

## DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

### Minutes of the meeting held on 10<sup>th</sup> September 2019

## CONFIRMED MINUTES

### Summary Points

#### Traffic lights

Drug	Decision
Safety needles (except GlucoRx & Mylife Clickfine)	BLACK – cost >£20 per 100 GREEN 2nd line – cost <£20 per 100
Fremanezumab (Ajovy)	BLACK
Galcanezumab (Emgality)	BLACK
Prasterone (Intarosa)	BLACK
Tezacaftor + ivacaftor (Symkevi)	RED (as per NHS England commissioning intentions)
Dolutegravir + lamivudine (Dovato)	RED (as per NHS England commissioning intentions)
Patisiran	RED (NHS England as per NICE HST10)
Cemiplimab	RED (NHS England as per NICE TA592)
Ribociclib with fulvestrant	RED (NHS England as per NICE TA593)
Brentuximab vedotin	BLACK (as per NICE TA594)
Dacomitinib	RED (NHS England as per NICE TA595)
Risankizumab	RED (as per NICE TA596)
Dapagliflozin with insulin for treating type 1 diabetes	RED (as per NICE TA597)
Olaparib	RED (NHS England as per NICE TA598)

#### Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Formoterol/acclidinium (Duaklir Genuair)	GREEN from BROWN
Vilanterol/umeclidinium (Anoro Ellipta)	GREEN from BROWN
Olodaterol/tiotropium (Spiolto Respimat)	GREEN from BROWN
Memantine	GREEN: 2 <sup>nd</sup> line (for dementia) after consultant/specialist initiation and stabilisation for 3 months. BROWN: 2 <sup>nd</sup> line option for acute use to treat BPSD as per local guidance – with a balance of clinical benefit over risk.
Silver sulfadiazine cream (Flamazine)	BROWN TVN recommendation as per wound care formulary or following specialist advice for radiotherapy reactions only.
Polymem dressing	BROWN Specialist or TV recommendation only for patients with radiotherapy reactions.
Vacuum Pumps	RED for out of area requests, GPs can accept on-going prescribing of replacement pumps if the specialist provides an area prescribing committee approved shared care protocol or evidence the device is approved by another area prescribing committee.
Aliskiren	BLACK for treatment resistant hypertension

## **Clinical Guidelines**

- Management of Dyspepsia and Gastro-Oesophageal Reflux Disease (GORD)

## **Patient Group Directions**

- Administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b and hepatitis B vaccine (DTaP/IPV/Hib/HepB) to individuals from 6 weeks (routinely 8 weeks) to under 10 years of age in accordance with the national immunisation programme.
- Administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis and *Haemophilus influenzae* type b conjugate vaccine (DTaP/IPV/Hib) to individuals from 3 years 4 months to under 10 years of age in accordance with the national immunisation programme for a pre-school booster of DTaP/IPV

## **Shared Care Guidelines**

- Azathioprine/6-mercaptopurine for patients 16+ years

<b>Present:</b>	
<b>Derby and Derbyshire CCG</b>	
Dr C Emslie	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)
Dr R Gooch	GP
Mr S Hulme	Director of Medicines Management and Clinical Policies
Mrs K Needham	Assistant Director of Medicine Optimisation and Delivery
Dr T Parkin	GP
Mrs S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Mr R Coates	Finance Manager
<b>Derby City Council</b>	
<b>Derbyshire County Council</b>	
<b>University Hospitals of Derby and Burton NHS Foundation Trust</b>	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr R Sutton	Pharmacist
Ms A Brailey	Deputy Chief Pharmacist
<b>Derbyshire Healthcare NHS Foundation Trust</b>	
Mr S Jones	Chief Pharmacist
<b>Chesterfield Royal Hospital NHS Foundation Trust</b>	
Mr M Shepherd	Chief Pharmacist
<b>Derbyshire Community Health Services NHS Foundation Trust</b>	
Ms J Shaw	Pharmacist
<b>Derby and Derbyshire Local Medical Committee</b>	
Dr K Markus	Chief Executive Officer
<b>Derbyshire Health United</b>	
Mr D Graham	Pharmacist
<b>Staffordshire CCG's</b>	
Ms S Bamford	Pharmacist
<b>In Attendance:</b>	
Ms E Khatib	Medicines Optimisation Pharmacist, Derby and Derbyshire CCG
Mrs K Rogers	Derby and Derbyshire CCG Senior Administrator (minutes)

