DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 12th December 2023

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Empagliflozin	GREEN specialist recommendation - NICE TA929: Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction
Cabozantinib	DNP - NICE TA928: Cabozantinib for previously treated advanced differentiated thyroid cancer unsuitable for or refractory to radioactive iodine- Not recommended.
Lutetium-177 vipivotide tetraxetan	DNP - NICE TA930: Lutetium-177 vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more treatments- Not recommended
Zanubrutinib	RED - NICE TA931: Zanubrutinib for treating chronic lymphocytic leukaemia. NHSE commissioned
Decitabine–cedazuridine	DNP - NICE TA932: Decitabine–cedazuridine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable. Terminated appraisal
Tisagenlecleucel	DNP - NICE TA933: Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies. Terminated appraisal, replaces NICE TA567
Foslevodopa–foscarbidopa	RED - NICE TA934: Foslevodopa–foscarbidopa for treating advanced Parkinson's with motor symptoms. NHSE commissioned
Idecabtagene vicleucel	DNP - TA936: Idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments
Atogepant (Aquipta)	Do Not Prescribe - await national guidance. ICB commissioned High-Cost Drug.
Copper histidinate	RED - SSC2577: Subcutaneous copper histidinate injections for presymptomatic neonates with classical Menkes disease as per NHSE commissioning intentions
Obinutuzumab	RED - SSC2579: Obinutuzumab elective therapy to prevent immune Thrombotic Thrombocytopenic Purpura (TTP) relapse in patients who are refractory or intolerant to rituximab (adults) as per NHSE commissioning intentions
Durvalumab with gemcitabine and cisplatin	RED - SSC2583: Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer as per NHSE commissioning intentions

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Simvastatin	Update from GREEN to GREY for use in those established on treatment or unable to tolerate atorvastatin/ rosuvastatin
Pravastatin	Update from GREEN to GREY for use in those established on treatment or unable to tolerate atorvastatin/ rosuvastatin
Dapagliflozin	Update from GREEN specialist initiation to GREEN specialist recommendation for treating chronic heart failure with preserved or mildly reduced ejection fraction as per NICE TA902

New Drug Assessment
Sodium zirconium cyclosilicate

Clinical Guidelines
Undernutrition in adults

PGD
Vitamin K

Present:	
Derby and Derbyshire ICB	
Dr R Gooch	GP (Chair)
Mr S Dhadli	Assistant Director of Clinical Policies and Decisions (Professional Secretary)
Mrs A Thai	Head of Medicines Management, Clinical Policies and High-Cost Interventions
Mr S Hulme	Director of Medicines Management & Clinical Policies
Dr R Dils	GP Clinical Lead, Moss Valley Medical Practice
Dr J Burton	GP Prescribing Lead, Hannage Brook Medical Centre
Dr A Mott	GP Prescribing Lead, Jessop Medical Practice Clinical Director of ARCH Primary Care Network
Mr R Coates	Finance Manager *(part attendee)*
Public Health England	
Ms K Webster	Registrar in Public Health
University Hospitals of Derby and Burton NHS Foundation Trust	
Mr D Moore	Deputy Chief Pharmacist Clinical Services & ePMA
Miss S Fatima	Advanced Pharmacist Renal Services *(Item 6a only)*
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mrs G Gough	Chief Pharmacist
Dr J Russell	Consultant Geriatrician
Derbyshire Community Health Services NHS Foundation Trust	
Mrs K Needham	Chief Pharmacist
Staffordshire and Stoke-on-Trent ICB's	
Ms S Bamford	Medicines Optimisation Senior Lead Pharmacist
In Attendance:	
Miss M Hill	Senior Pharmacy Technician High-Cost Interventions, DDICB (minutes)
Mrs E Evans	Chief Pharmacy Technician (Interface), UHDB/DDICB
Mr A Statham	Senior Medicines Optimisation Pharmacist, DDICB

