

## DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 10<sup>th</sup> November 2020

### CONFIRMED MINUTES

#### Summary Points

##### Traffic lights

Drug	Decision
Semaglutide (oral)	GREY by exceptionality defined as intolerance to the preferred 1 <sup>st</sup> line choice (Lixisenatide) or restricted by their licensing and unsuitable for subcut formulation
Rosuvastatin	GREY 2 <sup>nd</sup> line treatment option for Familial Hypercholesterolemia after unsuccessful trial of atorvastatin
Alpelisib (Piqray)	RED (as per NHS England commissioning intentions)
Cefiderocol (Fetroja)	DNP await national guidance or clinician request
Remdesivir (Veklury)	RED (as per NHS England commissioning intentions)
Solriamfetol (Sunosi)	DNP await national guidance or clinician request
Trastuzumab biosimilar (Zercepac)	RED (as per NHS England commissioning intentions)
Alverine + simeticone (SimAlvia)	DNP await national guidance or clinician request
Lauromacogol 400 (Aethoxysklerol)	DNP await national guidance or clinician request
Volanesorsen	RED (NHS England as per NICE HST13)
Alpelisib	DNP (as per NICE TA652)
Osimertinib	RED (NHS England as per NICE TA653)
Osimertinib	RED (NHS England as per NICE TA654)
Nivolumab	RED (NHS England as per NICE TA655)

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

Drug	Decision
Colestyramine	GREEN specialist recommendation for Familial Hypercholesterolaemia
Co-careldopa	GREEN specialist recommendation
Vitamin D (Colecalciferol)	GREY, Strivit D3 800units capsules cost-effective choice for exceptional use for maintenance following treatment of deficiency or insufficiency in patients with osteoporosis, osteopenia or hyperparathyroidism. (Multiple classification)

#### **Clinical Guidelines**

Nebulised Colistimethate injection (Colomycin®) in Pseudomonas aeruginosa lung Infections in Adults with Bronchiectasis (non-Cystic Fibrosis)  
 Identification and Management of Familial Hypercholesterolaemia

#### **Patient Group Directions (DCHSFT)**

Medroxyprogesterone Acetate (DMPA) injection  
 Combined hormonal contraceptive transdermal patch

## Shared Care Guidelines

Azathioprine/6-mercaptopurine for patients 16+ years – partial update to add neurological conditions

<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)
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
Dr H Hill	GP
Dr R Gooch	GP
Ms J Savoury	Assistant Chief Finance Officer
<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 D Moore	Lead Pharmacist Commissioning & High Cost Medication
<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 A Braithwaite	Chief Pharmacist
<b>Derby and Derbyshire Local Medical Committee</b>	
Dr K Markus	Chief Executive Officer
<b>Derbyshire Health United</b>	
Mr D Graham	Lead Clinical Pharmacist
<b>Staffordshire and Stoke-on-Trent CCG's</b>	
Ms S Bamford	Medicines Optimisation Senior Lead Pharmacist
<b>In Attendance:</b>	
Mrs E Evans	Chief Pharmacy Technician (Interface)
Mrs K Rogers	Derby and Derbyshire CCG Senior Administrator (minutes)

