

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 11th October 2022

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Trazodone	GREEN – for use at step 2 of antidepressant guideline.
Vortioxetine	GREEN - reclassified from RED to GREEN. For use in step 3 of antidepressant guideline, for patients who respond partially to serotonergic antidepressants but do not tolerate some side effects e.g., sexual dysfunction and nausea
Duloxetine	GREY for depression as alternative to venlafaxine for patients with previous history of antidepressant benefit
Phenelzine	GREEN spec initiation – for use at step 3 of antidepressant guideline
Amisulpride	GREEN after specialist initiation for psychosis. GREEN Specialist recommendation for chronic depression (low dose, NG222)
Haloperidol	GREEN after specialist initiation for psychosis, bipolar disorder (CG185)
Risperidone	GREEN after specialist initiation for psychosis, bipolar disorder (CG185), adjunct to antidepressant in unipolar depression
Sulpiride	GREEN after specialist initiation for psychosis
Trifluoperazine	GREEN after specialist initiation for psychosis
Aripiprazole	GREEN after specialist initiation for psychosis, bipolar disorder (CG185), depression
Olanzapine	GREEN after specialist initiation for psychosis, bipolar disorder (CG185), depression
Quetiapine	GREEN after specialist initiation for psychosis, bipolar disorder (CG185), depression
Chlorpromazine	GREEN after specialist initiation for psychosis
Flupentixol	GREEN after specialist initiation for psychosis
Zuclopenthixol	GREEN after specialist initiation for psychosis
Promazine	GREY to be prescribed within licensed indications
Lurasidone	RED for psychosis and bipolar depression
Flupentixol decanoate	RED
Haloperidol decanoate	RED
Zuclopenthixol decanoate	RED
Paliperidone (Xeplion®)	RED
Duplimumab	RED for the use in children 6 to 11 years old as add-on maintenance treatment for severe asthma with

	type 2 inflammation. NHSE commissioned
Tebentafusp	RED for monotherapy for the treatment of human leukocyte antigen A*02:01 positive adults with unresectable or metastatic uveal melanoma. NHSE commissioned
Axicabtagene ciloleucel	RED for the treatment of adults with relapsed or refractory follicular lymphoma after ≥3 lines of systemic therapy. NHSE commissioned
Birch bark extract (<i>Filsuvez</i>)	DNP for the treatment of pulmonary arterial hypertension in adults, adolescents and children (aged ≥8 to <18 years) of WHO Functional Class II to III, including use in combination treatment
Gozetotide (<i>Locametz</i>)	DNP for the treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa in patients aged ≥6 months
Lonafarnib (<i>Zokinvy</i>)	DNP for the Identification of prostate-specific membrane antigen-positive lesions by positron emission tomography in adults with prostate cancer, after radiolabelling with gallium-68
Dexamethasone (<i>Ozurdex</i>)	RED as per NICE TA824 for treating diabetic macular oedema. ICB commissioned
Vedolizumab	DNP as per NICE TA826 for treating chronic refractory pouchitis after surgery for ulcerative colitis (terminated appraisal)
Melphalan	DNP as per NICE TA822 for haematological diseases before allogeneic haematopoietic stem cell transplant (terminated appraisal).
Atezolizumab	RED as per NICE TA823 for adjuvant treatment of resected non-small-cell lung cancer. NHSE commissioned
Avacopan	RED as per NICE TA825 for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis. NHSE commissioned

Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
Fusidic acid 1% eye drops	Classified as GREY, significantly more expensive than chloramphenicol eye drops. Recommended by NICE/PHE as alternative to chloramphenicol eye drops. Suitable for use in pregnancy
Gentamicin 0.3% eye drops	Classified as GREY, alternative to chloramphenicol and fusidic acid eye drops. Significantly more expensive than chloramphenicol eye drops.
Azithromycin 1.5% eye drops	Classified as GREY, alternative to chloramphenicol eye drops. Suitable for use in pregnancy
DuoTrav eye drops	Classified as DNP, prescribe generically as travoprost / timolol eye drops
Azarga eye drops	Classified as DNP, prescribe generically as brinzolamide / timolol eye drops
Trusopt eye drops	Classified as DNP, prescribe generically as dorzolamide eye drops