Item		Action
1.	**APOLOGIES**	
	A Reid, E Kirk, H Hill	
2.	**DECLARATIONS OF CONFLICTS OF INTEREST**	
	Dr Gooch 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. One conflict of interest was declared in relation to this agenda prior to the meeting. The Chair investigated the professional conflict and it does not affect decisions made in today's meeting.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	Mr Dhadli raised two declarations of any other business: Attention Deficit Hyperactivity Disorder (ADHD) medication shortages briefing update and the National Patient Safety Alert for potential contamination of some carbomer-containing lubricating eye.	
4.	**JAPC BULLETIN**	
	The November 2023 bulletin was ratified.	
5.	**JAPC ACTION SUMMARY**	
a.	**Ranibizumab biosimilar** UHDBFT and CRHFT are required to report cumulative figures for ranibizumab biosimilar uptake. CRHFT has provided the ICB with their first cumulative figures this month. UHDBFT are looking to remove Lucentis as a stock option and complete the full switch to the biosimilar Ongavia.	
b.	**Penicillamine** Rheumatology, hepatology and renal specialities use is expected of this drug. The specialties at the acute trust have been tasked to review the penicillamine shared care noting the absence of national shared care protocol.	
c.	**Liothyronine** To be discussed at JAPC February actual meeting with Drugs and Therapeutics Committee involvement.	
6.	**NEW DRUG ASSESSMENT**	
a.	**<u>Sodium zirconium cyclosilicate</u>** Mr Dhadli advised the committee that this is a planned review following initial discussion in August 2022 JAPC and the interim recommendation to remain RED to gain more experience for using the treatment by the specialists. Sodium zirconium cyclosilicate is a non-absorbed cation-exchange compound that acts as a selective potassium binder in the GI tract and allows patients to stay on renin-angiotensin-aldosterone system (RAAS) inhibitor for longer. Mr Dhadli informed the committee NICE TA599 Sodium zirconium cyclosilicate is recommended as an option for treating hyperkalaemia in adults only if used in emergency care for acute life-threatening hyperkalaemia alongside standard care; or for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if	

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	they have a confirmed serum potassium level of at least 6.0 mmol/litre and, because of hyperkalaemia, are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor and are not on dialysis. NICE TA623 Patiromer shares the same NICE TA criteria but is used less frequently, interacts with more commonly used medications, and is more expensive thus has not been included in this application and will remain within secondary care. Mr Dhadli informed the committee that UHDB renal and cardiology department has been using the treatment successfully with approximately 50 patient being treated in the first year between renal and cardiology teams. Close monitoring of U&E is required during the titration phase which is done by the specialists. Following titration the monitoring is usually at 6 monthly interval and the proposal is for GP to continue prescribing. A prescribing and monitoring guidance has been produced to facilitate continuing management in primary care. JAPC members raised concerns around the safety of the monitoring required in primary care. GPs are required to stop treatment and contact the specialist for advice when potassium levels are <3.6mmol/L; and give half dose and repeat U&E after 1 week when potassium levels are <4.0mmol/L. These levels of potassium fall within normal potassium range therefore will not routinely be flagged as requiring action in primary care. This leads to significant risk of the action being missed and potential patient harm. GPs also questioned the benefit of changing the prescribing and monitoring to primary care when these patients continue to attend regular specialist follow-ups. Due to the issues raised, JAPC recommends sodium zirconium cyclosilicate to stay as RED and to review again with a view to change to GREEN specialist initiation or as a shared care agreement in the future. **Agreed:** JAPC agreed to keep as RED for the treatment of hyperkalaemia in adults. **Action:** Remove from JAPC Action Tracker. UHDBFT to bring back following further experience of use, with a view to change to GREEN specialist initiation or as a shared care agreement.	**CPD UHDBFT**
7.	**CLINICAL GUIDELINES**	
a.	**<u>Undernutrition in adults</u>** Mr Dhadli informed the committee the undernutrition in adults guideline has been updated as per the routine review and has undergone consultation with dieticians at UHDBFT and CRHFT. The aim of the guideline is to ensure effective patient centred oral nutrition support in Derbyshire by promoting a fortified diet and appropriate, effective prescribing or oral nutritional supplement (ONS). Minor updates to the guideline include appendix 2 and 3 Big Nutrition for Small Appetites patient information leaflet updated to include high calories drinks information and QR code for food fortification video, and to include lactose/dairy free/ vegan diets. Appendix 4 and 5 ONS Products information and prices has also been updated. **Agreed:** JAPC approved the undernutrition in adults guideline with a 3-year expiry.	

