For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 12th April 2022

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Olopatadine/mometasone (Ryaltris)	GREY for adults and adolescents 12 years of age and older for the treatment for moderate to severe seasonal and perennial allergic rhinitis
Sacubitril/Valsartan	Change from AMBER to GREEN specialist initiation, titration and stabilisation
Empagliflozin	GREEN consultant/specialist initiation & stabilisation as per NICE TA773 - for treating chronic heart failure with reduced ejection fraction
Dapagliflozin	GREEN consultant/specialist initiation as per NICE TA775 for treating chronic kidney disease
Sucroferric oxyhydroxide (Velphro)	RED
Atidarsagene autotemcel	RED - HST18 - Atidarsagene autotemcel for treating metachromatic leukodystrophy
Lenalidomide	DNP - TA774 - Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal)
Pitolisant hydrochloride	DNP - TA776 - Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea
Solriamfetol	DNP - TA777- Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea
Pegcetacoplan	RED - TA778 - Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria
Dostarlimab	RED - TA779 - Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency
Nivolumab	RED - TA780 - Nivolumab with ipilimumab for untreated advanced renal cell carcinoma
Sotorasib	RED - TA781 - Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer
Tagraxofusp	DNP - TA782 - Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm (terminated appraisal)

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Cyanocobalamin (oral)	Classified as DNP, oral cyanocobalamin is poorly absorbed
Probenecid	Classified as RED
Nitrofurantoin (long term prophylaxis)	Classified as GREEN, monitor FBC renal function and LFT every 6 months

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Clinical Guidelines:
Allergic Rhinitis
Clozapine info sheet for GP
Heart Failure
Phosphate Binders

PGDs:
HPV PGD
HPV PGD for men

Present:	
Derby and Derbyshire CCG	
Dr R Gooch	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 S Qureshi	Head of Medicines Management, Clinical Policies and High Cost Interventions
Dr H Hill	GP
Dr A Mott	GP
Ms R Dills	GP
Ms A Reddish	Clinical Quality Manager
Derby City Council	
Derbyshire County Council	
University Hospitals of Derby and Burton NHS Foundation Trust	
Mr M Prior	Deputy Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr A Hardy	Principal Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Chief Pharmacist
Ms Kate Needham	Chief Pharmacist
Derby and Derbyshire Local Medical Committee	
Derbyshire Health United	
Staffordshire and Stoke-on-Trent CCG's	
Mr K Claire	Medicines Optimisation Pharmacist
In Attendance:	
Mr A Brownlee	Chief Pharmacy Technician (Interface)