Betamethasone + clioquinol (Formally Betnovate C)	Classified as GREY after consultant/specialist initiation, for conditions as per specialist advice e.g., via A&G. Not for long-term use
Sodium hyaluronate (Hyacyst)	Classified as RED, bladder instillation indicated for treating Bladder Pain Syndrome

Clinical Guidelines

Antidepressants in unipolar depression
 Antipsychotic Prescribing and Management for mental health conditions
 Monitoring and Medication after Bariatric Surgery
 Management of Dyspepsia and Gastro-Oesophageal reflux disease

Present:	
Derby and Derbyshire ICB	
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
Mrs L G	Assistant Director of Medicines Optimisation and Delivery
Derby City Council	
Derbyshire County Council	
University Hospitals of Derby and Burton NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Ms Esther Kirk	Lead Pharmacist – High Cost Drugs and Commissioning
Mr M Prior	Deputy Chief Pharmacist
Mr O Ayeh	Clinical Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Dr M Broadhurst	Consultant Psychiatrist/Deputy Medical Director
Chesterfield Royal Hospital NHS Foundation Trust	
Ms A Brailey	Senior Pharmacist
Mrs J Russel	Consultant Geriatrician
Derbyshire Community Health Services NHS Foundation Trust	
Mrs K Needham	Chief Pharmacist
Mrs E Stelmach	Advanced Pharmacist
Derby and Derbyshire Local Medical Committee	
Derbyshire Health United	

Staffordshire and Stoke-on-Trent CCG's	
Mrs S Bamford	Medicines Optimisation Senior Lead Pharmacist
In Attendance:	
Mr A Brownlee	Chief Pharmacy Technician (Interface)
Miss S Greenwell	Senior Administrator, DDCCG (minutes)
Mrs A Thai	Guidelines, Formulary and Policy Manager
Mrs D Brandist	Senior Finance Manager

Item		Action
1.	APOLOGIES	
	Dr R Dils, Dr H Hill, Dr A Mott	
2.	DECLARATIONS OF CONFLICTS OF INTEREST	
	<p>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.</p> <p>No conflicts of interest were declared in relation to this agenda, in addition to the existing register of interests.</p>	
3.	DECLARATIONS OF ANY OTHER BUSINESS	
	There were no declarations of any other business.	
4.	JAPC ACTION SUMMARY	
a.	<p><u>Mycophenolate</u> The Guideline Group will be reviewing mycophenolate in line with the published RMOG template.</p>	
b.	<p><u>Inclisiran</u> JAPC to reconsider traffic light classification for inclisiran following feedback from lipidologist as D&Ts of its position in local guidance and if further national guidance is published.</p>	
c.	<p><u>Weekly GLP1</u> Place in therapy of weekly GLP1's being considered with diabetes guidance update.</p>	
d.	<p><u>Patiromer/Lokelma hyperkalaemia</u> Remains RED and to review classification in 12 months, to include costs/benefits and the projected increase in patient numbers.</p>	
e.	<p><u>Icosapent ethyl</u> Cardiologist/Lipidologist views managed entry of icosapent ethyl in non-FH/FH guidance.</p>	
5.	CLINICAL GUIDELINES	
a.	<p><u>Antidepressants in unipolar depression</u> Mr Jones presented the updated local antidepressants in unipolar depression guideline following the publication of NICE NG222 (July 2022). The update of the long-standing guidance on antidepressant use in unipolar depression was postponed due to the anticipated but delayed publication of NG222 by NICE, which refreshes guidance issued in 2009. The new national guideline is significantly different to the previous version in many respects.</p>	

