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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 11th August 2020

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Danazol	RED discontinuation of licensed drug as per CAS alert. Prescribing for off-label and licenced indications to remain with the specialist
Roflumilast	BROWN after respiratory consultant/specialist initiation. NICE TA461: (replaces TA244 - negative appraisal) Roflumilast for treating chronic obstructive pulmonary disease. Patients care to be transferred to primary care after 3 months under the respiratory consultant/specialist when the patient is stable and free from adverse effects.
Oxybutynin IR	GREEN 1st line standard/Immediate Release (IR) preparation for urinary incontinence.
Oxybutynin MR	BROWN Modified Release (MR) preparation. The MR preparation should only be used if the IR is unsuitable (i.e. for those who may be at higher risk of sudden deterioration in their physical or mental health).
Solifenacin	GREEN 2nd line for urinary incontinence
Trospium IR	GREEN 3rd line for urinary incontinence
*Trospium MR	BROWN Modified Release (MR) preparation.
Tolterodine IR	GREEN 3rd line: Immediate Release (IR) for urinary incontinence
Tolterodine MR	BROWN Modified Release (MR) preparation, significantly more expensive than IR preparation. (Neditol XL® is the preferred branded generic of tolterodine MR across Derbyshire).
Propiverine IR/MR	BROWN Immediate Release (IR)/Modified Release (MR) preparations alternate options for urinary incontinence.
Darifenacin MR	BROWN alternate option for urinary incontinence
Fesoterodine MR	BROWN alternate option for urinary incontinence
Mirabegron	BROWN NICE TA290: an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects
Atezolizumab	RED NICE TA638: with carboplatin and etoposide for untreated extensive stage small cell lung cancer. NHS England commissioned
Atezolizumab	RED NICE TA639: with nabpaclitaxel for untreated PDL1-positive, locally advanced or metastatic, triple-negative breast cancer. NHS England commissioned

***Post meeting note**

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Derbyshire Medicines Management Shared Care and Guideline Group Traffic Lights

Drug	Decision
FIASP (Insulin Aspart)	GREEN specialist recommendation. Now for use in children (>1 year) as well as adults, as per license extension.
Ferrous fumarate	GREEN 322mg tablet is the preferred formulary choice. 140mg/5ml oral solution SF solution
Sodium feredetate	GREEN oral solution (alternative if unable to tolerate ferrous fumarate)
Folic acid	GREEN 5mg tablet
Hydroxocobalamin	GREEN 1mg injection
Potassium	GREEN Kay-Cee-L syrup (Sando-K effervescent tablets

Clinical Guidelines

Primary Care management of Overactive Bladder (OAB) guideline – partial update to include price changes most notably for solifenacin.

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Present:	
Derby and Derbyshire CCG	
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
Ms J Savoury	Assistant Chief Finance Officer
Derby City Council	
Derbyshire County Council	
University Hospitals of Derby and Burton NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr D Moore	Lead Pharmacist Commissioning & High Cost Medication
Derbyshire Healthcare NHS Foundation Trust	
Mr S Jones	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms A Braithwaite	Chief Pharmacist
Derby and Derbyshire Local Medical Committee	
Dr K Markus	Chief Executive Officer
Derbyshire Health United	
Staffordshire and Stoke-on-Trent CCG's	
Ms S Bamford	Medicines Optimisation Senior Lead Pharmacist
In Attendance:	
Mrs P Dhillon	Chief Pharmacy Technician – Interface (DDCCG & UHDBFT)
Mrs K Rogers	Derby and Derbyshire CCG Senior Administrator (minutes)