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Item		Action
1.	**APOLOGIES**	
	Dr W Goddard, Robyn Dewis, S Bamford, Ms E Kirk	
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. Mrs Needham mentioned that her COI has been updated. No conflicts of interest were declared in relation to this agenda, in addition to the existing register of interests.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	There were no declarations of any other business.	
4.	**JAPC ACTION SUMMARY**	
a.	**Cannabis based medicine (Sativex)** Still awaiting Cannabis shared care agreement from University Hospital of Derby and Burton (UHDBFT).	
b.	**Mycophenolate** Mr Dhadli mentioned that the RMOC SCA is yet to be published following consultation.	
c.	**Inclisiran** Inclisiran will be reviewed in 12 months after secondary care have experience of using this.	
5.	**CLINICAL GUIDELINES**	
a.	**Allergic Rhinitis** Mr Dhadli highlighted that the Allergic Rhinitis guideline is due its periodic review. Mr Dhadli informed the committee of the background surrounding the local allergic rhinitis guideline. The local guideline was based on the 2017 NICE accredited British Society of Allergy and Clinical Immunology (BSACI) guideline and was primarily written to guide the use of Dymista (azelastine/fluticasone) – which is recommended after all other intranasal steroid treatments have failed, and before referral to secondary care. There have been no subsequent updates to the 2017 BSACI guidance. The specialists requested to include the bioavailability of nasal steroids and a new combination nasal spray called Ryaltris (olopatadine/mometasone), alongside Dymista (azelastine/fluticasone). Mr Dhadli informed the committee about the clinical efficacy and safety of Ryaltris was based on a phase two double-blind, randomized, parallel group, active and placebo-controlled study. The active treatment was compared with olopatadine, mometasone and placebo. Ryaltris demonstrated statistically significant improvement from baseline in average morning and evening patient-reported reflective Total Nasal Symptom Score (rTNSS). In the 2nd trial	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Item		Action
	ryaltris (olopatadine/mometasone) demonstrated significantly improved rTNSS vs placebo and vs olopatadine, but statistical significance was not demonstrated vs mometasone. There were no trials directly comparing Ryaltris to Dymista, but JAPC were reminded that they previously accepted trial results which had compared Dymista against placebo and the individual drug components alone. Also, the 6 month cost for Ryaltris was slightly cheaper than Dymista. The recommendation includes ryaltris (olopatadine/mometasone) as GREY for moderate to severe seasonal and perennial allergic rhinitis as a cost effective option alongside Dymista.	
b.	**<u>Clozapine info sheet for GP</u>** This paper was produced by Derbyshire Healthcare Trust (DHcFT) and the purpose is to inform the committee that the guidance has been reviewed and updated. Mr Jones reported that the main change is the preferred brand of clozapine has switched from Clozaril to Zaponex, along with additional clinical clarity from the Zaponex manufacturers. Other changes to the document include discontinuing Zaponex if the white blood cell count $<3.0x10^9$/L and the absolute neutrophil count $<1.5x10^9$/L. Nausea and vomiting have been removed from the adverse effects following feedback that this is rarely due to the Zaponex after initiation. Mr Jones reminded JAPC that patients treated with Zaponex may present in primary care with constipation and that it was vital to access these patients promptly and effectively as Zaponex (clozapine)is associated with gastrointestinal hypomotility and other complications, which may become life-threatening. Mr Jones also explained the Trust had switched to Zaponex because of the support available for a patient if needed through the company and also the range of formulations available. Ms Needham highlighted that the brand Zaponex could be unfamiliar across different care settings and asked that the committee consider the recommendation for the prescriber to label Clozapine. Mr Jones commented that the DCHSFT is the only trust that prescribes Clozapine. **Agreed: JAPC** approved the updated Clozapine information sheet for GPs.	**SD**
c.	**<u>Heart Failure</u>** Mr Dhadli reported that the heart failure with reduced ejection fraction (HFrEF) guidance and the sacubitril/valsartan shared care agreement were due their periodic review. Mr Dhadli highlighted that an extensive consultation with specialists/consultants from UHDBFT, CRHFT & DCHSFT had been undertaken for the heart failure guidance. Mr Dhadli informed the committee that NICE have published the NICE TA733 empagliflozin for treating chronic HFrEF. Empagliflozin is the second SGLT2i	