Item		Action
1.	<b>APOLOGIES</b>	
	Ms J Savoury.	
2.	<b>DECLARATIONS OF CONFLICTS OF INTEREST</b>	
	<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.	<b>DECLARATIONS OF ANY OTHER BUSINESS</b>	
	There were no declarations of any other business.	
4.	<b>MINUTES OF JAPC MEETING HELD ON 13 AUGUST 2019</b>	
	<p>The minutes of the meeting held on 13<sup>th</sup> August 2019 were agreed as a correct record after the following amendments:</p> <p>The correction of a spelling error in the surname of Dr K Markus.</p> <p>Where ibandronic acid is referred to on page 4 and 5, the word 'guidance' has been amended to 'guideline' to ensure the correct definition is used.</p>	
5.	<b>MATTERS ARISING</b>	
a.	<p><b><u>Bisphosphonates for breast cancer</u></b></p> <p>Mr Dhadli reported that bisphosphonates for breast cancer was being looked at due to non-compliance at University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) compared with the NICE guideline. It was considered to be an equity issue as it is prescribed in the North of Derbyshire via Sheffield. There were also some issues in regards to costings and figures given by UHDBFT, it was estimated there were 250 patients that could go onto treatment however the numbers were not what would be expected in terms of the NICE costing template and the figures reported in the North of Derbyshire.</p> <p>A paper has been prepared for the next Clinical and Lay Commissioning Committee (CLCC) meeting which highlights the non-compliance of UHDBFT and states that Derby and Derbyshire CCG are waiting for confirmation of the figures UHDBFT are anticipating. Mr Sutton asked if in terms of patient numbers whether the full costings were needed, Mr Dhadli confirmed that in compliance with NICE that is what would be recommended.</p> <p>A discussion took place around the re-organisation of the cancer networks as the way the areas are split within Derbyshire may be changing. Mr Shepherd confirmed that discussions were currently ongoing in Chesterfield.</p>	
b.	<p><b><u>Azithromycin and microbiology advice</u></b></p> <p>Mrs Qureshi reported that she had emailed Ms J Lacey, Antimicrobial Pharmacist UHDBFT, who responded to say she feels azithromycin is used in Chronic Obstructive Pulmonary Disease (COPD) more for its anti-inflammatory effects as opposed to its antimicrobial effects. JAPC members had asked at the last meeting if sensitivity to azithromycin could be looked at, as it is recommended for prophylaxis in COPD exacerbations. Ms Lacey didn't have any local figures, however she felt that they were very similar to the</p>	

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	<p>national figures which are approximately 88% sensitivity to azithromycin. Mr Dhadli confirmed that they have no concerns with following Public Health England advice.</p> <p><b>c. <u>Patent expiries for LABA + LAMA combinations</u></b>            Mrs Qureshi referred to a table within paper 5C which detailed when all of the patents will expire, the earliest being in September 2027. This paper has also been to a Derbyshire Medicines Management Shared Care and Guidelines Group meeting, who have accepted that the LABA + LAMA combinations have all changed to GREEN. Mrs Qureshi also reassured the committee that each formulary chapter is reviewed and updated on an annual basis through the Derbyshire Medicines Management Shared Care and Guidelines Group, during this time all devices are looked at, therefore if a new device comes out and has come off patent it will be reviewed. This would also be the case through the annual horizon scanning process.            Mr Dhadli advised that the patent should only be used as an indicator as there are no guarantees that a drug price will reduce on the date of the patent expiry. The committee were in agreement that all LABA + LAMA combinations were to remain GREEN as they are equally efficacious and have the same cost. The choice of drug will depend on availability and patient factors.</p> <p><b>d. <u>Classification for all other Safety Needles</u></b>            Mr Dhadli asked for clarification on the classification of safety needles from the previous meeting as he felt this was unclear. GlucoRx has been added to the formulary and Mylife Clickfine has remained as GREEN on the formulary whilst training materials are being sourced for GlucoRx. Mr Dhadli asked the committee to clarify if all other safety needles had been classified as BLACK or if they were to be DECLASSIFIED. Mrs Needham felt that it was essential that BD safety needles were classified as BLACK. Dr Emslie stated that there was a long debate on this topic at the last meeting and it was put to the committee that either all other safety needles were to be classified as BLACK, or everything priced less than or equal to £20 be classified as GREEN 2<sup>nd</sup> line and anything greater than this price was to be classified as BLACK. The committee were in agreement with the latter suggestion. Mr Dhadli advised that a post meeting note would be added to the August 2019 JAPC minutes to confirm this decision.            Dr Markus asked if a training package for GlucoRx has been sourced. Dr Emslie reported that she'd been informed by Ms Braithwaite that one had been found and relevant staff at Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) were to undertake this training in the near future.</p> <p><b>Agreed:</b> all safety needles with an acquisition cost &gt;£20 per 100 were classified as BLACK and those with a cost of &lt;£20 per 100 were classified as GREEN 2<sup>nd</sup> line, with GlucoRx safety needles GREEN 1<sup>st</sup> line.</p> <p><b>e. <u>Strategic Steering Groups</u></b>            Mr Dhadli stated that at the last meeting Mr Hulme had asked if the Oxygen Guideline and the COPD management guideline had been to any strategic steering group meetings of which there are four: gastro, respiratory, diabetes and cardiovascular. Mr Dhadli confirmed that the guidelines were sent onto these groups and that Ms J Lowrey Respiratory Consultant UHDBFT had</p>	<p></p> <p style="text-align: right;"><b>SD</b></p>

