to recommend the prescribing of Atomoxetine generically. DHcFT are happy with this proposal and JAPC committee members were in agreement.</p> <p>Agreed: JAPC approved the update to the ADHD shared care</p> | <p>SD</p> |

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| 10. | MISCELLANEOUS | |
| <p>a.</p> <p>b.</p> <p>c.</p> <p>d.</p> | <p><u>EU exit and continuity of medicine supply</u> Mr Dhadli advised that there are Q&A documents which patients can be sign posted to and there's also an FAQ for clinicians on the NHS England website that has been updated. Mr Dhadli proposed a temporary link be added to the Derbyshire Medicines Management website to support prescribers, patients and general queries. This would then be communicated out via the JAPC bulletin. Mrs Needham felt it should be reiterated that it is advised not to order extra medicines.</p> <p><u>High Cost Drugs Psoriasis algorithm</u> Mr Dhadli reported that NICE TA596 'Risankizumab for treating moderate to severe plaque psoriasis' was published in August 2019. The psoriasis algorithm for high cost drugs excluded from tariff has been updated to include Risankizumab based on the most cost effective treatment. The algorithm has been shared with dermatology consultants at UHDBFT and CRHFT, no further comments have been received. JAPC members accepted the updated algorithm.</p> <p><u>Prescribing specification</u> Mr Dhadli advised that the prescribing specification was due for its annual review and is currently out for consultation. The CCG name has been updated to reflect the commissioning CCG (Derby and Derbyshire), discharging summaries after A&E attendance has now been removed as this is in place. Key therapeutic topics which have been re-introduced by the MPC's have been added back into the document, these include lipid modifying drugs and anticoagulants. Reference to FP10 (HP's) under high cost drugs has been removed as CRHFT no longer use these. Where the document refers to 'National Gain Share Agreements' under appendix six, Mr Dhadli reported that it has been amended to say 'where national/regional schemes are in place'. Under high cost drugs excluded from tariff commissioned by CCG's, a sentence has been added to say provider trusts will ensure that the most cost efficient route for the supply of PBR excluded drugs is used. A discussion took place as to whether the most cost efficient route was the correct wording as factors like quality and safety must also be considered. Mr Dhadli advised that this would be part of the homecare procurement process. Mr Sutton added that UHDBFT usually follow the recommendations of the regional homecare group, Mr Dhadli advised he will amend the wording to reference the regional decision making process. The prescribing specification document will be bought back to the December 2019 JAPC meeting. Mr Hulme asked if the prescribing specification allows for the option of switching from one biosimilar to another in the future. Mr Dhadli responded to say the document already states that switching between biosimilars will be in agreement through JAPC with details of opportunity cost, patient safety and resource to switch as considerations.</p> <p><u>Uveitis</u> Mr Dhadli reported that there is a new TA (NICE TA590) for fluocinolone which has been added to the uveitis algorithm as a 2nd line option before immunosuppressive drugs. The updated high cost drugs algorithm has been</p> | <p>SD</p> <p>SD</p> |

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| | shared with ophthalmologists at UHDBFT who have confirmed they are happy with the update. | |
| 11. | JAPC BULLETIN | |
| | The September 2019 bulletin was ratified. | |
| 12. | MHRA DRUG SAFETY UPDATE | |
| | <p>The MHRA Drug Safety Alert for September 2019 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> • Hormone replacement therapy (HRT): further information on the known increased risk of breast cancer with HRT and its persistence after stopping. New data was published in <i>The Lancet</i> on 30th August 2019. Prescribers are asked to discuss the new information on the risk of breast cancer with women using or contemplating using HRT at their next routine appointment. • Fingolimod (Gilenya▼): increased risk of congenital malformations including cardiac, renal, and musculoskeletal defects when used in pregnancy; women of childbearing potential must use effective contraception during fingolimod treatment and for 2 months after discontinuation. Educational materials (physician’s checklist and patient’s guide) are being updated to include new information on the risk of congenital defects and required mitigation measures. • Elmiron (pentosan polysulfate sodium): rare risk of pigmentary maculopathy. Cases of pigmentary maculopathy leading to visual impairment have been reported particularly after long-term use at high doses. Ensure patients have regular ophthalmic examinations and ask them to promptly seek medical advice in case of visual changes. • Montelukast (Singulair): reminder of the risk of neuropsychiatric reactions. Prescribers should be alert for neuropsychiatric reactions in patients taking montelukast and carefully consider the benefits and risks of continuing treatment if they occur. More information to better describe the risks of neuropsychiatric events has also been added to the Summary of Product Characteristics and Patient Information Leaflet. <p>Avastin</p> <p>Mr Dhadli stated that MHRA have published advice about the use of Avastin, the document referred to is titled ‘Review of MHRA published statements on the supply and use of Avastin (bevacizumab) for intravitreal use’. In September 2018 Bayer Plc and Novartis Pharmaceuticals UK Ltd challenged the lawfulness of a policy adopted by 12 CCGs from the North of England where Avastin was used to treat Age-related Macular Degeneration (ARMD). The MHRA was requested by the High Court to review “whether the process of compounding bevacizumab exceeds what is permissible for a given use to be ‘off-label’. The MHRA considers that further clarification of its published statements of 2009 and 2011 is necessary following the request from the court. The pertinent part of the article is ‘... process of bevacizumab for intravitreal use may involve repackaging of the licensed medicine (a “concentrate for solution for infusion”) to produce multiple small volume aliquots, usually in plastic syringers. This activity does not in itself make the product “unlicensed”’. A CCG policy of favouring the use of compounded</p> | |