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8.	**PATIENT GROUP DIRECTION**	
a.	**Phytomenadione (Vitamin K)** Mr Dhadli reminded the committee the need for an ongoing vitamin K PGD in Derbyshire was previously discussed at JAPC in October 2023. The PGD is used by nurse/ pharmacist working under anticoagulant management service in primary care. The current PGD was further extended to April 2024 under exceptional circumstance to avoid service disruption and to clarify signatories required for authorisation to meet legal requirement. Mr Dhadli informed the committee the existing PGD has been reviewed by the PGD working group which consist of a doctor, pharmacists and nurse working under the PGD, and also agreed at Guideline Group. Main updates include clarifying inclusion criteria to be INR equal or greater than 8.0 (aligns to Derbyshire primary care anticoagulation management service specification) and removing repeat dosing under PGD. Other minor updates include removing duplicated content from 'qualification' section, updating initial training section with up-to-date guidance, criteria for inclusion/ exclusion, off-label use, and records section aligned to UHDB vitamin K PGDs, clarifying preparation used (phytomenadione 2mg/0.2ml solution for injection ampoules), and updating references. An application for PGD reauthorisation has been completed as per DDICB PGD development and review process. **Agreed:** JAPC approved the vitamin K PGD with a 3-year expiry.	
9.	**MISCELLANEOUS**	
a.	**Prescribing Specification 2024/25** Mr Dhadli informed the committee the prescribing specification is part of the healthcare services contract commissioners (ICB) has with provider organisations. This document outlines the role and responsibilities of our provider trusts in ensuring a transparent and collaborative approach to the safe and effective management of medicines, seamless care of patients between NHS organisations and ensuring high quality prescribing. Changes include JAPC agreed principles in 2023 for formulary process for the planned introduction of new and existing drugs into the Derbyshire ICB formulary, in the appropriate clinical setting and process for introducing shared care agreements, Trusts with the ICB will undertake an active annual will horizon scan to agree a plan for appropriate clinical setting and highlight to JAPC financial implications and the ICB and providers will work collaboratively to plan and horizon scan biosimilars where there are savings to the ICS, engaging with clinicians and directorates as appropriate. A statement has been included in the prescribing specification that the ICB has commissioning pathways for High-Cost Drugs excluded from tariff and drug options are listed in order of best value. Providers are to follow these commissioned pathways, however exceptions to this should be escalated to the ICB, which may include capacity issues within a service. Mr. Dhadli asked for comments from the committee and the provider trusts. **Agreed:** To bring back to the next JAPC meeting for agreement.	

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b.	**Horizon Scan 2024/25** Mrs Thai informed the committee the Specialist Pharmacy Service (SPS) Prescribing Outlook has published the 2024-2025 horizon scan document. This includes new medicines for 2024-25 supports managed entry and budget planning for new medicines, new indications, and patent expiries in the NHS. Mrs Thai summarised the information available from the prescribing outlook and presented three papers; Primary care drugs (including initiation and continuation) or Secondary care led drugs (to be prescribed in a secondary care setting), and ICB commissioned High-Cost Drugs (HCD) which are commissioned by ICB (currently under block arrangements). High impact items for primary care and HCD were highlighted. **Agreed:** To set up a working group across the Derbyshire system who will review collaboratively to inform impacts to primary and secondary care.	
c.	**Specialised circulars** Mr Dhadli advised that the specialised circulars has been tabled for information and are available upon request.	
d.	**Anastrozole for primary prevention of breast cancer** Specialised circular SSC2582: Licensing of anastrozole for primary prevention of breast cancer was received in November 2023. The NICE guideline (CG164) on familial breast cancer has recommended anastrozole off-label since 2017. The NICE guideline has been updated to reflect that anastrozole is now licensed for prevention. If a patient contacts primary care, the NICE guideline recommends that primary care professionals should offer to refer potentially eligible patients to secondary care. The first prescription is likely to be in secondary care. If there is prior agreement from primary care, continued prescribing may be from primary care. Existing JAPC traffic light classification GREEN after specialist recommendation remain unchanged.	
10.	**GLOSSOP TRANSFER GMMMG DECISIONS**	
	Mr Dhadli reported that this is tabled in JAPC for information. GMMMG classified daridorexant as GREEN or specialist advice, and tirzepatide as GREEN. Both drugs are currently classified as RED in Derbyshire, however, they are on the JAPC action tracker to be reviewed.	
11.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in November 2023 was noted. Mr Dhadli highlighted the following: Traffic Lights: • Simvastatin - Update from GREEN to GREY for use in those established on treatment or unable to tolerate atorvastatin/ rosuvastatin • Pravastatin - Update from GREEN to GREY for use in those established on treatment or unable to tolerate atorvastatin/ rosuvastatin • Dapagliflozin - Update from GREEN specialist initiation to GREEN	