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	<p>already previously been consulted in regards to the COPD guideline. The general consensus from the steering groups was that if there has been clinical engagement in reviewing these guidelines then there is no real need for it to go to the steering groups, they can however provide assistance with guidelines that have been agreed through JAPC in terms of support, implementation and communicating to GP's and general practice. Mr Dhadli reported that some of the pharmacists within the Medicines Management team link into the strategic steering groups and so it was suggested that relevant clinical guidelines agreed through JAPC are sent to those pharmacists.</p> <p>Mr Hulme commented that the question was based more around the consultation process. Dr Emslie suggested that these groups should be utilised. Mr Dhadli stated that the guidelines are usually sent to consultants who represent their department; however, he can also include the steering groups going forward.</p> <p>Dr Goddard asked Mr Dhadli if he could send the list of representatives to him for the gastro steering group.</p>	<b>SD</b>
<b>6.</b>	<b>JAPC ACTION SUMMARY</b>	
<p><b>a.</b></p> <p><b>b.</b></p>	<p><b><u>Hydroxychloroquine</u></b></p> <p>Mr Dhadli reported that a sub group had been formed which included Ms S Baughen Head of Planned Care, Dr R Dewis consultant in Public Health Medicine, Mr N Davis Registrar in Public Health, Ms C Burgess Senior Commissioning Officer, Derby and Derbyshire CCG and himself. There were some actions following the most recent Clinical Policies and Decisions (CPAG) meeting. Dr R Dewis is to attend the Derby and Derbyshire, Derby and Chesterfield ophthalmology Clinical Interest Group (CIG) meeting in September to review the options; this will include a virtual tariff pathway. Mr Dhadli advised that he is going to develop an interim position statement which sets out the current position of monitoring for hydroxychloroquine. Dr R Dewis is also going to look at flexibility within the Royal Collage of Ophthalmology guidelines in terms of which type of monitoring the ophthalmologists can do and which ones can be done virtually. Ms C Burgess would then give an update to that particular group on patient numbers.</p> <p><b><u>Liothyronine</u></b></p> <p>Mr Dhadli stated that there is a liothyronine working group that is due to meet on the 20<sup>th</sup> September 2019. Ms Brailey asked what information or data is needed for the working group. Mrs Needham advised that there is a draft agenda for this meeting which contains some data received from UHDBFT. Ms Brailey asked if the agenda could be circulated in preparation for the meeting and it was agreed that this would be sent to all JAPC members.</p> <p>Ms Brailey and Dr Goddard expressed that they are keen to get this resolved and are happy to provide any accessible information requested by Derby and Derbyshire CCG. Mr Jones asked when the guideline or shared care for liothyronine is developed; will it include treatment for depression? It was confirmed by the committee that this will not be included and it will remain RED for treatment resistant depression.</p>	