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Item		Action
1.	**APOLOGIES**	
	Ms A Reddish, Ms J Derricott, Dr R Gooch	
2.	**DECLARATIONS OF CONFLICTS OF INTEREST**	
	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. 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.	**MINUTES OF JAPC MEETING HELD ON 14 JULY 2020**	
	The minutes of the meeting held on 14th July 2020 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Immunomodulating drugs monitoring** Mr Moore advised that a discussion will be taking place with the University Hospitals of Derby and Burton NHS Foundation Trust (UHDBFT) on 12th August 2020 to gain consensus as to why the trust has chosen to follow different DMARD monitoring guidelines to those set out within the national Specialist Pharmacy Service (SPS) guidance. This will be discussed at the September 2020 JAPC meeting.	**DM**
6.	**JAPC ACTION SUMMARY**	
a.	**Continence guidance** Mr Dhadli confirmed that the continence guidance action has currently been put on hold due to the COVID-19 pandemic. When there is capacity to do so, Ms H Greaves Lead Clinical Nurse will plan a meeting with the continence team at UHDBFT, to discuss why continence nurses are not complying with some of the formulary choices. **H2A/PPI guidance** Mr Dhadli confirmed that the H2A/PPI guidance is an agenda item which will be discussed in detail, further into the meeting.	
7.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**Danazol** Mr Dhadli advised that Sanofi have discontinued danazol from the UK market in December 2019 and supplies are no longer available. Another manufacturer, Mylan, have identified a problem with the active pharmaceutical ingredient which has led to the discontinuation of danazol capsules in the UK and supplies of all strengths are now exhausted. The Department of Health and Social Care (DHSC) has released a Supply Disruption Alert, this highlights that danazol is used for various indications which include use in licensed and unlicensed treatments. The alert recommends that clinicians should not initiate new patients on danazol, GPs should identify all patients prescribed danazol and secondary care should	

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	consider ordering unlicensed supplies of danazol 100mg and 200mg capsules. There is currently a small amount of prescribing in primary care. A suggestion was made to assign a traffic light classification to danazol and look to consider whether it should be prescribed in primary care or whether it is more suitable for secondary care. Chesterfield Royal Hospital NHS Foundation Trust (CRHFT) reported a small number of patients under dermatology who will be maintained on an unlicensed supply of danazol by the hospital. UHDBFT have a small number of patients being treated for mastalgia, where it may be appropriate for their medication to be changed to tamoxifen as an alternative. Dr Markus asked how many prescriptions have been issued in primary care and should these patients be reviewed, Mr Dhadli responded to say that EPACT data over the last 12 months would indicate approximately 7 patients have been issued a prescription for this. Mrs Needham advised that these patients have been identified and reviewed and the outcome of this was that the hospital wished for them to remain on danazol. Mrs Needham also informed the committee that danazol is classified as RED in Nottingham and it is not classified in Sheffield, therefore the recommendation should be that prescribing stays with the specialist within the out of area prescribing guidance. Ms Braithwaite questioned whether the timing of this potential change would be appropriate under the current circumstances during the COVID-19 pandemic. A discussion took place and the committee acknowledged that in addition to clinical monitoring in all patients, appropriate laboratory monitoring should be considered which may include periodic measurement of hepatic function and haematological state. For long-term treatment (>6 months) or repeated courses of treatment, biannual hepatic ultrasonography is recommended. The JAPC committee agreed for danazol to be classified as RED, GP practices are to discuss not necessarily referral, with specialists whether alternative treatment options are appropriate and the repatriation of patients. **Agreed:** JAPC classified danazol as **RED**.	**SD**
b.	**<u>Roflumilast</u>** Mr Dhadli reported that Mr A Hardy, principle pharmacist at CRHFT has requested a change to the current RED traffic light classification of roflumilast, to allow ongoing prescribing in primary care. Roflumilast is a phosphodiesterase type-4 inhibitor with anti-inflammatory properties recommended by NICE TA461. It is used as an add-on to bronchodilator therapy in patients with severe COPD in adults with chronic bronchitis, if the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, and the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy. Treatment is initiated by consultants in respiratory medicine; therapy is generally well tolerated however weight loss and gastrointestinal adverse effects can lead to discontinuation in some patients. All patients started on roflumilast will have respiratory follow ups to monitor clinical efficacy and adverse effects. If treatment is not tolerated then it is stopped and only continued if a patient demonstrates benefit. Patients are	