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	specialist recommendation for treating chronic heart failure with preserved or mildly reduced ejection fraction as per NICE TA902 Formulary Update – Skin: • Anthelios added to sunscreen table with cost and pack size. • Following brand names removed from chapter- Canesten HC, Efudix, Fucidin, Silkis, Skinoren • Link to British Association of Dermatologist (BAD) specials updated. • Link to SPS on aqueous cream removed as no longer available. Clinical Guidelines (minor updates)/ website changes: • Acne guideline and traffic light classification for isotretinoin updated to include links to patient information leaflets and latest MHRA drug safety warning. • DDICB Patient Group Direction Development and Review Process amended - The authorised signatory for signing PGDs on behalf of the ICB has been updated from the Executive Medical Director to Director of Medicines Management & Clinical Policies for the ICB. • SPS Continuing management of the ADHD medicines shortage link added to the CNS chapter/ Shared care page. • Minor amendment for migraine High-Cost Drug algorithm dosing table to align to BNF doses. • Vitamin D PIL in Urdu removed from website. It is currently being investigated by our contracted translating service. • Prescribing of Stoma Accessories minor update to Derby contact details. • Shared Care Guidelines azathioprine and mycophenolate contact details updated to include Sheffield Teaching Hospitals. • Continence community formulary updated to include correct customer service number for Prosys Bed Stand. Guideline Timetable: The guideline table action summary and progress was noted by JAPC.	
12.	**BIOSIMILAR REPORT**	
	Mr Dhadli reported the biosimilar monthly percentage update to JAPC members.	
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for November 2023 was noted. Mr Dhadli highlighted the following MHRA advice: • <u>Ozempic (semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products</u> Falsified, potentially harmful Ozempic and Saxenda products have been found in the UK. We ask healthcare professionals to remind patients using these products to always obtain prescription medicines from a qualified healthcare provider and not to use products they suspect are falsified as this may lead to serious health consequences. We also ask healthcare professionals to remain vigilant for symptoms linked to hypoglycaemia in patients who may have obtained a falsified product containing insulin.	