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	<p>The new updated local guideline focuses on the use of medicines in the treatment of depression but does not intend to undermine the emphasis NICE places on psychological intervention to resolve symptoms. The updated local guidance introduces changes while attempting to keep the presentation of the sequencing flowchart used previously. The alternative of separate flowcharts for different types of depression was drafted but felt unwieldy and unhelpful for busy clinicians to work through without confusion.</p> <p>Mr Dhadli highlighted that the updated local guidance for antidepressants in unipolar depression has undergone consultation at the Derbyshire Healthcare NHS Foundation Trust (DHcFT). A summary of the main updates was discussed; mirtazapine was retained as an alternative to SSRIs and SNRIs for reasons of patient safety. Venlafaxine is recommended as the SNRI of choice, in line with current traffic lights. Vortioxetine was previously classified as RED and is a more expensive choice than SSRIs/SNRIs however it is no more difficult to prescribe and manage than an SSRI.</p> <p>JAPC was asked to consider the proposal for Vortioxetine reclassification from RED to GREEN 3rd line, in line with the NG222 and TA267. The green status would allow primary care an additional option other than referrals to secondary care; retaining red status would create an otherwise unnecessary use of limited resources. This would likely be useful in the cohort of patients who respond at least partially to serotonergic antidepressants but who do not tolerate some of the side effects, particularly sexual dysfunction, and nausea. How to switch antidepressants is retained in the main flowchart. The flowchart for dose recommendations for citalopram has been retained in the new guidance.</p> <p>A discussion took place, it was suggested that Derbyshire needs a local pathway for depression treatment to maximise the non-drug aspect of the guidance. The committee agreed to discuss this in a future Integrated Pharmacy & Medicines Optimisation meeting.</p> <p>Agreed: The committee approved the adoption of the updated local antidepressants in unipolar depression guideline that will support implementation of the medicines-related elements of NG222.</p> <p>Agreed: The committee approved the reclassification of vortioxetine from RED to GREEN 3rd Line.</p> <p>Agreed: The committee approved the reclassification of duloxetine from GREEN to GREY for depression as an alternative to venlafaxine for patients with previous history of antidepressant benefit.</p> <p>Agreed: The committee approved the GREEN specialist initiation classification for phenazone as step 3 of the antidepressant guideline.</p> <p>b. <u>Antipsychotic Prescribing and Management for mental health conditions</u> Mr Jones informed the committee that DHcFT have produced a new document to clarify the formulary status of antipsychotic medicines in the context of a range of mental health conditions, in a user-friendly format. This is to reinforce JAPC agreed expectations of professional responsibility with respect to physical health monitoring related to antipsychotic use. Mr Jones highlighted the main reasoning for the development of this guideline</p>	<p></p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>

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	<p>is that the majority of antipsychotics have a traffic light status, however some do not for largely historical reasons. A single traffic-light status does not represent the nuances of antipsychotic choice in a range of mental health conditions and there is a lack of consistency in current traffic light allocations to antipsychotic drugs. There is a lack of awareness of, or adherence to the agreed physical health monitoring guideline for people prescribed antipsychotics and this is a cause of friction at the interface between primary and secondary care. There is also a lack of local guidance on prescribing psychotropic medicines, including antipsychotics, in response to periods of crisis linked to some personality disorders and a risk of inappropriate use of antipsychotics in this context which is not in the patients' interest and leads to unnecessary utilisation of resources.</p> <p>The committee was recommended to approve several traffic light status amendments. Lurasidone is currently RED for bipolar affective disorder depression and is recommended to be changed to RED for psychosis, to diversify the range of available medications. Cariprazine is also recommended to be changed to RED for psychosis, due to CI in pregnancy. Haloperidol is currently GREEN for non-cognitive symptoms of dementia under primary care. All depot and long-acting injectable antipsychotic medicines (1st and 2nd generation) have a RED traffic light status under secondary care.</p> <p>A discussion took place, the committee agreed the guidance is clear on which drugs are being used for which indications and it also gives a clear reference for internal teams regarding monitoring of antipsychotics before moving to primary care.</p> <p>JAPC agreed to accept all proposed traffic light classifications.</p> <p>Agreed: JAPC approved of the Antipsychotic Prescribing and Management for mental health conditions guidance as a useful reference for primary care prescribers wanting to understand prescribing by specialists.</p> <p>Agreed: JAPC accepted all proposed traffic light classifications.</p>	<p>SD</p> <p>SD</p>
<p>c.</p>	<p><u>Monitoring and Medication after Bariatric Surgery</u></p> <p>Mr Dhadli highlighted the main changes made to the monitoring and medication after bariatric surgery guidance. The updated guidance for monitoring and medication after bariatric surgery has undergone extensive consultation with a consultant endocrinologist at UHDBFT, a bariatric dietician with the East Midlands Bariatric and Metabolic Institute, a Chief pharmacist at Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) and a bariatric dietician/consultant at Sheffield Teaching Hospital (NHSFT). At the 2019 review UHDBFT requested that all patients are issued with a vitamin and mineral supplementation via their GP following bariatric surgery. UHDBFT specialists felt this is in line with NHS England Guidance which states 'Vitamins and minerals, exceptions – medically diagnosed deficiency, including for those patients who may have a lifelong or chronic conditions or have undergone surgery that results in malabsorption.'</p> <p>From historical discussions at JAPC regarding the principles of vitamin supplementation self-care versus prescribing, as a general principle from JAPC and across Derbyshire, self-care is recommended, and treatments would only be recommended if there is a medical diagnosis. The rationale for promoting self-care is due to the cost impact for primary care, the inequity</p>	