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c.	<p><b><u>Amiodarone</u></b>            A draft shared care has been developed and it is on the agenda for JAPC to review at this meeting.</p>	
7.	<p><b>CLINICAL GUIDELINES</b></p>	
a.	<p><b><u>Dyspepsia and Gastro-Oesophageal Reflux Disease (GORD)</u></b>            Mr Dhadli reported that the Dyspepsia and GORD guideline has been reviewed and updated. It was last updated in September 2017, based on NICE CG184 Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management (Nov 2014). There are minor changes in terms of wording for H pylori association with up to 95% duodenal ulcer and 70% gastric ulcer updated on consultant feedback.            Mr Dhadli raised a point that Public Health England dosing for clarithromycin differs from that found in the National Institute of Health and Care Excellence (NICE) and the British National Formulary (BNF). UHDBFT and Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) follow the BNF's recommendations. The Public Health England document was recently updated a few months ago and their guidance states a dose of 500mg BD. Mr Dhadli added that there is also a query around the tetracycline dose, Public Health England recommend four times a day whereas the NICE GORD guidance recommends twice a day. Mr Dhadli contacted someone from the MPC who replied that the dyspepsia guidance is quite old and that it will be updated in line with Public Health England advice. In regards to the clarithromycin dose, Mr Dhadli has contacted the BNF who responded to say that they are aware of the Public Health England information and it is in their work plan to do an update in the future. The options are to either wait until NICE update their GORD guidance and the BNF update theirs also, or to follow Public Health England guidelines and inform UHDBFT, CRHFT and microbiologists that this is the recommendation. A discussion took place in regards to whether a GP in practice or pharmacist in a dispensary might look for this in the BNF and how many queries this may generate if the dosage in our guidelines are different to that of the BNF. Mr Dhadli suggested another option would be to wait and review this again in three months' time when NICE and the BNF may have updated this given the fact they appear later in the clinical patient pathway. The rest of the guidance was agreed by JAPC members.</p> <p><b>Agreed:</b> JAPC ratified the guidelines for Management of Dyspepsia and Gastro-Oesophageal Reflux Disease (GORD) with a review date of three years. A review will be done in three months' time to look at NICE and BNF recommendation for clarithromycin dose.</p>	
8.	<p><b>PATIENT GROUP DIRECTIONS</b></p>	
a.	<p>The following PGDs from Public Health England were noted by JAPC:</p> <p>Effective from 1st September 2019</p> <ul style="list-style-type: none"> <li>Administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, <i>Haemophilus influenzae</i> type b and hepatitis B vaccine (DTaP/IPV/Hib/HepB) to individuals from 6 weeks (routinely 8 weeks) to under 10 years of age in accordance with the national immunisation programme.</li> </ul>	

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	<p>Expired on 31<sup>st</sup> August 2019 and not renewed</p> <ul style="list-style-type: none"> <li>Administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis and Haemophilus influenzae type b conjugate vaccine (DTaP/IPV/Hib) to individuals from 3 years 4 months to under 10 years of age in accordance with the national immunisation programme for a pre-school booster of DTaP/IPV.</li> </ul>	
<b>9.</b>	<b>SHARED CARE GUIDELINES</b>	
<b>a.</b>	<p><b><u>Azathioprine/Mercaptopurine</u></b></p> <p>Mr Dhadli reported that this has gone out for wider consultation with both UHDBFT and CRHFT. It is based on the 2017 BSR guideline however there are some criteria that have been included across all of the immunomodulating drugs which include transferring care (when treatment stable or predictable), when immunisation with live vaccine is permitted and updated contacts/links and resources. Immunisation clarification has been added to say that patients on azathioprine &lt;3mg/kg/day or mercaptopurine &lt;1.5mg/kg/day can have live vaccine with caution as per Green Book.</p> <p>The contraindication where it mentions seriously impaired hepatic or bone marrow function/ pancreatitis is as per Summaries of Product Characteristics (SPC).</p> <p>Pregnancy &amp; breast feeding was previously listed as a specific contraindication under the SPC, however that restriction was relaxed based on consultant advice and it was also backed up by similar advice in the BSR guidance and SPC advice.</p> <p><b>Agreed:</b> JAPC ratified the shared care agreement for Azathioprine/6-mercaptopurine for patients 16+ years, with a review date of three years.</p>	<b>SD</b>
<b>b.</b>	<p><b><u>Leflunomide</u></b></p> <p>Mr Dhadli reported that this has gone out for wider consultation with both UHDBFT and CRHFT. It is based on the 2017 BSR guideline however there is some criteria that has been included across all of the immunomodulating drugs which include transferring care (when treatment stable or predictable), immunisation live vaccine permitted and updated contacts/links and resources. There has been a question mark about the evidence base for the live vaccine as the Green Book does not reflect if leflunomide is a high or traditional dose DMARD. The SPC and BNF both list the vaccine as a contraindication irrespective of dose. Mr Dhadli liaised with Dr Laxminarayan consultant Rheumatologist UHDBFT, Dr K Fairburn consultant Rheumatologist CRHFT and Dr L Badcock ACD Rheumatology and Consultant Rheumatologist UHDBFT who all confirmed that a dose of 20mg daily would be considered a standard dose. A discussion took place as to whether this was based on local expert opinion, as national guidance doesn't mention this. The committee decided that this would require further clarification as to the evidence base for this; Mr Dhadli would bring the shared care agreement to a future JAPC meeting once this information had been obtained.</p> <p><b>Action:</b> it was agreed that the shared care agreement for leflunomide for patients 16+ years would be brought back to a future JAPC meeting, once</p>	