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	reviewed on a 3-6 monthly basis depending on stability. The Medicines and Healthcare products Regulatory Agency (MHRA) in 2014 looked at roflumilast and the risk of suicidal behaviour. It was recommended that roflumilast is not prescribed for patients with a history of depression associated with suicidal ideation or behaviour, patients and caregivers should be asked to notify the prescriber and their healthcare provider of any changes to behaviour or mood, and any suicidal ideation. Roflumilast should be discontinued if new or worsening psychiatric symptoms or suicidal behaviour are identified. CRHFT have reported 25 patients currently being treated with roflumilast. CRHFT pharmacy supplies roflumilast directly to patients through outpatient prescriptions. UHDBFT do not have any patients on this drug at present. Experience of using roflumilast at UHDBFT is very limited. Dr. G Lowrey, Respiratory Consultant, ImpACT+ UHDBFT, has reported use in one patient only and it wasn't tolerated due to side effects. Its use would be considered as one of the last options for exacerbators. Dr W Elston, Respiratory Consultant UHDBFT also agrees with this. In local neighbouring areas Leicestershire, Nottinghamshire and Greater Manchester classify roflumilast as the Derbyshire equivalent of GREEN specialist initiation/recommendation. It is classified as AMBER in Sheffield and RED in South Staffordshire. EPACT data shows there is a low level of prescribing even with the current classification of RED. The annual cost of prescribing for 25 patients was discussed and it was agreed that this did not have a significant impact on budget. NICE TA461 (August 2017) suggests no significant resource impact is anticipated, the expected uptake of the technology is small because the therapy should only be started by specialists in secondary care, and the unit cost for the intervention is small. Further information from Mr A Hardy goes on to state that respiratory will be responsible for patient follow ups for 6 to 12 months, the respiratory clinic would usually monitor the patient after the first prescription at 2 to 3 months then further monitoring would depend on underlying disease needs. Mr Hardy has also included some guidance for primary care which advises that ongoing GP prescribing and care of patients on roflumilast should only be considered if the patient is stable and free from adverse reactions, after a minimum of 3 months treatment under the respiratory specialist. A clinic letter from the specialist should highlight an assessment of any potential adverse effects including weight loss and psychiatric symptoms, response to treatment and reason for continuation of treatment. Contact details for the respiratory specialist should be provided in the clinic letter. The recommendation is to change the classification of roflumilast from Red to Brown specialist initiation as per NICE TA461. The hospital would manage the first 3 months supply to ensure tolerability and dose titration prior to transferring the prescribing to primary care. Drug information is to be included in the COPD guidance. A discussion took place in regards to whether this should be considered as a shared care agreement due to the increased monitoring involved, however it was agreed that this would not be appropriate as the monitoring surrounded the disease more so than the drug. It was also questioned whether the drug should be moved from a RED	