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	<p>across Derbyshire, where patients in the North are asked to buy multivitamins OTC and the Guideline Group interpretation of the NHSE guidance. JAPC in June 2019 agreed to continue recommending OTC multivitamins, unless a deficiency is detected, in line with Sheffield guidelines and relevant self-care policies.</p> <p>A discussion took place, GW asked the committee how vulnerable patients are assessed that are unwilling or unable to purchase vitamins. It was further discussed that although the JAPC guidance is clear that treatments would only be recommended if there is a medical diagnosis, discharge letters from the gastrointestinal consultants at UHDBFT state GPs will prescribe multivitamins although this has not been agreed. The committee confirmed for the first two years after surgery, patients are actively supervised and supported by bariatric service follow ups. After the patient is discharged from the bariatric service, GPs will offer to annually monitor the nutritional status and appropriate supplementation will be given.</p> <p>The committee discussed the inequity issue in prescribing across Derbyshire in more depth and agreed to strengthen the GP monitoring principle within the guidance and inform the gastrointestinal consultants at UHDBFT of the JAPC decision.</p> <p>Staffordshire and Stoke-on-Trent CCG highlighted that the British Obesity and Metabolic Surgery Society (BOMSS) guidance recommends Forceval by name, and although there are other ways of getting a similar nutritional requirement the consultants at Royal Stoke University Hospital Foundation Trust (RSUHFT) were adamant on keeping Forceval in their local guidance. Gastric band patients are excluded from this and are advised to purchase self-care supplements. The RSUHFT consultants were also concerned for patients in deprived areas would potentially not purchase the self-care supplements. The committee continued to discuss the different vitamin supplementation recommendations in other areas, it was suggested for JAPC to review the ethical framework to ensure the JAPC principles are transparent and just.</p> <p>Agreed: JAPC accepted the updated monitoring and medication after bariatric surgery guidance.</p> <p>Agreed: JAPC recognised that Staffordshire and Stoke-on-Trent need to be considered in future cover sheets when considering traffic light proposals.</p> <p>Agreed: JAPC agreed to reiterate the decision made to the gastrointestinal consultants at UHDBFT but if a compelling case is brought to JAPC this will be considered.</p> <p>Action: JAPC to strengthen the annual monitoring policy in the monitoring and medication after bariatric surgery guidance.</p> <p>d. <u>Management of Dyspepsia and Gastro-Oesophageal reflux disease</u> Mr Dhadli advised that this is a routine review to an existing guideline. The guideline has undergone wide consultation with Consultant Gastroenterologists at UHDBFT. Mr Dhadli highlighted the minor changes which include cost comparison table for the H2 receptor antagonists and a condensed H.Pylori eradication section, as the local trust now align with NICE/PHE.</p>	<p></p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>