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<p>c.</p>	<p>clarification has been sought on the evidence base for the live vaccine dosage.</p> <p><b><u>Amiodarone</u></b>            Mr Dhadli reported that amiodarone is included in NHSE 'Items which should not routinely be prescribed in primary care' version two document, which recommends that amiodarone could be a shared care agreement and shouldn't be initiated in Primary Care. It has been brought to the meeting in draft form as there are some queries that have been raised by the cardiologists at UHDBFT and CRHFT. Dr Baron cardiologist UHDBFT commented that due to prevalence of ECG facility in primary care this should be done/reviewed by a GP with specialist support if necessary. Dr Markus commented that routine ECG's in Primary Care had recently been discussed at an Enhanced Services Review meeting and there was some concern around ECG monitoring in Primary Care, as this may cover a vast amount of conditions which might not be funded within this specification.            A discussion took place and questions were raised as to what the monitoring requirements would be, the process to follow if an abnormality is found, how often patients should be seen for follow up appointments, what are the recommendations on when to stop treatment, do GP's feel comfortable with doing this and what capacity do they have. Dr Emslie suggested that these questions are raised through the Cardiovascular Steering Group.            The Derbyshire Medicines Management Shared Care and Guideline Group had also agreed that there needs to be an agreement on what is reasonable for Primary Care to be responsible for and how it will be funded.            Mr Dhadli advised that the alternative to a shared care agreement would be to follow NHSE recommendations and repatriate patients back to the acute trust. Dr Goddard questioned what the process would be for current patients, as the draft shared care agreement only refers to new ones. Mr Dhadli responded to say that the NHSE document may state that by exception there could be a shared care agreement for these patients.            There had also been another comment from cardiologists at CRHFT in regards to abnormal LFTs as there are specific values written within the previous amiodarone guideline, CRHFT suggested to quote 'X' times 'upper limit of normal' instead of specifying ALT value.            Mr Hulme asked if the number of patients on amiodarone were known, Mr Dhadli had a guide figure so Mrs Needham suggested she run an exact report that will provide a more accurate indication of patient numbers. This report will also help to determine where the patients are within Derbyshire.</p> <p><b>Action:</b> it was agreed that the draft shared care agreement for amiodarone would be brought back to a future JAPC meeting in 3 months' time once further clarification has been sought on the points raised and discussed.</p>	<p>SD</p> <p>KN</p> <p>SD</p>
<p>10.</p>	<p><b>MISCELLANEOUS</b></p>	
<p>a.</p>	<p><b><u>Menopause guideline – HRT shortage</u></b>            Mr Dhadli advised that resources have been sent out from the British Menopausal Society who has recently produced an update on the availability of HRT products. There have been availability issues with many HRT products. Some of these are related to manufacturing shortages, while others</p>	