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	classification if patients are receiving follow up appointments with a specialist, however members of the committee confirmed that patients will not necessarily receive follow up appointments at the respiratory clinic if their disease is stable once on roflumilast and if the disease is managed in primary care it may negate the need for an appointment at the respiratory clinic. It was also noted that it may be difficult for primary care to carry out 12 monthly reviews for these patients. The committee were in agreement for roflumilast to be classified as BROWN consultant/specialist initiation, with patients care to be transferred to primary care after 3 months roflumilast treatment under the Respiratory Consultant/Specialist. The COPD guideline will be updated to reflect this. **Agreed:** JAPC classified roflumilast as **BROWN after Respiratory Consultant/Specialist initiation:** NICE TA461: Roflumilast for treating chronic obstructive pulmonary disease as add on to triple therapy. Primary care continuation of prescribing after consultant/specialist 3 month assessment of efficacy and no adverse effects.	**SD** **SD**
8.	**CLINICAL GUIDELINES**	
a.	**<u>BLACK drugs policy</u>** Mr Dhadli advised that there was a need to review and update the Derbyshire BLACK drugs policy (first produced in August 2018) and to consider expectations of managing the Individual Funding Request (IFR) process. The current BLACK drugs policy advises clinicians to submit an IFR if the clinician feels the patient is exceptional and wishes to initiate/continue a BLACK drug. It also clearly defines 'exceptional clinical circumstances' and provides relevant advice regarding submitting an IFR. Derby and Derbyshire CCG are receiving a number of IFR requests for branded medicines, which are being screened out as these requests fall outside of IFR definitions. Mr Dhadli highlighted to JAPC members that the completion of the form requires time from clinicians, NHS resources into the IFR process and also may unnecessary raise patient expectations. As a result of this there is question over the usefulness of the BLACK drugs policy document and whether or not it is being referred to. Consideration needs to be given as to how this can be amended to reflect the best use of time for clinicians and the IFR team. Mr Dhadli felt that as the document does clearly define 'exceptional clinical circumstances' the only thing that may add further value would be to include a reference to branded medicines. A discussion took place and it was agreed that most patients are very unlikely to meet the criteria for IFR; therefore clinicians can use the BLACK drugs policy to support that conversation with patients to evidence this. There was general consensus that some clinicians are utilising IFR referrals to support them in stopping prescribing a BLACK drug. It was suggested that a review take place of the black drugs list. The second part of the discussion needed was Mr Dhadli informed the committee that in light of Black Lives Matter and equality and diversity, a concern had been raised in regards to utilising the category 'BLACK' for drugs that are recommended not to be prescribed, within the Derbyshire traffic light classification list.	

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	The Drug Tariff Part XVIIIA list drugs, medicines and other substances that may not be ordered under the National Health Service, were historically known as the 'blacklist' and Derbyshire JAPC traffic light classification terminology derived from this. The Drug Tariff no longer refers to the 'blacklist' however; the NHS has not completely stopped the terminology of using the word BLACK as an alert. The BLACK triangle is something that is still used currently in Central Alerting Systems (CAS). This was raised with Ms C Haynes, Involvement Manager DDCCG to see if it is something that needs to be reviewed within the organisation or whether there is a discussion underway at a national level. Consideration was given to what other areas do, most CCG's do use a traffic light classification, however they also include other colours such as grey. It was noted that the Derbyshire Medicines Management website is a public facing website where the classification of drugs and further information surrounding this can be found. GP's can use this website to inform patients and direct them to it. There have not been any complaints to date; the concern had been raised by a GP. Consideration also needs to be given as to whether a review is needed for the BROWN traffic light classification. These classifications are embedded across decision making, across all JAPC guidelines, the Derbyshire Medicines Management website, GP clinical systems etc. Ms C Haynes will be taking this discussion to the Derbyshire County Council BME forum; JAPC will await feedback from this. Mr Dhadli has also contacted NHS England and SPS however he has not had a response to date. A discussion took place and committee members agreed that this will be a matter of when and how the Traffic Light Classifications names are reviewed and updated. RED, AMBER and GREEN classifications are likely to remain with a view to consider appropriate alternative colours/symbols/terminology to replace BLACK/BROWN. Options are to be considered in further detail at the September 2020 JAPC meeting, including scope of work and practicality of a change.	**SD**
b.	**<u>Overactive bladder (OAB)</u>** Mr Dhadli reported that this is a partial update to primary care management of the Overactive Bladder (OAB) guideline due to significant price changes to solifenacin and tolterodine. Wider consultation has been sought on this and Mr Dhadli has received feedback from Urologists at UHDBFT, CRHFT and Ms H Greaves, Lead Clinical Nurse Specialist Continence Derbyshire Community Health Services NHS Foundation Trust (DCHSFT). NICE NG123 Urinary incontinence in women states to offer the anticholinergic medicine with the lowest acquisition cost to treat overactive bladder or mixed urinary incontinence in women [2019]. Evidence suggests there is little difference between OAB drugs in terms of efficacy. In regards to side effects, solifenacin has a better effect and less risk of dry mouth compared to tolterodine. Mr Dhadli referred to a table titled oral antimuscarinic drugs for OAB, in paper 8b where information showed that the Anticholinergic Burden Scale are much the same and both solifenacin and oxybutynin are very cost effective, with tolterodine being more costly than trospium. Mr Dhadli also advised that non-pharmacological/lifestyle advice has been added to the guideline.	