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	• <u>Nirmatrelvir, ritonavir (Paxlovid): be alert to the risk of drug interactions with ritonavir</u> There is a risk of harmful drug interactions with the ritonavir component of the COVID19 treatment Paxlovid due to its inhibition of the enzyme CYP3A, which metabolises many commonly used drugs. Prescribers should obtain a detailed patient history of current medications before prescribing Paxlovid, checking the Paxlovid product information for known and potential drug interactions. • <u>E-cigarette use or vaping: reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the Yellow Card scheme</u> Healthcare professionals should be vigilant for suspected adverse reactions and safety concerns associated with e-cigarettes and e-liquids, commonly known as vapes. Please report adverse reactions to the Yellow Card scheme and promote vigilance among patients.	
14.	**HORIZON SCAN**	
a.	**<u>Monthly Horizon Scan</u>** Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations. New drug launches in the UK which require a traffic light: • Atogepant (Aquipta) 10mg and 60mg tablets classified as Do Not Prescribe - await national guidance.	
15.	**NICE SUMMARY**	
	Mrs Thai informed JAPC of the comments for the ICB which had been made for the following NICE guidance in November 2023. ICB commissioned drugs: • TA929 Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction - GREEN specialist recommendation. In line with dapagliflozin (NICE TA902) for the same indication. NHSE commissioned drugs: • TA928 Cabozantinib for previously treated advanced differentiated thyroid cancer unsuitable for or refractory to radioactive iodine - Not recommended. DNP as per NICE TA928 • TA930 Lutetium-177 vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more treatments - Not recommended. DNP as per NICE TA930 • TA931 Zanubrutinib for treating chronic lymphocytic leukaemia - RED as per NICE TA931. NHSE commissioned. • TA932 Decitabine–cedazuridine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable – DNP NICE TA932 terminated appraisal. • TA933 Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies - DNP NICE TA933 terminated appraisal. Replaces TA567. • TA934 Foslevodopa–foscarbidopa for treating advanced Parkinson's with motor symptoms - RED as per NICE TA9341. NHSE commissioned.	

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	• TA936 Idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments - DNP NICE TA936 terminated appraisal.	
16.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	<u>Classifications</u> • Empagliflozin - GREEN specialist recommendation - NICE TA929: Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction • Cabozantinib - DNP - NICE TA928: Cabozantinib for previously treated advanced differentiated thyroid cancer unsuitable for or refractory to radioactive iodine- Not recommended. • Lutetium-177 vipivotide tetraxetan - DNP - NICE TA930: Lutetium-177 vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more treatments- Not recommended • Zanubrutinib - RED - NICE TA931: Zanubrutinib for treating chronic lymphocytic leukaemia. NHSE commissioned • Decitabine–cedazuridine - DNP - NICE TA932: Decitabine–cedazuridine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable. Terminated appraisal • Tisagenlecleucel - DNP - NICE TA933: Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies. Terminated appraisal, replaces NICE TA567 • Foslevodopa–foscarbidopa - RED - NICE TA934: Foslevodopa–foscarbidopa for treating advanced Parkinson's with motor symptoms. NHSE commissioned • Idecabtagene vicleucel - DNP - TA936: Idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments • Atogepant (Aquipta) - Do Not Prescribe - await national guidance. ICB commissioned High-Cost Drug. • Copper histidinate - RED - SSC2577: Subcutaneous copper histidinate injections for presymptomatic neonates with classical Menkes disease as per NHSE commissioning intentions • Obinutuzumab - RED - SSC2579: Obinutuzumab elective therapy to prevent immune Thrombotic Thrombocytopenic Purpura (TTP) relapse in patients who are refractory or intolerant to rituximab (adults) as per NHSE commissioning intentions • Durvalumab with gemcitabine and cisplatin - RED - SSC2583: Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer as per NHSE commissioning intentions	
17.	**ANY OTHER BUSINESS**	
a.	**<u>Attention Deficit Hyperactivity Disorder (ADHD)</u>** The medication shortages briefing has been further updated by DHCFT to include messages: supply chains remain fragile thus products may only be available on a temporary basis and may go out of stock at short notice; not to recommend switching to an alternative product unless under exceptional circumstances; patients should not be initiated on products affected by shortage until the supply issues resolve. Advice from this briefing applies to both primary and secondary care.	

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	<u>Potential contamination of some carbomer-containing lubricating eye products with Burkholderia cenocepacia</u> A National Patient Safety Alert for certain batches of eye gels are subject to recall at present. As a precautionary measure, while further testing is conducted, avoid use of all carbomer-containing lubricating eye products for patients in the following groups: individuals with cystic fibrosis; patients being cared for in critical care settings (e.g., adult, paediatric and neonatal ICU); severely immunocompromised; patients awaiting lung transplantation. Where an alternative non carbomer-containing product is not available or not suitable, apply clinical risk assessment as appropriate.	
18.	**DATE OF NEXT MEETING**	
	Tuesday 9th January 2024, papers are to be circulated and agreed virtually.	