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	<p>are related to supply issues. In light of this the menopause guideline has been updated with some alternative products. For Elleste Solo the recommendation would be either Zumenon (which is out of stock until the middle of September 2019) or Progynova. For Evorel the recommendation is Estraderm MX and for Elleste Duet the recommendation is Novofem. The only brands that are not able to be replaced as like for like are Tridestra and Kliovance, however this is currently the closest available alternative.</p> <p>Mrs Needham suggested adding the link to the Monthly Index of Medical Specialities (MIMS) out of stock action tracker into that section of the Menopause guideline so that users can refer to it. It was also suggested that this be communicated out via Ms S Travis Controlled Drugs Accountable Officer for NHS England - North Midlands to community pharmacies. The committee were in agreement.</p>	<p>SD</p> <p>SD</p>
b.	<p><b><u>Changes to NICE antimicrobial prescribing guidance – managing common infections</u></b></p> <p>Mr Dhadli informed the committee that Public Health England have made some updates to their prescribing guidance – managing common infections, in July 2019. It was tabled at the JAPC meeting for information. Mr Dhadli has also asked that this paper be tabled at the next Derbyshire Medicines Management Shared Care and Guideline Group meeting so that it can be reviewed for anything that may need looking at in further detail. Dr Emslie asked if Public Health England has updated their document which is linked from the Derbyshire Medicines Management website, Mr Dhadli confirmed that they have.</p>	
c.	<p><b><u>PrescQIPP Melatonin</u></b></p> <p>Mr Dhadli reported that PrescQIPP have released a summary on the newly licensed melatonin preparations which are indicated for jet lag. As the JAPC committee discussed at the August meeting, it states that Melatonin 1mg/ml oral solution contains the following excipients which may be potentially problematic when used in children: Propylene glycol 150.37 mg per 1ml dose, Ethanol 0.00045 mg per 1ml dose and Sorbitol 140mg per 1ml dose. Mr Dhadli also referred to a cost comparison table which showed the strength and number of doses per day, this was discussed for information.</p>	
d.	<p><b><u>Hepatitis B in Chronic Kidney Disease (CKD)</u></b></p> <p>Mr Dhadli advised that NHSE Specialised Commissioning has sent out a letter in regards to the commissioning and provision of Hepatitis B vaccination for patients with Chronic Kidney Disease, this details how the responsibility and associated funding now rests with the renal service and not with general practice.</p> <p>Dr Emslie asked Mrs Qureshi if she had received assurances from the local renal team that they are aware of these changes. Mr Dhadli advised that written communication has been sent to Nottingham, Derby and Sheffield so they have been informed. Mrs Qureshi was asked to update the classification of Hepatitis B in CKD to RED for vaccination of at risk renal patients.</p>	<p>SQ</p>
e.	<p><b><u>Sayana Press</u></b></p> <p>Mr Dhadli reported that a letter from the Department of Health and Social Care (DHSC) had been sent to all GP practices in England to advise them</p>	

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	<p>that Sayana Press (medroxyprogesterone acetate 104mg) injection will be out of stock until at least the end of 2019 due to manufacturing delays. Depo-Provera (medroxyprogesterone acetate 150mg) is currently available and able to support the market during this time. Mr Dhadli advised that this information be relayed to DCHSFT to find out what stock they currently hold and to ensure that there will be no prescribing of Sayana Press once current stock is used.</p>	<b>AB/JS</b>
<b>11.</b>	<b>JAPC BULLETIN</b>	
	<p>The August 2019 bulletin was ratified following an update on the clarification of the classification of safety needles and the removal of 'ancillary equipment when supplied on an FP10' under the Methotrexate Shared Care Agreement section.</p>	<b>SQ</b>
<b>12.</b>	<b>MHRA DRUG SAFETY UPDATE</b>	
	<p>The MHRA Drug Safety Alert for August 2019 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> <li>• Daratumumab (Darzalex ▼): risk of reactivation of hepatitis B virus.            A recent EU cumulative review of worldwide data has identified reports of hepatitis B virus reactivation in patients treated with daratumumab. Establish hepatitis B virus status before initiating daratumumab and in patients with unknown hepatitis B virus serology who are already being treated with daratumumab.</li> <li>• Naltrexone/bupropion (Mysimba ▼): risk of adverse reactions that could affect ability to drive.            An EU review of cumulative data has identified somnolence as a common risk with naltrexone/bupropion and loss of consciousness as a rare risk. Given these and other adverse reactions, a new warning has been added to the product information that naltrexone/bupropion may affect the ability to drive, operate machinery, or perform dangerous tasks.</li> <li>• Carfilzomib (Kyprolis ▼): reminder of risk of potentially fatal cardiac events.            Anti-cancer therapy with carfilzomib has been associated with cases of cardiac arrest, cardiac failure, and myocardial infarction, including in patients without pre-existing cardiac disorders. Monitor patients for signs and symptoms of cardiac disorders before and during exposure to carfilzomib.</li> </ul> <p>MHRA Hormone replacement therapy (HRT): further information on the known increased risk of breast cancer with HRT and its persistence after stopping.            The risk of breast cancer is increased during use of all types of HRT, except vaginal estrogens.            New analysis shows some excess risk of breast cancer persists for more than 10 years after stopping HRT. There is little or no increase in risk of breast cancer with current or previous use of HRT for less than 1 year; however, there is an increased risk with HRT use for longer than 1 year. The latest evidence comes from a meta-analysis by the Collaborative Group on Hormonal Factors in Breast Cancer, published 29 August 2019 in The Lancet. Mr Dhadli advised that the menopause guideline will be updated to reference the MHRA advice.</p>	