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	Agreed: JAPC classified oxybutynin IR **GREEN** 1st line, solifenacin **GREEN** 2nd line, trospium IR **GREEN** 3rd line, tolterodine IR **GREEN** 3rd line, all other products including oxybutynin MR to be classified as **BROWN** (see traffic light classifications for full list)	**SD**
	Agreed: JAPC ratified the partial update to Primary Care Management of Overactive Bladder guideline	**SD**
c.	**Chronic pain** Mr Dhadli stated that NICE is consulting on its draft guidance for chronic pain, which is now open to public consultation until 14th September 2020. It states that people with chronic primary pain should be offered supervised group exercise programmes, some types of psychological therapy, or acupuncture (option for some people with chronic primary pain, provided it is delivered within certain, clearly defined parameters). Pharmacological treatments which should not be offered for chronic primary pain because there is little or no evidence that these treatments work and could have possible harm include opioids, NSAIDs, benzodiazepines, antiepileptic drugs including gabapentinoids, local anaesthetics, local anaesthetics/corticosteroids combinations, paracetamol, ketamine, corticosteroids and antipsychotics. The Derbyshire JAPC non-malignant chronic pain in primary care guideline has been compared with the NICE draft guidance. The draft guidance refers to definitions of chronic pain and chronic primary pain. It also refers to the ICD-11 definition. In regards to non-pharmacological management of chronic primary pain the draft guidance mentions psychological therapies and acupuncture or dry needling. Where pharmacological treatment is discussed it states to consider antidepressant (duloxetine, fluoxetine, paroxetine, citalopram, sertraline or amitriptyline) after full discussion of benefits and risks. Mr Dhadli has been considering how JAPC can comment on this and suggested that feedback and views are sought from the pain consultants and other consultees across the Derbyshire system so that a co-ordinated response can be developed and sent to NICE. Dr Goddard advised that currently there is not good access to psychological therapies and acupuncture therefore patients need to be offered an alternative, he suggested that investment is needed in alternative therapies. Ms Bamford highlighted that NICE discourage the use of opioids if alternative treatments are not affective. **Action:** Mr Dhadli advised that he will co-ordinate a response to NICE on behalf of DDCCG, once feedback from the pain consultants has been received and comments are agreed.	**SD**
9.	**MISCELLANEOUS**	
a.	**Buccal Midazolam** Mr Dhadli reported that there are two preparations of buccal midazolam that are available, which are Epistatus and Buccolam. Concerns have been raised by a consultant neurologist at Sheffield Teaching Hospital who has informed JAPC of a significant incident where a patient in	