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	<p>JAPC are recommended to ratify the updated Management of dyspepsia GORD guideline and to consider a more cost-effective alternative option for ranitidine based on availability of the H2RA.</p> <p>Agreed: JAPC accepted the updated management of dyspepsia and gastro-oesophageal reflux disease guidance.</p>	SD
6.	MISCELLANEOUS	
a.	<p><u>Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis</u></p> <p>Mrs Qureshi presented the updated Derbyshire commissioning guidance for the treatment of moderate to severe atopic dermatitis, following a new NICE TA814 for Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis which was published in August 2022.</p> <p>Action: ICB to circulate the finalised Derbyshire commissioning guidance for the treatment of moderate to severe atopic dermatitis virtually.</p> <p>Agreed: The committee approved the updated Derbyshire commissioning guidance for the treatment of moderate to severe atopic dermatitis.</p>	<p>SD</p> <p>SD</p>
b.	<p><u>Diabetic macular oedema</u></p> <p>Mrs Qureshi advised that NICE have released a NICE TA820 for Brolucizumab for treating diabetic macular oedema was published in August 2022, and a NICE TA824 for Dexamethasone intravitreal implant for treating diabetic macular oedema was published in September 2022 which replaces NICE TA349. The Derbyshire commissioning pathway for the treatment of Diabetic Macular Oedema (DMO) has been updated to include brolucizumab and the updated dexamethasone.</p> <p>Action: ICB to update the Derbyshire commissioning pathway for the treatment of Diabetic Macular Oedema (DMO) with cost effective choices.</p> <p>Action: ICB to circulate the finalised Derbyshire commissioning pathway for the treatment of Diabetic Macular Oedema (DMO) virtually.</p> <p>Agreed: JAPC approved the updated Derbyshire commissioning pathway for the treatment of Diabetic Macular Oedema (DMO).</p>	<p>SD</p> <p>SD</p> <p>SD</p>
c.	<p><u>Guselkumab for treating active psoriatic arthritis</u></p> <p>Mrs Qureshi reported that the Derbyshire commissioning guidance for treatment of psoriatic arthritis has been updated to include Guselkumab following a NICE TA815 for Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs was published in August 2022. Guselkumab, alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is recommended only if they have had 2 conventional DMARDs and have had at least 1 biological DMARD, or tumour necrosis factor (TNF) - alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept,</p>	

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9.	GLOSSOP TRANSFER GMGG DECISIONS	
a.	<p><u>GMMMG Decision summaries</u> Mr Dhadli reported that this will be tabled in JAPC for the next 12 months to review and highlighted that the Insuman® Comb 50 has been discontinued.</p>	
10.	GUIDELINE GROUP KEY MESSAGES	
	<p>The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in September 2022 was noted.</p> <p>Mr Dhadli highlighted the following:</p> <p>Traffic Lights:</p> <ul style="list-style-type: none"> ○ Fusidic acid 1% eye drops – classified as GREY, significantly more expensive than chloramphenicol eye drops. Recommended by NICE/PHE as alternative to chloramphenicol eye drops. Suitable for use in pregnancy. ○ Gentamicin 0.3% eye drops – classified as GREY, alternative to chloramphenicol and fusidic acid eye drops. Significantly more expensive than chloramphenicol eye drops. ○ Azithromycin 1.5% eye drops – classified as GREY, alternative to chloramphenicol eye drops. Suitable for use in pregnancy. ○ DuoTrav eye drops – classified as DNP, prescribe generically as travoprost / timolol eye drops ○ Azarga eye drops – classified as DNP, prescribe generically as brinzolamide / timolol eye drops ○ Trusopt eye drops – classified as DNP, prescribe generically as dorzolamide eye drops ○ Betamethasone + clioquinol (Formally Betnovate C) – classified as GREY after consultant/specialist initiation, for conditions as per specialist advice e.g., via A&G. Not for long-term use ○ Sodium hyaluronate (Hyacyst) – classified as RED, bladder instillation indicated for treating Bladder Pain Syndrome <p>Formulary Update:</p> <p>Eye:</p> <ul style="list-style-type: none"> ○ Gentamicin eye drops removed as 2nd line due to significant cost increase. Chloramphenicol eye drops remain treatment of choice, with fusidic acid, gentamicin, and azithromycin eye drops as alternative treatment options. ○ With the exception of a few combination preparations, it is cost-effective to prescribe eye drops used in glaucoma generically, with some significant difference in costs compared to some brands. See local glaucoma guideline for more detail. For consistency, DuoTrav, Azarga, and Trusopt eye drops have been classified as DNP. Primary care clinicians to prescribe generically as per glaucoma guideline, unless specifically indicated by ophthalmologist to prescribe by brand (this would be rare). ○ AproMel is recommended as cost-effective brand of Hypromellose eye drops. Alternative cost-effective brands include Lumecare Tear Drops & Teardrew. 	