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| | <p>bevacizumab for the treatment of wet ARMD is currently the subject of a legal challenge. This guidance will be reviewed, and updated if necessary, following the conclusion of those proceedings.</p> <p>Mr Hulme felt that the local ophthalmologists should be contacted to seek their views on the document. Mr Dhadli will inform the committee of their comments at the next JAPC meeting.</p> | SD |
| 13. | HORIZON SCAN | |
| a. | <p><u>Monthly Horizon Scan</u></p> <p>Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations:</p> <p>New drug launches in the UK:</p> <ul style="list-style-type: none"> • Cemiplimab (Libtayo) – classified as RED (as per NHS England commissioning intentions) • Lorlatinib (Lorviqua) – classified as RED (as per NHS England commissioning intentions) • Teriparatide biosimilar (Terrosa) – classified as RED CCG commissioned for women, NHS England for men • Dupilumab (Dupixent) – classified as RED <p>Drug discontinuations:</p> <ul style="list-style-type: none"> • Ethinylestradiol/gestodene (Aidulan 20/75) • Fentanyl (Breakyl) • Chloramphenicol (Chloromycetin) • Estradiol valerate/norgestrel (Cyclo-Progynova 2mg) • Olaratumab (Lartruvo) • Co-amilozone (Moduret 25) • Sodium aurothiomalate (Myocrisin) • Ganirelix (Orgalutran) • Sodium cromoglicate (Vividrin Drops) • Ethinylestradiol/gestodene (Aidulan 30/75) • Tacrolimus (Capexion) • Chloramphenicol (Chloromycetin Redidrops) • Tolterodine (Efflosomyl XL) • Milex Arcing Style • Ethinylestradiol/desogestrel (Munalea 20/150) • Theophylline (Nuelin SA) • Follitropin beta (Puregon) • Aluminium hydroxide (Alu-Cap) • Carbzero • Losartan (Cozaar Suspension) • Lactulose (Lactugal) • Milex Omniflex • Ethinylestradiol/desogestrel (Munalea 30/150) • Theophylline (Nuelin SA-250) • Ofloxacin (Tarivid) • Amikacin (Amikin) • Compact Test Strips • Influenza vaccine (Influenza vaccine Mylan) | |

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| | <ul style="list-style-type: none"> • Cefalexin (Keflex suspension) • Pancreatin (Pancrex Granules) • Ranitidine (Zantac tablets) • Colecalciferol (Aviticol) • Insulin (PZI) (Hypurin Bovine PZI) • Influenza vaccine (Influvac) • Cefalexin (Keflex tablets) • Pancreatin (Pancrex V Forte tablets) • BD Micro-Fine+ Lancets • Influenza vaccine (Imuvac) • Cefalexin (Keflex) • Atovaquone/proguanil (Mafamoz 62.5/25) • Fluocinolone (Synalar cream 1 in 10) | |
| 14. | NICE SUMMARY | |
| | <p>Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in September 2019:</p> <p>TA599 Sodium zirconium cyclosilicate for treating hyperkalaemia – reclassified from BLACK to RED (as per NICE TA599)</p> <p>TA600 Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer – classified RED (NHS England Cancer Drugs Fund as per NICE TA600)</p> <p>TA601 Bezlotoxumab for preventing recurrent Clostridium difficile infection (terminated appraisal) – classified as BLACK (as per NICE TA601)</p> <p>TA602 Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) – classified as BLACK (as per NICE TA602)</p> <p>TA603 Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma (terminated appraisal) – classified as BLACK (as per NICE TA603)</p> <p>TA565 Benralizumab for treating severe eosinophilic asthma – remains classified as RED (as per NICE TA565)</p> <p>NG87 Attention deficit hyperactivity disorder: diagnosis and management – the ADHD Shared Care Agreement has been updated</p> | |
| 15. | GUIDELINE GROUP ACTION TRACKER | |
| | <p>The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in September 2019 was noted.</p> <p>Mr Dhadli highlighted the following:</p> <p>Traffic Lights:</p> <ul style="list-style-type: none"> • Vacuum Pumps (existing/clarification) – classified as RED for out of area | |