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	Derbyshire was prescribed Buccolam instead of Epistatus by a GP for several months without the treatment protocol being updated. The concerns raised include JAPC BLACK traffic light classification status for Epistatus, switching from Epistatus (10mg/ml) to Buccolam (10mg/2ml), especially in adults and communications to GPs regarding switching preparations. As a result of this, it has been tabled at JAPC to reconsider the cost, safety and efficacy of Buccolam. Mr Dhadli confirmed that both products are licenced in children under the age of 18 years and both unlicensed in the 18s and over, however Buccolam is the most cost effective option. DDCCG Medication Safety pharmacists and provider trusts have recently been consulted with to enquire if there have been any reports of errors involving Buccolam/Epistatus transition. There has not been any reports involving transition of Epistatus to Buccolam via NRLS or reported by practice teams directly to DDCCG in the last 2 years. A further safety issue considered by JAPC, at the time of the change, was the potential risk of having two preparations with different strength and training requirements across the Derbyshire health economy, therefore it was recommended to gradually move all patients to one preparation - Buccolam. JAPC recognised the risk of prescribing two different products and formulations, with different strengths and administration requirements for adults and children, and also the risks associated with any change. Thus it was recommended that there should be a gradual change, supplemented by having appropriate training plans in place. The decision to assign BLACK traffic light status to Epistatus was reached at the JAPC meeting in May 2018, in the presence of acute trust representatives, and after extensive consultation with specialists. This was after a long period of review and negotiation with stakeholders to ensure an appropriate training package was in place before the change. A primary care prescribing guidance was made available. For an interim period of four years (May 2014 – April 2018) Epistatus was assigned a BROWN traffic light classification (use in exceptional circumstances) for transition of new patients to start. The committee were in agreement that the existing traffic light classification – Epistatus BLACK, Buccolam GREEN specialist initiation will remain, however communication will be included in the next JAPC bulletin to primary care, to reinforce the message that Buccolam is the preferred choice and the importance of education and training before switching, this includes having an up-to-date care plan in place at the next review with the specialist.	**SD** **SQ**
b.	**<u>H2 Antagonist and PPI</u>** At previous JAPC meetings, discussions have taken place regarding the supply issue with all H2 antagonists. PPI's are recommended as an alternative. If a PPI is unsuitable then other cost effective H2 antagonists must be considered. UHDBFT are in the process of producing a H2 antagonists/PPI guidance. Dr Goddard highlighted types of patients who may require a H2 antagonist: Those needing acid suppression who are genuinely allergic or intolerant or contraindicated to all PPIs, which is rare. Those needing acid suppression where low magnesium occurs, which is felt as very rare. If the patient has critical acid related disease (e.g. recurrent oesophageal stricture, severe	

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	oesophagitis, persistent ulcer, etc.) then an ongoing H2 blocker is needed as the patient will otherwise get further complications/admissions/interventions. For those who have needed upward titration for reflux symptoms despite high dose PPIs, where addition of a H2 blocker (generally at night time) helps, the patient would be recommended to go back to PPI and antacids. Patients suitable for antireflux procedures should be referred at this point, but generally the H2+PPI combination is used for those not suitable for this, or who would not do well with antireflux surgery (e.g. elderly frail etc. and those where there is a functional element to symptoms). This advice will be incorporated into the Gastro-Oesophageal Reflux Disease (GORD) guideline on the Derbyshire Medicines Management website.	**SD**
c.	**<u>Luteinizing hormone-releasing hormone (LHRH)</u>** Mr Dhadli informed the committee that a paper has been submitted by the Enhanced Service Review Group in regards to changing the process of LHRH first dose administration from secondary care to primary care on request of Royal Derby Hospital (RDH) Urology. Wider consultation has been sought which includes input from the Local Medical Committee (LMC), Consultant Urologists at both UHDBFT and CRHFT and Ms L Merriman GP Cancer Lead. RDH and CRHFT currently use a different process to Queens Hospital Burton (QHB). In view of COVID-19 infection risk posed by multiple visits to hospital, and to align practice across UHDBFT, urologists at RDH have asked if it would be possible to move to the same process used by QHB urologists. CRHFT have indicated they would support and follow the new process with RDH if the change is agreed. Currently at RDH men with metastatic disease are seen in outpatient clinics and initiated on bicalutamide and supplied a LHRH. These patients are asked to return to clinic after 1 week to have their injection administered and then the GP is asked to continue prescribing the 3 monthly injection. Conversely, at QHB patients have their initial appointment and are issued the bicalutamide, the GPs are then asked to prescribe and administer the 3 monthly injection 7-14 days after the bicalutamide has been initiated. Timeliness has also been assessed from hospital to GP practice. Patients will be counselled to contact their GP as soon as possible and to take a copy of their outpatient letter to the GP with medication issued at their first appointment in hospital. The timeline between the 1st and 2nd appointment is 21 days, as such the patient will have this time frame to book an appointment as the injection needs to be administered at the 2nd appointment between days 14 to 21. The new proposed process will emphasise that the patient is expected to contact their practice immediately to arrange an appointment to avoid missed doses or delay in administration of the first dose. The patient will be advised to take a copy of their outpatient letter to the GP for their second appointment. A hospital prescription for bicalutamide tablets and a 3 monthly LHRH injection will be issued during the appointment and taken home by the patient. LHRH injection is taken to the GP practice by the patient for their 2nd appointment for administration. The first LHRH injection is to be administered once the patient has received at least 7 days of the bicalutamide and no later than 14 days after initiation of the bicalutamide. Mr Dhadli advised that this has been tabled at JAPC to acknowledge the	