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	<p>Clinical Guidelines (minor updates):</p> <ul style="list-style-type: none"> ○ C.Diff guideline - fidaxomicin (Dificlir) oral suspension for swallowing difficulties added. ○ CVS formulary chapter - Appendix 2 Blood Pressure targets for patients with Type 1 diabetes updated to be in line with targets for general population, following update to NICE NG17 Type 1 diabetes in adults. ○ CNS chapter/ osteoarthritis guideline - oral paracetamol dosing in adults updated following updates to CKS ○ CNS chapter - zolpidem included in the notes as option for patients with swallowing difficulty. Remove traffic light classification (historical). ○ Dry eye position statement - Eyeaze 0.2% eye drops replaces Hydramed 0.2% as cost effective preferred brand for PF sodium hyaluronate eye drops. ○ Blood glucose monitoring meter formulary - awaiting PrescQIPP publication. Due to high volume of FOI requests the review date is extended for 6 months. <p>MHRA drug safety update:</p> <ul style="list-style-type: none"> ○ Messaged inserted to CNS formulary chapter and ADHD shared care guideline. Methylphenidate long-acting (modified-release) preparations: caution if switching patients between different long-acting formulations of methylphenidate due to differences in formulations. Prescribe by brand. <p>Guideline Timetable - The guideline table action summary and progress was noted by JAPC.</p> <ul style="list-style-type: none"> ○ OPAT – The committee agreed for the review date extension of March 2023 	SD
11.	JAPC BULLETIN	
	The September 2022 bulletin was ratified.	SD
12.	MHRA DRUG SAFETY UPDATE	
	<p>The MHRA Drug Safety Alert for September 2022 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> ● Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations Prescribers and dispensers should use caution if switching patients between different long-acting formulations of methylphenidate (Concerta XL, Medikinet XL, Equasym XL, Ritalin LA, and generics) as different instructions for use and different release profiles may affect symptom management. ● Rucaparib (Rubraca ▼): withdrawal of third-line treatment indication The third-line treatment indication for rucaparib has been withdrawn following a review of the findings of the ARIEL-4 trial, which showed lower overall survival for rucaparib treatment versus standard chemotherapy in patients with high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. 	