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| | <p>requests, GPs can accept initial prescribing after assessment or on-going prescribing for replacement pumps if the specialist provides an APC approved shared care protocol or evidence the device is approved by another APC.</p> <ul style="list-style-type: none"> • Triamcinolone acetone injection – classified as GREEN 10mg/1ml ampoules; 40mg/1ml vials. Cost effective alternative to methylprednisolone acetate injection. • Fexofenadine – classified as BROWN alternative option when other antihistamines on formulary are not effective <p>Formulary Update (Chapter 11 – Eye):</p> <ul style="list-style-type: none"> • Added link to self-care section on Derbyshire Medicines Management website. • Aciclovir eye ointment removed as discontinued in June 2019. • VIZcellose 1% 10ml PF bottle and VIZcellose 0.5% 10ml PF bottle replaces Celluvisc 1% UDV and Xailin Fresh 0.5% UDV as the formulary choice for PF carmellose. <p>Clinical Guidelines:</p> <ul style="list-style-type: none"> • Menopause guideline – updated to include latest MHRA drug safety information on risk of breast cancer with HRT; alternative HRT preparations to formulary choices have also been included due to extensive stock shortages. • Freestyle Libre – information on disposal added to JAPC briefing. Used sensor to be placed in clinical waste sharps box. • Methotrexate SCG – further information on interaction with PPI has been added. There appears to be limited evidence involving the doses of methotrexate used for inflammatory disease. Local consultants advise that there are no concerns for this interaction at methotrexate doses used in this guideline. • Wound care formulary – Cellona Padding added to be used under actico compression bandage. • Management of undernutrition in Adult – included Energy shake as a powdered formulary option. • Stoma accessory guideline – product name updated following rebranding of ‘Respond’ products. No change in formulary choices. <p>Guideline Timetable:</p> <ul style="list-style-type: none"> • The guideline table action summary and progress was noted by JAPC. | |
| 16. | BIOSIMILAR REPORT | |
| | <p>Mr Dhadli reported that CRHFT are achieving the targets expected, there was a query around the etanercept use at UHDBFT as there was a drop in May and June 2019. However this has now improved and patient numbers are to be provided rather than a percentage figure only. This will be tabled at the November 2019 JAPC meeting.</p> <p>Mr Dhadli also advised that teriparatide will need to be added in the near future.</p> | SD |

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| 17. | TRAFFIC LIGHTS – ANY CHANGES? | |
| | <p><u>Classifications</u> Adapalene – GREEN Liothyronine (in combination with levothyroxine) – AMBER for existing patients who have been reviewed by a specialist and the treatment dose has been stabilised for 3 months. Liothyronine – BLACK for NEW patients. Liothyronine is in the black section of the traffic light drug list in Derbyshire and should not be initiated in new patients. If there is an exceptional clinical need, such as difficulty in tolerating or absorbing levothyroxine, then a request to prescribe must be made via the IFR process by an NHS endocrinology specialist. Liothyronine – RED When used as monotherapy, resistant depression and in doses exceeding 60mcg per day. Cemiplimab (Libtayo) – already classified as RED (as per NHS England commissioning intentions) Lorlatinib (Lorviqua) – RED (as per NHS England commissioning intentions) Teriparatide biosimilar (Terrosa) – RED Dupilumab (Dupixent) – RED Sodium zirconium cyclosilicate – RED (as per NICE TA599) Pembrolizumab with carboplatin and paclitaxel – RED (NHS England Cancer Drugs Fund as per NICE TA600) Bezlotoxumab – BLACK (as per NICE TA601) Pomalidomide with bortezomib and dexamethasone – BLACK (as per NICE TA602) Lenalidomide with bortezomib and dexamethasone – BLACK (as per NICE TA603) Benralizumab – already classified as RED (as per NICE TA565)</p> | |
| 18. | MINUTES OF OTHER PRESCRIBING GROUPS | |
| | <ul style="list-style-type: none"> • Sheffield Area Prescribing Group 20.06.2019 • Regional Medicines Optimisation Committee (North) 27.06.2019 • Regional Medicines Optimisation Committee (London) 03.07.2019 • UHDBFT Drugs and Therapeutics 16.07.2019 • Medicines Optimisation Safety Team 04.07.2019 • Chesterfield Drugs and Therapeutics 17.09.2019 <p>The following items were highlighted: Mr Dhadli noted that the Sheffield Area Prescribing Group minutes discuss Vitamin B Compound Strong and how they are taking steps to reduce inappropriate prescribing. Sheffield CCG produced an action sheet that looked at reviewing and stopping prescribing unless patients were deficient or being prescribed for refeeding syndrome, their APG agreed with this approach. The minutes also highlight supply issues for HRT, linaclotide and bile acid sequestrants, which may now have been resolved.</p> | |
| 19. | ANY OTHER BUSINESS | |
| a. | <p><u>JAPC meeting dates and venue for 2020</u> Dr Emslie noted the venue and meeting dates for the JAPC meetings taking place next year. Mr Dhadli highlighted the deadline for paper submissions.</p> | |