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	change in the treatment pathway and the discussion of practicalities elsewhere within the CCG. Dr Markus added that she has been involved in discussions about this and as GP's initiate LHRH analogues to patients on an ongoing basis, it would appear reasonable for primary care to administer the first dose. It was requested that the hospital issue the first prescription and the patient is given responsibility for booking an appointment with their GP, as there can be a delay in the letter arriving from the clinic. Dr Markus pointed out a discrepancy in the paper as it states that the first LHRH injection is to be administered no later than day 14 after initiation of the bicalutamide, however the paper also states that the injection needs to be administered at the 2nd appointment between days 14 to 21. Due to the COVID-19 pandemic, finding appointment slots for patients may be more difficult than usual in primary care, therefore it may cause problems if administration of the injection were to take place by day 14. It was also highlighted that if a patient does not book an appointment, clarification is needed as to where the responsibility lies for contacting the patient to follow this up. The JAPC classification of GREEN consultant/specialist initiation to remain for leuprorelin, goserelin and triptorelin**. JAPC members were happy to support this proposal subject to the Enhanced Service Review Group giving final agreement once outstanding issues have been resolved. Mr Dhadli advised that he will add this to the JAPC action summary and liaise with Ms K Marira, Senior Pharmacist Outcomes and Contracts DDCCG as to when this is agreed and confirmed. It will then be communicated through the JAPC bulletin to raise awareness of the service change. **Agreed:** Leuprorelin, goserelin and triptorelin **to remain as GREEN after consultant/specialist initiation**.** ****Post meeting note**	**SD** **SD**
10.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Shared Care and Guideline Group meeting held in July 2020 was noted. Mr Dhadli highlighted the following: Traffic Lights: • FIASP (Insulin Aspart) – classified as GREEN specialist recommendation. Now for use in children (>1 year) as well as adults, as per license extension. • Ferrous fumarate – classified as GREEN 322mg tablet is the preferred formulary choice. 140mg/5ml oral solution SF solution. • Sodium feredetate – classified as GREEN oral solution (alternative if unable to tolerate ferrous fumarate). • Folic acid – classified as GREEN 5mg tablet • Hydroxocobalamin – classified as GREEN 1mg injection • Potassium – classified as GREEN Kay-Cee-L syrup (Sando-K effervescent tablets Formulary Update (Chapter 9 – Nutrition and Blood):	