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	<ul style="list-style-type: none"> • Covid-19 vaccines and medicines: updates for September 2022 <ul style="list-style-type: none"> ○ The MHRA have approved the Pfizer/BioNTech bivalent COVID-19 Vaccine as a booster after it was found to meet our standards of safety, quality and effectiveness. The brand name for the bivalent vaccine is Comirnaty Original/Omicron BA.1. ○ MHRA statement: COVID-19 vaccines are safe and effective during pregnancy and breastfeeding - MHRA reassure the public that their advice has not changed. MHRA advice remains that the COVID-19 vaccines are safe and effective during pregnancy and breastfeeding and there is substantial evidence to support this advice. ○ MHRA continue to publish the summaries of the Yellow Card reporting for the COVID-19 vaccines being used in the UK. The report summarises information received via the Yellow Card scheme and includes other data such as usage of COVID-19 vaccines and relevant epidemiological data. The report is updated regularly to include other safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy. ○ Report suspected side effects to medicines, vaccines, medical device and test kit incidents used in coronavirus (COVID-19) testing and treatment using the dedicated Coronavirus Yellow Card reporting site or via the Yellow Card app. 	
13.	HORIZON SCAN	
a.	<p><u>Monthly Horizon Scan</u> 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"> • <u>Ambrisentan</u> (<i>Volibris</i>) – classified as RED • <u>Avacopan</u> (<i>Tavneos</i>) – classified as RED • <u>Dupilumab</u> (<i>Dupixent</i>) – classified as RED, DNP for other indications as per NHSE commissioning intentions • <u>Pembrolizumab</u> (<i>Keytruda</i>) – classified as RED, DNP • <u>Tebentafusp</u> (<i>Kimmtrak</i>) – classified as RED as per NHSE commissioning intentions • <u>Trastuzumab deruxtecan</u> (<i>Enhertu</i>) – classified as RED • <u>Zanubrutinib</u> (<i>Brukinsa</i>) – classified as RED <p>New indications in the UK:</p> <ul style="list-style-type: none"> • Botulinum A toxin (Botox) – classified as RED • <u>Axicabtagene ciloleucel</u> (<i>Yescarta</i>) – classified as RED as per NHSE commissioning intentions • <u>Botulinum A toxin</u> (<i>Dysport</i>) – classified as RED • <u>Nivolumab</u> (<i>Opdivo</i>) – classified as RED, DNP • <u>Tisagenlecleucel</u> (<i>Kymriah</i>) – classified as RED <p>New formulation launches in the UK:</p> <ul style="list-style-type: none"> • <u>Budesonide</u> (<i>Jorveza</i>) – classified as RED <p>Approved in the UK:</p>	

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	<ul style="list-style-type: none"> • <u>Ambrisentan</u> (<i>Volibris</i>) – classified as RED • <u>Birch bark extract</u> (<i>Filsuvez</i>) – classified as DNP await clinician request • <u>Gozetotide</u> (<i>Locametz</i>) – classified as DNP await clinician request • <u>Lonafarnib</u> (<i>Zokinvy</i>) - classified as DNP await clinician request • <u>Lutetium (177Lu) vipivotide tetraxetan</u> (<i>Pluvicto</i>) – classified as RED • <u>Olipudase alfa</u> (<i>Xenpozyme</i>) – classified as RED 	
14.	NICE SUMMARY	
	<p>Mrs Qureshi informed JAPC of the comments for the ICB which had been made for the following NICE guidance in September 2022:</p> <p>ICS commissioned drugs: TA824 Dexamethasone intravitreal implant (Ozurdex) for treating diabetic macular oedema (partial review of NICE TA349) – classified as RED (as per NICE TA824)</p> <p>TA826 Vedolizumab for treating chronic refractory pouchitis after surgery for ulcerative colitis (terminated appraisal) – classified as DNP (as per NICE TA826)</p> <p>NHSE Commissioned drugs: TA822 Melphalan for haematological diseases before allogeneic haematopoietic stem cell transplant (terminated appraisal) – classified as DNP (NHS England as per NICE HST21)</p> <p>TA823 Atezolizumab for adjuvant treatment of resected non-small-cell lung cancer RED (NHS England as per NICE TA823)</p> <p>TA825 Avacopan for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis RED (NHS England as per NICE TA825)</p>	
15.	MINUTES OF OTHER PRESCRIBING GROUPS	
a.	<ul style="list-style-type: none"> • Medication Optimisation Safety Team 28/07/2022 • Sheffield Area Prescribing Group 21/07/2022 	
16.	TRAFFIC LIGHTS – ANY CHANGES?	
	<p>Classifications</p> <p>Trazodone – GREEN - Step 2 of antidepressant guideline.</p> <p>Vortioxetine – GREEN - reclassified from RED to GREEN. For use in step 3 of antidepressant guideline, for patients who respond partially to serotonergic antidepressants but do not tolerate some side effects e.g., sexual dysfunction and nausea.</p> <p>Duloxetine – GREY for depression as alternative to venlafaxine for patients with previous history of antidepressant benefit.</p> <p>Phenelzine – GREEN after specialist initiation - Step 3 of antidepressant guideline.</p> <p>Amisulpride – GREEN after specialist initiation for psychosis. Specialist recommendation for chronic depression (low dose, NG222).</p> <p>Haloperidol – GREEN after specialist initiation for psychosis, bipolar disorder (CG185).</p> <p>Risperidone – GREEN after specialist initiation for psychosis, bipolar disorder (CG185), adjunct to antidepressant in unipolar depression.</p>	