Item		Action
1.	<b>APOLOGIES</b>	
	No apologies were received.	
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 OCTOBER 2020</b>	
	The minutes of the meeting held on 13 <sup>th</sup> October 2020 were agreed as a correct record.	
5.	<b>MATTERS ARISING</b>	
a.	<p><b><u>Traffic Light Classification Work Plan</u></b></p> <p>Mr Dhadli advised that in light of Black Lives Matter and the issues to address equality and diversity, JAPC has taken the decision to rename the BLACK and BROWN drug traffic light classifications to avoid any negative connotations which may be associated with these references. Under the new proposal all BLACK drugs will change to “Do Not Prescribe (DNP)” and all BROWN drugs will change to “GREY”. The Red, Green and Amber classification will remain the same.</p> <p>Communications have been drafted in readiness for sending out via the JAPC bulletin and to the Local Medical Committee (LMC), community pharmacies, GP practices etc. An update will be provided on the Derbyshire Medicines Management website with a clear explanation in regards to the change in references for the traffic light classifications.</p> <p>Mr Dhadli confirmed that this work will need to be carried out in 2 phases; users will see an immediate changeover to the new nomenclature of Grey and DNP in the traffic light section of the Derbyshire Medicines Management website during phase 1. Following this, BNF chapters, clinical and non-clinical guidelines will gradually be transitioned over in phase 2. The Clinical Policies and Decisions team are planning to complete phase 1 by the end of November 2020 and phase 2 by 31st March 2021.</p> <p>Due to the size of this task it is not practical to amend previously published communication; these include previous JAPC minutes, JAPC bulletins, JAPC Annual Reports and Medicines Management Newsletters.</p> <p>JAPC were in agreement with the draft statement and the communications plan. The timescales for completing this work were acknowledged subject to competing interests that may be incurred during this time.</p> <p>Mr Dhadli highlighted that practice clinical system formularies will need to be updated and there may be a slight misalignment during the transition period.</p> <p>The University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) and Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) will update their formularies accordingly. Ms Braithwaite confirmed that</p>	

Item		Action
	<p>Derbyshire Community Health Services NHS Foundation Trust (DCHSFT) only refer to the traffic light classifications via the Derbyshire Medicines Management website, therefore no direct change within DCHSFT will be needed.</p> <p>It was noted that neighbouring CCG's and trusts should also be informed of this change.</p>	<b>SD</b>
<b>6.</b>	<b>JAPC ACTION SUMMARY</b>	
<b>a.</b>	The action summary was noted by JAPC, there were no new or current outstanding items.	
<b>7.</b>	<b>NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION</b>	
<b>a.</b>	<p><b><u>Rybelsus (oral semaglutide)</u></b></p> <p>Mr Dhadli reported that Rybelsus (oral semaglutide) is a new oral GLP-1 formulation which is now available. UHDBFT and CRHFT consultants support the proposal for oral semaglutide to be added to the Derbyshire formulary. It has a licensed indication for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as monotherapy when metformin is inappropriate (intolerance or contraindications) or in combination with other medicinal products for the treatment of diabetes. The latter licensing of combination therapy is in line with the local diabetes guideline. The oral preparation is taken daily, 3mg for 1 month which is then increased to 7mg with a maximum dose of up to 14mg. It must be taken on an empty stomach; at least 30 minutes before eating/drinking/taking other oral medications. No dose adjustment is necessary in the elderly or renal/hepatic impairment patients. The adverse effects are gastrointestinal disorders including nausea, diarrhoea and vomiting which are all common.</p> <p>Evidence on efficacy has been taken from 8 pivotal trials published in 2019 comparing oral semaglutide with placebo or active control (empagliflozin, sitagliptin, liraglutide). Results showed superiority or non-inferiority in outcomes such as HbA1c reduction and weight loss. In the PIONEER 6 trial, results suggested that oral semaglutide may reduce the risk of adverse cardiovascular events compared with placebo, but the difference was not statistically significant. In the US, a draft report from the Institute for Clinical and Economic Review (ICER) concluded that oral semaglutide plus background therapy would underperform the SGLT-2 inhibitor, empagliflozin, in cost effectiveness, as measured by quality-adjusted life years gained. ICER evaluation of clinical trial data for oral semaglutide vs empagliflozin, liraglutide, and sitagliptin concluded that oral semaglutide provided incremental benefit in preventing MACE but that MACE prevention is only part of the treatment puzzle and other treatments may provide better overall benefit and at lower cost.</p> <p>Specialist Pharmacy Service (SPS) reviewed the SUSTAIN-6 trial which demonstrated cardiovascular safety. The lower cardiovascular risk with semaglutide was principally driven by a statistically significant decrease in the rate of non-fatal stroke and a non-significant decrease in non-fatal MI. There was no significant difference in the rate of cardiovascular death. Overall NICE concluded that this trial provided inconclusive evidence of the cardiovascular benefits of semaglutide. The ADA/EASD conclude that the evidence of cardiovascular benefit is favourable, although acknowledge that the reduction</p>	