Item		Action
	for treating symptomatic chronic HFrEF in adults as an add-on, (NICE had previously published guidance for dapagliflozin for HFrEF) with the recommendation of initiating on the advice of a heart failure specialist and has been added as a treatment option as per the following criteria: Recommended as an option for treating symptomatic chronic HFrEF in adults as an add-on to optimised standard care with either - • An ACEi or ARB + beta blocker + MRA (if tolerated) • Sacubitril/valsartan + beta blocker + MRA (if tolerated) Evidence from EMPEROR-Reduced trial showed that empagliflozin plus standard care reduces the risk of dying from cardiovascular causes compared with placebo plus standard care. It also shows that it reduces the likelihood of hospitalisation for heart failure. There were no trials directly comparing empagliflozin with dapagliflozin. However, an indirect comparison suggests that empagliflozin is likely to be similar to dapagliflozin in reducing the risk of dying and the likelihood of hospitalisations for heart failure. In patients with reduced eGFR, there are different recommendations for when not to use a SGLT2 inhibitor (empagliflozin eGFR<15ml/min and dapagliflozin eGFR <20ml/min). For patients with reduced renal function specialists will advise on a case-by-case basis, weighing the risk vs benefits. There was also a request from UHDBFT cardiologists to change the traffic light classification for SGLT2i from specialist initiation to specialist recommendation. However, JAPC considered specialist initiation is an appropriate classification. A UHDBFT cardiologists highlighted that the European Society of Cardiology (ESC), 2021 guideline are classifying people with left ventricular ejection fraction (LVEF) between 41-49% as mildly reduced ejection fraction. (the current HFrEF is defined as heart failure with a LVEF <40%). The evidence base for this is retrospective data and it was requested that the current definition of heart failure to be changed, which would potentially allow more patients to be treated. Mr Dhadli stated that JAPC follow NICE guidance, which includes clinical and cost effectiveness, whereas the ESC does not consider cost effectiveness. UHDBFT cardiologists have also recommended changing the traffic light status for sacubitril/valsartan (Entresto) NICE TA388from AMBER to GREEN specialist initiation & stabilisation only, since there is not ongoing monitoring for sacubitril/valsartan. JAPC accepted this change as it would still be in line with the NICE (treatment should be started by a heart failure specialist with access to multidisciplinary heart failure team.). A further request for a reclassification was made for sodium zirconium cyclosilicate (Lokelma) (current classification is RED). Mr Dhadli advised the committee to keep the classification as RED until we know more on the reclassification proposal.	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Item		Action
	Heart failure guideline has been reformatted for ease of reading and now includes one management flowchart highlighting primary and secondary care responsibilities. A patient information leaflet has been incorporated into appendix 6. **Agreed:** JAPC agreed toEmpagliflozin - GREEN consultant/specialist initiation & stabilisation for HFrEF & sacubitril/valsartan (entresto) - GREEN specialist initiation, titration & stabilisation (shared care to also be removed (Sodium zirconium cyclosilicate (lokelma) will stay RED. HFrEF guideline agreed.	**SD**
d.	**Phosphate Binders** Mr Dhadli stated that the phosphate binders guideline was due for its periodic review and had been sent for comment to the renal specialists at UDBFT. The guidance is based on a NICE NG203 Chronic kidney disease guidance (last updated Nov 2021). This was re classified from AMBER (shared care) to GREEN after specialist initiation by the committee in November 2014. Updates include minor wording change on p.1 and the addition of sucroferric oxyhydroxide information, which has been recommended to be classified as RED as it is a NHSE funded high cost drug. **Agreed:** JAPC ratified the phosphate binder guideline and a RED traffic light classification for sucroferric oxyhydroxide.	**SD**
6.	**PATIENT GROUP DIRECTIONS**	
	The following PGDs from Public Health England were noted and agreed by JAPC: • Administration of Human papillomavirus (HPV) vaccine to individuals from 12 years of age or from school year 8 in accordance with the national immunisation programme. • Administration of human papillomavirus (HPV) vaccine to men who have sex with men (MSM), who attend Specialist Sexual Health Services (SSHS) and/or HIV clinics.	
7.	**MISCELLANEOUS**	
a.	**Glucose monitoring interim position statement** Mr Dhadli informed the committee that NICE have recently updated guidelines - NG17, NG18 and NG28. The guidelines recommend the use of either intermittently scanned continuous glucose monitoring (isCGM) known as “Flash”, or real time continuous glucose monitoring (rtCGM) for adults, and children with type 1 or type 2 diabetes. A summary of the CGM in NICE and local recommendations for children and adults with type 1 & 2 diabetes, and a summary of the updated NICE recommendations was presented to JAPC. In anticipation of high demand for CGM, an interim position statement has been produced, which recognises NICE guidance, and that a Derbyshire - wide diabetes group is developing a business case to support equitable and	

Item		Action
	cost-effective use of CGM alongside competing priorities and opportunities. It was noted that NICE had not published any costings templates yet, but the diabetes group were currently developing a business case. This would need to be reviewed by the CCG in terms of affordability. Mr Dhadli highlighted that because there is a significant financial impact attached, a timeline cannot be produced as the position statement will need to be presented at multiple committees. Mr Dhadli also mentioned that NICE are set to review how they evaluate the cost effectiveness of the TA's and will be potentially incorporating more patient factors in the new NICE guidelines. **Action:** JAPC ratify the interim position statement subject to a minor amendment.	**SQ**
b.	**Private NHS care** Mr Dhadli notified the committee of the document 'Define the barriers between private and NHS care' policy. This policy sits with the Clinical Policy Advisory Group, which was approved in March 2022. It was brought to JAPC for information and any potential questions, as the policy mentions prescribing information. A number of the principles within the 'Define the barriers between private and NHS care' policy are also within the primary care prescribing guide. Mr Prior expressed concerns to the committee regarding patients who start their treatment privately then move over to the NHS to continue treatment. **Action:** Wording to be agreed and added to the primary care prescribing guideline regarding patients that start private treatment then transfer to NHS treatment.	**SQ**
c.	**Specialised Circulars** Mr Dhadli advised that the specialised circulars has been tabled for information and are available upon request.	
8.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire medicines management shared care and guideline group meeting held in March 2022. Mr Dhadli highlighted the following: **March 2022** Traffic Lights: • Cyanocobalamin – classified as DNP, oral cyanocobalamin is poorly absorbed • Probenecid – classified as RED • Nitrofurantoin – classified as GREEN, monitor FBC renal function and LFT	