Item		Action
	<p>Sulpiride – GREEN after specialist initiation for psychosis.</p> <p>Trifluoperazine – GREEN after specialist initiation for psychosis.</p> <p>Aripiprazole – GREEN after specialist initiation for psychosis, bipolar disorder (CG185), depression.</p> <p>Olanzapine – GREEN after specialist initiation for psychosis, bipolar disorder (CG185), depression.</p> <p>Quetiapine – GREEN after specialist initiation for psychosis, bipolar disorder (CG185), depression.</p> <p>Chlorpromazine – GREEN after specialist initiation for psychosis.</p> <p>Flupentixol – GREEN after specialist initiation for psychosis.</p> <p>Zuclopenthixol – GREEN after specialist initiation for psychosis.</p> <p>Promazine – GREY to be prescribed within licensed indications.</p> <p>Lurasidone – RED for psychosis and bipolar depression.</p> <p>Flupentixol decanoate – RED</p> <p>Haloperidol decanoate – RED</p> <p>Zuclopenthixol decanoate – RED</p> <p>Paliperidone (Xeplion®) – RED</p> <p>Duplimumab – RED for the use in children 6 to 11 years old as add-on maintenance treatment for severe asthma with type 2 inflammation. NHSE commissioned.</p> <p>Tebentafusp – RED for monotherapy for the treatment of human leukocyte antigen A*02:01 positive adults with unresectable or metastatic uveal melanoma. NHSE commissioned.</p> <p>Axicabtagene ciloleucel – RED for treatment of adults with relapsed or refractory follicular lymphoma after ≥3 lines of systemic therapy. NHSE commissioned.</p> <p>Birch bark extract (<i>Filsuvez</i>) – DNP for treatment of pulmonary arterial hypertension in adults, adolescents and children (aged ≥8 to <18 years) of WHO Functional Class II to III, including use in combination treatment [new 2.5mg tablet formulation].</p> <p>Gozetotide (<i>Locametz</i>) – DNP for treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa in patients aged ≥6 months.</p> <p>Lonafarnib (<i>Zokinvy</i>) – DNP for the Identification of prostate-specific membrane antigen-positive lesions by positron emission tomography in adults with prostate cancer, after radiolabelling with gallium-68.</p> <p>Dexamethasone (Ozurdex) – RED as per NICE TA824 for treating diabetic macular oedema.</p> <p>Vedolizumab - RED as per NICE TA826 for treating chronic refractory pouchitis after surgery for ulcerative colitis (terminated appraisal).</p> <p>Melphalan – DNP as per NICE TA822 for haematological diseases before allogeneic haematopoietic stem cell transplant (terminated appraisal).</p> <p>Atezolizumab – RED as per NICE TA823 for adjuvant treatment of resected non-small-cell lung cancer.</p> <p>Avacopan – RED as per NICE TA825 for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis.</p>	
16.	ANY OTHER BUSINESS	
a.	Mr Dhadli informed the committee of a notification of supply shortages for dulaglutide (all strengths) that has limited supplies until January 2023, and	SD

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Item		Action
	semaglutide (1mg) that is out of stock until mid-October. The recommendation is that no new patients should be started on these treatments until adequate stock levels are available.	
17.	DATE OF NEXT MEETING	
	Tuesday 13 th December 2022, papers are to be circulated and agreed virtually as per JAPC interim Terms of Reference, which is effective during the COVID-19 pandemic.	