Item		Action
<b>13.</b>	<b>HORIZON SCAN</b>	
a.	<p><b><u>Monthly Horizon Scan</u></b>            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"> <li>• Dacomitinib (Vizimpro) – classified as <b>RED</b> (as per NHS England commissioning intentions)</li> <li>• Fremanezumab (Ajoovy) – classified as <b>BLACK</b></li> <li>• Galcanezumab (Emgality) – classified as <b>BLACK</b></li> <li>• Patisiran (Onpattro) – classified as <b>RED</b> (as per NHS England commissioning intentions)</li> <li>• Prasterone (Intarosa) – classified as <b>BLACK</b></li> <li>• Tezacaftor + ivacaftor (Symkevi) – classified as <b>RED</b> (as per NHS England commissioning intentions)</li> </ul> <p>New formulation launches in the UK</p> <ul style="list-style-type: none"> <li>• Dolutegravir + lamivudine (Dovato) – classified as <b>RED</b> (as per NHS England commissioning intentions)</li> </ul> <p>Drug discontinuations:</p> <ul style="list-style-type: none"> <li>• Myocrisin (Sodium aurothiomalate)</li> </ul>	
<b>14.</b>	<b>NICE SUMMARY</b>	
	<p>Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in August 2019:            HST10 Patisiran for treating hereditary transthyretin amyloidosis – classified as <b>RED</b> (NHS England as per NICE HST10).</p> <p>TA592 Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma – classified as <b>RED</b> (NHS England as per NICE TA592)</p> <p>TA593 Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer – classified as <b>RED</b> (NHS England as per NICE TA593)</p> <p>TA594 Brentuximab vedotin for untreated advanced Hodgkin lymphoma – classified as <b>BLACK</b> (as per NICE TA594 due to no evidence submission)</p> <p>TA595 Dacomitinib for untreated EGFR mutation-positive non-small-cell lung cancer – classified as <b>RED</b> (NHS England as per NICE TA595)</p> <p>TA596 Risankizumab for treating moderate to severe plaque psoriasis – classified as <b>RED</b> from <b>BLACK</b> (as per NICE TA596)</p> <p>TA597 Dapagliflozin with insulin for treating type 1 diabetes – classified as <b>RED</b> for type 1 diabetes (as per NICE TA597)</p> <p>TA598 Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-</p>	