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	<p>in events is driven by the reduction in the rate of stroke. Treatment with a GLP-1 is recommended as per NICE NG or local guidance only after other treatment options have been considered. Criteria for initiating and continuation of treatment must also be met. Currently Lixisenatide is 1<sup>st</sup> line choice in Derbyshire based on choice and cost effectiveness.</p> <p>The Scottish Medicines Consortium (SMC) previously reviewed semaglutide and the sub-cut (SC) injection (Ozempic) was accepted. Oral semaglutide (Rybelsus) has also been accepted, as there is no cost increase per day for using this over the semaglutide SC injection; however the effect of switching between oral and SC semaglutide cannot easily be predicted because of high pharmacokinetic variability of oral semaglutide. Clinical effectiveness should be considered when making switching decisions between formulations.</p> <p>There has also been a Northern (NHS) Treatment Advisory Group review which showed that oral semaglutide was generally associated with greater reductions in HbA1c, body weight and fasting plasma glucose than comparators (placebo, sitagliptin, empagliflozin, and liraglutide), but these are surrogate outcomes. Comparative effectiveness of oral semaglutide has not been established against all available competitors.</p> <p>Consultant endocrinologist feedback from CRHFT noted that during the COVID-19 pandemic, initiation may be done over the phone to reduce unnecessary physical contact; however it may not be possible to demonstrate to a patient how a GLP1 should be used.</p> <p>There do not appear to be any formal assessments carried out by neighbouring CCG's and it has not been added to their local formulary. Financial data shows that oral semaglutide is comparable in cost to weekly GLP-1 SC injections, however this also compares with other oral antidiabetic products included within the Derbyshire formulary i.e. metformin, gliclazide, pioglitazone, alogliptin and empagliflozin which are more cost effective.</p> <p>A discussion took place and JAPC agreed a classification of GREY however the committee acknowledged the need to monitor prescribing trends to ensure it is used in line with the diabetes guidance.</p> <p><b>Agreed:</b> JAPC classified Rybelsus (oral semaglutide) once daily oral preparation as <b>GREY</b> by exceptionality defined as intolerance to the preferred 1st line choice (Lixisenatide) or restricted by their licensing and unsuitable for subcut formulation.</p>	<b>SD</b>
<b>8.</b>	<b>CLINICAL GUIDELINES</b>	
<b>a.</b>	<p><b><u>Nebulised Colomycin</u></b></p> <p>Mr Dhadli advised that there has been an update to the Nebulised Colomycin guideline following a routine review. The guideline was sent to respiratory consultants/specialists at both UHDBFT and CRHFT, following comments received the key contact information and reference has been updated. Nebuliser equipment Ventstream has been replaced by Side Stream Plus.</p> <p><b>Agreed:</b> JAPC ratified the Use of nebulised Colistimethate injection (Colomycin®) in <i>Pseudomonas aeruginosa</i> lung Infections in Adults with Bronchiectasis (non-Cystic Fibrosis) guideline, with a review date of 3 years.</p>	<b>SD</b>