Item		Action
	every 6 months **Formulary update – Respiratory:** • Tiogiva replaces Braltus as cost effective choice of tiotropium DPI • EasyChamber Spacer replaces A2A spacer as the cost-effective choice • WockAIR added as another budesonide + formoterol DPI choice for asthma (≥12years of age) and COPD • Fixkoh Airmaster added as cost effective alternative to Seretide Accuhaler. Fixkoh is licensed for asthma (≥12years of age) and COPD. • Combisal MDI replaces AirFluSal as cost effective alternative to Seretide Evohaler • Combisal is licensed for asthma (>4 years of age).	
9.	**BIOSIMILAR REPORT**	
	Mr Dhadli advised that the biosimilar report has been tabled for information.	
10.	**JAPC Bulletin**	
	The March 2022 bulletin was ratified. Mr Dhadli highlighted that the bulletin was tabled for information.	
11.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for **March 2022** was noted. • Cladribine (mavenclad): new advice to minimise risk of serious liver injury • Amiodarone (cordarone X): reminder of risks of treatment and need for patient monitoring and supervision • Metformin in pregnancy: study shows no safety concerns during pregnancy • COVID-19 vaccines and medicines: updates for March 2022	
12.	**HORIZON SCAN**	
	Monthly Horizon Scan – March 2022 Mrs S Qureshi advised JAPC that there were no new drug launches, new drug formulations, licence extensions or drug discontinuations to report.	
13.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance: TA773 - Empagliflozin for treating chronic heart failure with reduced ejection fraction – classified as GREEN TA775 - Dapagliflozin for treating chronic kidney disease – classified as GREEN NG17- Type 1 diabetes in adults: diagnosis and management - Derbyshire pathway and guideline currently being co-ordinated NG18 - Diabetes (type 1 and type 2) in children and young people: diagnosis and management – Derbyshire pathway and guideline currently being co-ordinated	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Item		Action
	NG28 - Type 2 diabetes in adults: management – CPD currently working on updating the guideline NG91 - Otitis media (acute): antimicrobial prescribing - CPD currently working on updating the guideline NG136 - Hypertension in adults: diagnosis and management – Slight amendment to local guidance (through guideline group) HST18 - Atidarsagene autotemcel for treating metachromatic leukodystrophy - classified as RED TA774 - Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal) - classified as DNP TA776 - Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea - classified as DNP TA777- Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea - classified as DNP TA778 - Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria - classified as RED TA779 - Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency - classified as RED TA780 - Nivolumab with ipilimumab for untreated advanced renal cell carcinoma - classified as RED TA781 - Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer - classified as RED TA782 - Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm (terminated appraisal) - classified as DNP It was highlighted that the committee need to make it clear to CLCC that there will be a large cost pressure to fund empagliflozin/dapagliflozin, and investments into preventative measures is a must to avoid actual events happening. **Action:** The committee agreed to produce a statement for the director of finance explaining the cost pressures for empagliflozin/dapagliflozin.	**SQ**

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@nhs.net

Item		Action
14.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Sheffield APG Minutes February 2022	
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications: • Olopatadine/mometasone (Ryaltris) - GREY for adults and adolescents 12 years of age and older for the treatment for moderate to severe seasonal and perennial allergic rhinitis • Sacubitril/Valsartan - Change from AMBER to GREEN specialist initiation, titration and stabilisation • Empagliflozin GREEN consultant/specialist initiation & stabilisation as per NICE TA773 - for treating chronic heart failure with reduced ejection fraction • Dapagliflozin GREEN consultant/specialist initiation as per NICE TA775 for treating chronic kidney disease Sucroferric oxyhydroxide (Velphro) – RED • Atidarsagene autotemcel – RED - HST18 - Atidarsagene autotemcel for treating metachromatic leukodystrophy • Lenalidomide – DNP - TA774 - Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal) • Pitolisant hydrochloride - DNP - TA776 - Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea • Solriamfetol – DNP - TA777- Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea • Pegcetacoplan – RED - TA778 - Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria • Dostarlimab – RED - TA779 - Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency • Nivolumab – RED - TA780 - Nivolumab with ipilimumab for untreated advanced renal cell carcinoma • Sotorasib – RED - TA781 - Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer • Tagraxofusp – DNP - TA782 - Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm (terminated appraisal)	
16.	**ANY OTHER BUSINESS**	
	There were no items of any other business.	
17.	**DATE OF NEXT MEETING**	
	Tuesday, 10th May 2022, papers are to be circulated and agreed virtually as per JAPC interim Terms of Reference, which is effective during the COVID-19 pandemic.	