Item		Action
	line platinum-based chemotherapy – classified as <b>RED</b> (NHS England as per NICE TA598)	
<b>15.</b>	<b>GUIDELINE GROUP ACTION TRACKER</b>	
	<p>The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in August 2019 was noted.</p> <p>Mr Dhadli highlighted the following:</p> <p>Traffic Lights:</p> <ul style="list-style-type: none"> <li>• Formoterol/acclidinium (Duaklir Genuair) – classified as GREEN from BROWN (see local COPD guidance).</li> <li>• Vilanterol/umeclidinium (Anoro Ellipta) – classified as GREEN from BROWN (see local COPD guidance).</li> <li>• Olodaterol/tiotropium (Spiolto Respimat) – classified as GREEN from BROWN (see local COPD guidance).</li> <li>• Memantine – classified as GREEN 2nd line (for dementia) after consultant/specialist initiation and stabilisation for 3 months. BROWN 2nd line option for acute use to treat BPSD as per local guidance - with a balance of clinical benefit over risk.</li> <li>• Silver sulfadiazine cream (Flamazine) – classified as BROWN TVN recommendation as per wound care formulary or following specialist advice for radiotherapy reactions only.</li> <li>• Polymem dressing – classified as BROWN specialist or TV recommendation only for patients with radiotherapy reactions.</li> <li>• Vacuum Pumps – classified as RED for out of area requests, GPs can accept on-going prescribing of replacement pumps if the specialist provides an area prescribing committee approved shared care protocol or evidence the device is approved by another area prescribing committee.</li> <li>• Aliskiren – classified as BLACK for treatment resistance hypertension.</li> </ul> <p>Formulary Update (Chapter 10 – Musculo-skeletal and joint diseases):</p> <ul style="list-style-type: none"> <li>• Added link to self-care section on Derbyshire Medicines Management website.</li> <li>• Indometacin suppositories removed from formulary.</li> </ul> <p>Clinical Guidelines:</p> <ul style="list-style-type: none"> <li>• Bisphosphonate treatment break – clarification on             <ul style="list-style-type: none"> <li>○ recommencing therapy after treatment break – risk assess with FRAX + DXA if eligible.</li> <li>○ patients who have been on &gt;10 years treatment – review individual case with specialist support.</li> </ul> </li> <li>• Clozapine GP information – minor updates to include additional information on treatment of constipation.</li> <li>• Melatonin for the treatment of sleep disorders in children – minor update to include melatonin 1mg/1ml solution (Colonis) – BLACK.</li> <li>• OPAT pathway – teicoplanin dose and monitoring confirmed with CRHFT/DCHS</li> <li>• Type 2 Diabetes guideline – p.19 dapagliflozin use in renal impairment advice corrected as per SPC. Do not initiate- GFR&lt;60ml/min.</li> </ul>	

Item		Action
	<p>Website Changes/Miscellaneous:</p> <ul style="list-style-type: none"> <li>• CKD detailing aid reviewed with no change. This resource can be found under the Clinical Guidelines front page.</li> <li>• 'Infection control contact details' document removed as the document is no longer being updated. Details can be found in the relevant local antimicrobial guidelines.</li> <li>• JAPC stakeholder map has been updated to include CCG condition specific delivery groups (CVD, diabetes, respiratory, gastroenterology).</li> </ul> <p>Guideline Timetable:</p> <ul style="list-style-type: none"> <li>• The guideline table action summary and progress was noted by JAPC.</li> </ul>	
<b>16.</b>	<b>BIOSIMILAR REPORT</b>	
	<p>Mr Dhadli advised that the use of etanercept was actively being looked at; there has been a slight upturn from 67% to 74%. Ms Brailey commented that UHDBFT would expect to see that trend continue following letters being sent to patients at the beginning of July 2019.</p>	
<b>17.</b>	<b>TRAFFIC LIGHTS – ANY CHANGES?</b>	
	<p><b>Classifications</b></p> <p>All safety needles (except GlucoRx safety needles &amp; Mylife Clickfine Autoprotect safety needles) – BLACK where the cost is &gt;£20 per 100 and GREEN 2<sup>nd</sup> line where the cost is &lt;£20 per 100.</p> <p>Fremanezumab (Ajoyv) – BLACK        Galcanezumab (Emgality) – BLACK        Prasterone (Intarosa) – BLACK        Tezacaftor + ivacaftor (Symkevi) – RED (as per NHS commissioning intentions)        Dolutegravir + lamivudine (Dovato) – RED (as per NHS commissioning intentions)        Patisiran – RED (NHS England as per NICE HST10)        Cemiplimab – RED (NHS England as per NICE TA592)        Ribociclib with fulvestrant – RED (NHS England as per NICE TA593)        Brentuximab vedotin – BLACK (as per NICE TA594)        Dacomitinib – RED (NHS England as per NICE TA595)        Risankizumab – RED (as per NICE TA596)        Dapagliflozin with insulin for treating type 1 diabetes – RED (as per NICE TA597)        Olaparib – RED (NHS England as per NICE TA598)</p>	
<b>18.</b>	<b>MINUTES OF OTHER PRESCRIBING GROUPS</b>	
	<p>Chesterfield Drugs and Therapeutic Committee 16.07.2019</p>	
<b>19.</b>	<b>ANY OTHER BUSINESS</b>	
	<p>There were no items of any other business.</p>	
<b>20.</b>	<b>DATE OF NEXT MEETING</b>	
	<p>Tuesday, 8<sup>th</sup> October 2019 at 1.30pm in the Coney Green Business Centre, Clay Cross.</p>	