Item		Action
b.	<p><b><u>Lipid Modification Familial Hypercholesterolaemia (FH)</u></b></p> <p>Mr Dhadli reported that the lipid modification FH guideline has been updated following a routine review. Comments were received from consultants at both Sheffield Teaching Hospitals NHS Foundation Trust and UHDBFT. Previously the recommendation in the guideline advised to start with atorvastatin 10mg. NICE guidance recommends offering a high intensity statin, defined as reduction in LDL cholesterol above 40% (which can be achieved by atorvastatin 20mg, simvastatin 80mg or rosuvastatin 10mg). Following feedback from consultants, the local guideline has been amended to recommend 20mg atorvastatin, with the option to use 10mg as a way of titrating up dosage to reduce adverse effects.</p> <p>During the review it was highlighted by consultant feedback and the Derbyshire Medicines Management Shared Care and Guideline Group (MMSCGG) that the cost of rosuvastatin 10mg has decreased and it is now more cost effective than simvastatin 80mg. JAPC agreed that rosuvastatin should be re-classified as GREY 2<sup>nd</sup> line for familial hypercholesterolemia, as an alternative option after atorvastatin. Use of rosuvastatin will be reviewed within the lipid guideline non FH.</p> <p><b>Agreed:</b> JAPC classified rosuvastatin as <b>GREY 2<sup>nd</sup> line for familial hypercholesterolemia</b>, after unsuccessful trial of atorvastatin.</p> <p><b>Agreed:</b> JAPC ratified the Identification and Management of Familial Hypercholesterolaemia with a review date of 3 years.</p>	<p>SD</p> <p>SD</p>
9.	<b>PATIENT GROUP DIRECTIONS</b>	
a.	<p><b><u>Medroxyprogesterone Acetate (DMPA) injection PGD and Combined hormonal contraceptive transdermal patch PGD</u></b></p> <p>Mr Dhadli and Ms Braithwaite advised that the Medroxyprogesterone Acetate injection PGD and the Combined hormonal contraceptive transdermal patch PGD are both based on a national template and have been approved and signed off by DCHSFT. DCHSFT are the host organisation for community pharmacies and their PGD's are hosted on the Derbyshire Medicines Management website to enable community pharmacies to have access to them.</p> <p>They have been tabled at the JAPC meeting for information only and will be uploaded to the Derbyshire Medicines Management website following the meeting.</p>	SD
10.	<b>SHARED CARE</b>	
a.	<p><b><u>Azathioprine/6-mercaptopurine and Methotrexate</u></b></p> <p>Mr Dhadli reported that there has been a request from UHDBFT to add neurological conditions to the azathioprine and methotrexate shared care agreements. The autoimmune neurological conditions covered by this agreement can be broadly split into four major categories:</p> <ul style="list-style-type: none"> <li>• Neuromuscular junction disorders – most commonly myasthenia gravis, although can be paraneoplastic (such as Lambert-Eaton myasthenic syndrome). This is referenced in British Neurologists management guideline, 2015, which recommends Azathioprine as 1<sup>st</sup> line for myasthenic syndrome. Other agents include mycophenolate, MTX, ciclosporin or rituximab.</li> </ul>	

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	<ul style="list-style-type: none"> <li>• Inflammatory neuropathies – most commonly chronic inflammatory demyelinating polyneuropathy (CIDP). This is referenced in the European Federation of Neurological Societies (EFNS) task force. Randomized controlled trials have been reported only for azathioprine and methotrexate. Azathioprine (2mg/kg) showed no benefit when added to prednisone in 14 patients for 9 months, but the trial was probably too short and the dose too low to be able to show a benefit.</li> <li>• A subset of central nervous system inflammatory diseases – referenced from the Neuromyelitis Optica Study Group. Azathioprine and rituximab are suggested as first line treatments, the latter being increasingly regarded as an established therapy with long-term efficacy and an acceptable safety profile in NMO patients. Other immunosuppressive drugs, such as methotrexate, mycophenolate mofetil and mitoxantrone, are recommended as second-line treatments.</li> <li>• Autoimmune encephalitis – treatment with azathioprine and mycophenolate mofetil are among those recommended by international experts (Dalmau J, Lancaster E, Martinez-Hernandez E, Rosenfeld MR, Balice-Gordon R. These agents are already approved for the use in neurological conditions in other neighbouring CCG's for azathioprine only and not methotrexate. Patient numbers within Derbyshire are predicted to be small and consistent. A discussion took place and the committee concluded that the indications would be added to the azathioprine shared care agreement; however they would not be added to the methotrexate shared care agreement due to little demand.</li> </ul> <p><b>Agreed:</b> JAPC ratified the partial update to add neurological conditions to Azathioprine/6-mercaptopurine for patients 16+ years</p>	<b>SD</b>
<b>11.</b>	<b>MISCELLANEOUS</b>	
<p><b>a.</b></p> <p><b>b.</b></p> <p><b>c.</b></p>	<p><b><u>Guideline Group Terms of Reference (ToR)</u></b>          Mr Dhadli informed the committee that the MMSCGG Terms of Reference has been routinely reviewed and tabled for information as there are no changes to this.</p> <p><b><u>JAPC Terms of Reference (ToR)</u></b>          Mr Dhadli advised that the JAPC Terms of Reference has been routinely reviewed and there are a couple of additions to note.          There are currently interim arrangements within the ToR which are in place during the COVID-19 pandemic, these have been previously agreed. Information in regards to chairmanship has been added to page 4, along with administrative support, agenda setting and information as to when papers are usually circulated.          The committee were in agreement with these additions.</p> <p><b><u>Name of JAPC members</u></b>          Mr Dhadli stated that the named JAPC members' paper has been reviewed and updated. This includes details of committee members who attend JAPC and their named deputies.          Healthwatch Derbyshire has an open invite to JAPC meetings; they have been contacted to confirm that they are still happy with these arrangements.</p>	<b>SD</b>