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| b. | <p><u>Equality Impact Assessment (EIA)/Quality Impact Assessment (QIA)</u></p> <p>Mr Dhadli advised that the Director of Nursing within Derby and Derbyshire CCG is looking into all decision making processes within the CCG and to consider whether they require an EIA/QIA. This includes the decisions made by the JAPC committee where a question was asked as to whether every drug, decision and formulary change requires an EIA and QIA.</p> <p>Previously in 2017 Mr Dhadli met with the QIA/EIA manager to review JAPC's process. Following on from this it was confirmed that all recommendations and decisions proposed to JAPC are to be accompanied by a front cover sheet which includes a section with a prompt to consider whether an EIA and QIA are required. JAPC consciously looks at equality duty as part of the process of decision making and takes into consideration equality issues including protected characteristics. Following the review in 2017 and greater understanding of the JAPC processes the conclusion drawn was to EIA/QIA a decommissioned medicine when there are no alternatives available.</p> <p>JAPC makes recommendations primarily on traffic light classifications; the only time when JAPC advises a clinician not to prescribe is for a BLACK drug classification. Where there is no alternative to a classified BLACK drug, a full QIA and EIA will be undertaken.</p> <p>Mr Dhadli reported that he has produced a document which outlines how JAPC makes its decisions around shared cares, formularies and switches. This will be going to a future EIA/QIA panel therefore Mr Dhadli asked that the JAPC committee read through this document and evaluate if there should be any amendments within this or anything that needs clarity. There is a proposal within the paper for the QIA and EIA team to have an open invite to attend JAPC and/or to receive the papers ahead of the JAPC monthly meeting to access if there are any issues that need discussing. Going forward there will also be an EIA/QIA assessment document which will be embedded into the JAPC front cover sheet for process purposes.</p> <p>Action: Members of the JAPC committee to review the 'JAPC and EIA QIA' document and feedback any comments on this at the November 2019 JAPC meeting.</p> | <p>All Members</p> |
| c. | <p><u>Serious Shortage Protocol</u></p> <p>Mr Dhadli advised that the NHS have produced Serious Shortage Protocols (SSP) as a result of certain drug shortages. This is aimed towards community pharmacists who can make some amendments as to what they supply, following the recommendations within the guidance. The committee agreed that a link to the SSP page should be added to the Derbyshire Medicines Management website and communicated out in the JAPC bulletin.</p> | |
| d. | <p><u>Declaration of Interest forms</u></p> <p>Mr Dhadli stated that the Declaration of Interest forms which are usually circulated on an annual basis in October will now be sent out in March/April to bring it in line with Derby and Derbyshire CCG's timetable for this. The intention is to streamline the process as it will mean that CCG members only complete one form for all meetings rather than individual ones. Dr Emslie reiterated the need for all members to have completed a form and for the register of interests to reflect this.</p> | |

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| e. | <p><u>Thank you to Dr T Parkin</u> JAPC members expressed thanks to Dr T Parkin for his input and contribution throughout his time as a valued member of the committee. Dr Parkin is retiring in January 2020 and members wished him well for the future.</p> | |
| 20. | <p>DATE OF NEXT MEETING</p> | |
| | <p>Tuesday, 12th November 2019 at 1.30pm in the Coney Green Business Centre, Clay Cross.</p> | |