Item		Action
	It was noted that there is a short term gap in regards to representation from Public Health due to reduced capacity during the COVID-19 pandemic.	SD
<b>12.</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 October 2020 was noted.</p> <p>Mr Dhadli highlighted the following:</p> <p>Traffic Lights:</p> <ul style="list-style-type: none"> <li>• Colestyramine – reclassified as GREEN specialist recommendation from GREEN for Familial Hypercholesterolaemia</li> <li>• Co-careldopa – reclassified as GREEN specialist recommendation, DNP removed due to cost effectiveness</li> <li>• Vitamin D (Colecalciferol) – addition of GREY, Strivit D3 800units capsules cost-effective choice for exceptional use for maintenance following treatment of deficiency or insufficiency in patients with osteoporosis, osteopenia or hyperparathyroidism. (Multiple classification)</li> </ul> <p>Formulary Update (Chapter 12 – Ear, Nose and Oropharynx):</p> <ul style="list-style-type: none"> <li>• Message regarding variation for nystatin dosage removed as no longer relevant.</li> </ul> <p>Clinical Guidelines:</p> <ul style="list-style-type: none"> <li>• NOAC for suspected DVT – JAPC guideline removed. Wells score criteria and detailed NOAC prescribing information have been incorporated within the Derbyshire Shared Care Pathology (SCP) Primary Care Management of Suspected DVT guideline. The SCP guideline has been recently updated following NICE NG158 to clearly direct referrals/set out initial treatments for suspected DVT.</li> </ul> <p>Website Changes/Miscellaneous:</p> <ul style="list-style-type: none"> <li>• Medicines Management in Care Homes: Best Practice Guidance for GP Practices, Community Pharmacists and Care Home Providers updated with no major change. Links to further guidance and references updated.</li> <li>• Expiry dates of medication within community care setting – table with medication and recommend expiry dates simplified and updated as per latest guidance.</li> <li>• Three patient booklets under CV other information have been reviewed and agreed no update required.             <ul style="list-style-type: none"> <li>○ Atrial Fibrillation (AF) patient information booklet</li> <li>○ Lowering cholesterol to reduce the risk of coronary heart disease and stroke</li> <li>○ Non-vitamin K Antagonist Oral Anticoagulation (NOAC) patient information booklet</li> </ul> </li> <li>• MHRA drug safety advice September 2020 added to             <ul style="list-style-type: none"> <li>○ Formulary CNS chapter and non-malignant chronic pain guideline – opioids risk of addiction and fentanyl patch C/I in opioid naïve patients.</li> <li>○ Formulary endocrine chapter &amp; type 2 diabetes guideline – advice on insulin risk of cutaneous amyloidosis at injections site.</li> <li>○ Formulary MSK chapter and methotrexate SCG – Methotrexate once weekly: new measures to reduce risk of fatal overdose.</li> </ul> </li> </ul>	



Item		Action
	<ul style="list-style-type: none"> <li>QIPP delivery group has recommended that Questran Light is the cost-effective brand for colestyramine sugar free preparation.</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>13.</b>	<b>JAPC BULLETIN</b>	
	The October 2020 bulletin was ratified pending inclusion of information regarding changes to the traffic light classifications.	<b>SQ</b>
<b>14.</b>	<b>MHRA DRUG SAFETY UPDATE</b>	
	<p>The MHRA Drug Safety Alert for July 2020 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice, mostly relating to secondary care with the exception of warfarin:</p> <ul style="list-style-type: none"> <li>5-fluorouracil (intravenous), capecitabine, tegafur: DPD testing recommended before initiation to identify patients at increased risk of severe and fatal toxicity. Patients with complete or partial dihydropyrimidine dehydrogenase (DPD) deficiency are at increased risk of severe and fatal toxicity during treatment with medicines containing 5-fluorouracil (intravenous), capecitabine, and tegafur. All patients should be tested for DPD deficiency before initiation to minimise the risk of these reactions.</li> <li>Flucytosine (Ancotil): new contraindication in patients with DPD deficiency. Flucytosine is a prodrug of 5-fluorouracil used to treat systemic yeast and fungal infections and can cause life-threatening and severe toxicity in patients with complete and partial dihydropyrimidine dehydrogenase (DPD) deficiency. Although pre-testing of DPD status before flucytosine treatment is not required, a new contraindication for patients with complete DPD deficiency has been introduced.</li> <li>Niraparib (Zejula▼): reports of severe hypertension and posterior reversible encephalopathy syndrome (PRES), particularly in early treatment. There have been reports of severe hypertension (including rare cases of hypertensive crisis) with niraparib, including some with onset in the first month of treatment. Rare cases of posterior reversible encephalopathy syndrome (PRES) have also been reported, many associated with hypertension and within the first month of treatment. Increase the frequency of blood pressure monitoring to at least weekly for the first 2 months, and then monitor monthly for the first year and periodically thereafter during treatment.</li> <li>Dolutegravir (Tivicay▼, Triumeq▼, Juluca▼): updated advice on increased risk of neural tube defects. Updated safety recommendations have been issued as part of the European review evaluating cases of neural tube defects in babies born to mothers who became pregnant while taking the HIV medicine dolutegravir. Evidence collected as more women have given birth while on dolutegravir treatment shows a smaller increased risk than previously thought, almost comparable to other HIV drugs. The previous restrictions against use in pregnancy are no longer in place – inform women of the potential risk of</li> </ul>	

Item		Action
	<p>neural tube defects with dolutegravir and discuss the benefits and risks of continuing treatment if a woman plans pregnancy.</p> <ul style="list-style-type: none"> <li>• Warfarin and other anticoagulants: monitoring of patients during the COVID-19 pandemic.</li> </ul> <p>Following concerns raised by clinicians during the COVID-19 pandemic, MHRA have issued advice to healthcare professionals and patients regarding the safe use of warfarin and other anticoagulants.</p> <ul style="list-style-type: none"> <li>○ acute illness may exaggerate the effect of warfarin and necessitate a dose reduction; patients on warfarin or other vitamin K antagonists should therefore be asked to tell their GP or healthcare team if they have symptoms of, or confirmed, COVID-19 infection</li> <li>○ continued INR (international normalised ratio) monitoring is important in patients taking warfarin or other vitamin K antagonists if they have suspected or confirmed COVID-19 infection, so they can be clinically managed at an early stage to reduce the risk of bleeding</li> <li>○ both vitamin K antagonists and direct-acting oral anticoagulants (DOACs) may interact with other medicines, follow advice in the product information</li> <li>○ if patients are switched from warfarin to a DOAC, warfarin treatment should be stopped before the DOACs is started to reduce the risk of over-anticoagulation and bleeding</li> <li>○ patients taking vitamin K antagonists should be reminded to carefully follow the instructions for use for anticoagulant medicines and to contact their GP/healthcare team if there is any change to their health, medication or scheduled blood tests</li> </ul>	
15.	<b>HORIZON SCAN</b>	
a.	<p><b><u>Monthly Horizon Scan</u></b></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"> <li>• Alpelisib (Piqray) – classified as <b>RED</b> (as per NHS England commissioning intentions)</li> <li>• Cefiderocol (Fetroja) – classified as <b>DNP</b> await national guidance or clinician request</li> <li>• Remdesivir (Veklury) – classified as <b>RED</b> (as per NHS England commissioning intentions)</li> <li>• Solriamfetol (Sunosi) – classified as <b>DNP</b> await national guidance or clinician request</li> <li>• Trastuzumab biosimilar (Zercepac) – 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>• Alverine + simeticone (SimAlvia) – classified as <b>DNP</b> await national guidance or clinician request</li> <li>• Lauromacogol 400 (Aethoxysklerol) – classified as <b>DNP</b> await national guidance or clinician request</li> </ul> <p>Licence extensions:</p> <ul style="list-style-type: none"> <li>• Durvalumab (Imfinzi) – previously classified as <b>RED</b></li> </ul>	

Item		Action
	<ul style="list-style-type: none"> <li>• Ibrutinib (Imbruvica) – previously classified as <b>DNP/RED</b></li> <li>• Lurasidone (Latuda) – previously classified as <b>DNP</b></li> </ul> <p>Drug discontinuations:</p> <ul style="list-style-type: none"> <li>• Anthelios XL SPF 50+ Cream</li> <li>• AYMES Acusist Clear</li> <li>• Cefradine Syrup</li> <li>• Cilodex (Dexamethasone/ciprofloxacin)</li> <li>• Co-fluampcil oral suspension</li> <li>• Delytba (Delamanid)</li> <li>• Depocyte (Cytarabine)</li> <li>• Fenactol (Diclofenac)</li> <li>• Fenistil (Penciclovir)</li> <li>• Nardil (Phenelzine)</li> <li>• Orgran</li> <li>• Paramax Sachets (Paracetamol/metoclopramide)</li> <li>• Parlodel (Bromocriptine)</li> <li>• Sporanox IV (Itraconazole)</li> <li>• Tagamet (Cimetidine)</li> <li>• Tarivid Infusion (Ofloxacin)</li> <li>• Zantac Injection (Ranitidine)</li> <li>• Zantac Syrup (Ranitidine)</li> </ul>	
16.	<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 October 2020:</p> <p>HST13 Volanesorsen for treating familial chylomicronaemia syndrome – classified as <b>RED</b> (NHS England as per NICE HST13)</p> <p>TA652 Alpelisib with fulvestrant for treating hormone-receptor positive, HER2-negative, PIK3CA-positive advanced breast cancer (terminated appraisal) – classified as <b>DNP</b> (as per NICE TA652)</p> <p>TA653 Osimertinib for treating EGFR T790M mutationpositive advanced non-smallcell lung cancer – classified as <b>RED</b> (NHS England as per NICE TA653)</p> <p>TA654 Osimertinib for untreated EGFR mutation-positive nonsmall-cell lung cancer – classified as <b>RED</b> (NHS England as per NICE TA654)</p> <p>TA655 Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy – classified as <b>RED</b> (NHS England as per NICE TA655)</p> <p>NG100 – Rheumatoid arthritis in adults: management updated to include 1.2.1 Treat active RA in adults with the aim of achieving a target of remission or low disease activity if remission cannot be achieved (treat-to-target). Achieving the target may involve trying multiple conventional disease-modifying antirheumatic drugs (cDMARDs) and biological DMARDs with different mechanisms of action, one after the other. [2018, amended 2020]</p>	

Item		Action
<b>17.</b>	<b>MINUTES OF OTHER PRESCRIBING GROUPS</b>	
a.	<ul style="list-style-type: none"> <li>• Chesterfield Drugs and Therapeutics Committee 15/09/2020</li> <li>• Medication Optimisation Safety Team 03/09/2020</li> <li>• Sheffield Area Prescribing Group 16/07/2020</li> </ul>	
<b>18.</b>	<b>TRAFFIC LIGHTS – ANY CHANGES?</b>	
	<p><b><u>Classifications</u></b>            Semaglutide (oral) – GREY by exceptionality defined as intolerance to the preferred 1<sup>st</sup> line choice (Lixisenatide) or restricted by their licensing and unsuitable for subcut formulation            Rosuvastatin – GREY 2<sup>nd</sup> line treatment option for Familial Hypercholesterolemia, after unsuccessful trial of atorvastatin            Alpelisib (Piqray) – RED (as per NHS England commissioning intentions)            Cefiderocol (Fetroja) – DNP await national guidance or clinician request            Remdesivir (Veklury) – RED (as per NHS England commissioning intentions)            Solriamfetol (Sunosi) – DNP await national guidance or clinician request            Trastuzumab biosimilar (Zercepac) – RED (as per NHS England commissioning intentions)            Alverine + simeticone (SimAlvia) – DNP await national guidance or clinician request            Lauromacogol 400 (Aethoxysklerol) – DNP await national guidance or clinician request            Volanesorsen – RED (NHS England as per NICE HST13)            Alpelisib – DNP (as per NICE TA652)            Osimertinib – RED (NHS England as per NICE TA653)            Osimertinib – RED (NHS England as per NICE TA654)            Nivolumab – RED (NHS England as per NICE TA655)</p>	
<b>19.</b>	<b>ANY OTHER BUSINESS</b>	
a.	<p><b><u>FreeStyle Libre</u></b>            Mr Dhadli informed the committee that as of 1<sup>st</sup> November 2020, FreeStyle Libre 2 is available in the drug tariff. FreeStyle Libre 2 is marketed at the same price as the original FreeStyle Libre. New and existing patients could transition over to FreeStyle Libre 2 within the next 12 months, Abbot are currently working on training and support material.            Originally, prescribing of Flash Glucose monitoring systems was restricted to selected patients with Type 1 diabetes; however NHS England has recently added a new indication for the use of FreeStyle Libre. It can now be offered to all patients with a learning disability and diabetes and on the GP register, who use insulin to manage their condition.            This guidance has been issued because there was a recommendation specific to diabetes from the Learning Disabilities Mortality Review (LeDeR) programme in 2019. The report concluded that a third of deaths of people with a learning disability were shown to have been due to treatable causes, compared with 8% in the general population. It related to appropriate provision of support for people with diabetes, particularly in community settings, however the recommendation did not refer to Freestyle Libre or flash meters specifically.            The Association of British Clinical Diabetologists (ABCD) published a Nationwide Audit in September 2020. Data showed that 97% of users with</p>	

Item		Action
b.	<p>type 1 diabetes demonstrated a reduction in HBA1c and hypoglycaemic control, which results in reduced ambulance call out and hospital admissions. NHS England has identified additional funding to support the initiative until 31 March 2021, at which point responsibility for Flash Glucose monitoring will revert to CCGs.</p> <p>A discussion took place and it was identified that there are approximately 150 - 200 patients across Derbyshire that may meet the criteria for this.</p> <p>It was noted that information in regards to the new indication for the use of FreeStyle Libre 2 had not been communicated to DDCCG very effectively, Mr Dhadli has written to SPS and the Regional Medicines Optimisation Committee (RMOOC) to express his concerns.</p> <p>Mr Hulme highlighted that there is limited evidence base surrounding FreeStyle Libre 2. The committee also considered whether other available Flash Glucose Meters should be explored and agreed to review this along with FreeStyle Libre 2.</p> <p>It was confirmed that the Derbyshire FreeStyle Libre briefing document will be updated to include further information in regards to frequency of monitoring and learning disability patients as an eligibility criteria, as per NHSE/I document. It will then be shared with UHDBFT and CRHFT specialists for comment and brought back to the December 2020 JAPC meeting. Secondary care clinicians will be informed of this decision immediately.</p> <p><b><u>JAPC meeting dates 2021</u></b>            The JAPC meeting dates for 2021 were tabled for information.</p>	<p>SD</p> <p>SD</p>
20.	<b>DATE OF NEXT MEETING</b>	
	Tuesday, 8 <sup>th</sup> December 2020 at 1.30pm to be held virtually via Microsoft Teams.	