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	• Ferrous fumarate 322mg tablets replace 305mg capsules as the cost effective formulary choice. Information on dosing has been added. • Strivit D3 replaces Fultium D3 as the cost effective choice of vitamin D treatment choice. Information on suitability for people with nut/soya allergy and special diets has been added. Clinical Guidelines: • ACS dual antiplatelet – NSTEMI/unstable angina and STEMI guideline review date extended to January 2021 to coincide with NICE ACS guideline update November 2020. • GORD in children – acidex advance replaces gaviscon advance; lansoprazole is the cost effective choice of PPI (guidance contains prescribing information for both). Website Changes/Miscellaneous: • Ibandronate 50mg tablet traffic light status updated to remove RED as this is historical and duplicate indication in breast cancer (GREEN specialist initiation). • Black drugs policy – reviewed with no change. • Cover administration of medicine – updated with no major change. • Medicines in short supply – updated with no major change. • Opioid resources – new section added on the Derbyshire Medicines Management website under clinical guidelines. This includes implementation resources such as patient agreement templates and patient information leaflets. • Valproate Medicines PPP pathway – removed as the process is now embedded and the document is no longer being referred to. Guideline Timetable: • The guideline table action summary and progress was noted by JAPC.	
11.	**REGIONAL MEDICINES OPTIMISATION COMMITTEE (RMOC)**	
a.	**Biologics for sequential use** Mr Dhadli stated that biologic cancer medicines are excluded from the biologics for sequential use guidance.	
12.	**JAPC BULLETIN**	
	The July 2020 bulletin was ratified.	**SD**
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for July 2020 was noted for information. This included the following MHRA advice: • Systemically administered VEGF pathway inhibitors: risk of aneurysm and artery dissection A recent European review concluded that all systemically administered VEGF pathway inhibitors may promote the formation of aneurysm and artery dissection. The product information for all systemically administered VEGF pathway inhibitors has been updated to include a warning about the risk of aneurysm and artery dissection and to recommend carefully considering these risks before initiating in patients with risk factors, such as	

Item		Action
	hypertension. • Liposomal and lipid-complex formulations: name change to reduce medication errors Following reports of serious medication errors (some leading to deaths), liposomal and lipid-complex medicines with a high risk of medication error will explicitly include the qualifier 'liposomal', 'pegylated-liposomal', or 'lipid-complex' within their name. This recommendation aims to reduce the risk of mix-up between different formulations of these medicines. The product information and labelling of new injectable liposomal-formulated medicines will also include reference to 'dispersion', which is the accepted descriptor term for these types of formulations. For medicines administered topically or via non-injectable routes, 'liposomal', 'pegylated-liposomal' or 'lipid-complex' will only be added to the name if a clear risk to patient safety has been identified.	
14.	**HORIZON SCAN**	
a.	**Monthly Horizon Scan** Mr Dhadli tabled the following new drug formulations, licence extensions and drug discontinuations at JAPC for information: New formulation launches in the UK: • Daratumumab (Darzalex) – to remain classified as **RED** • Turoctocog alfa pegol (Esperoct) – to remain classified as **RED** (as per NHS England commissioning intentions) • Vedolizumab (Entyvio) – to remain classified as **RED** Licence extensions: • Anakinra (Kineret) – previously classified as **RED** when used for periodic fevers and auto-inflammatory diseases and **BLACK** for all other conditions • Caplacizumab (Cablivi) – previously classified as **RED** (as per NHS England commissioning intentions) • Encorafenib (Braftovi) – previously classified as **RED** • Ivacaftor (Kalydeco) – previously classified as **RED** (as per NHS England commissioning intentions) • Ixekizumab (Taltz) – previously classified as **RED** Drug discontinuations: • Diltiazem (Dilzem XL) • Testosterone (Restandol Testocaps) • Fluocortolone/ cinchocaine (Ultraproct ointment) • Mitomycin-C (Mitomycin-C Kyowa) • Salbutamol (Salamol Steri-Neb) • Selegiline (Zelapar) • Diflucortolone valerate (Nerisone Forte) • Fluocortolone/ cinchocaine (Ultraproct) • Mirtazapine (Zispin Soltab)	
15.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCG which had been made for the following NICE guidance in July 2020:	

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Item		Action
	TA638 Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer – classified as **RED** (as per NICE TA638) TA639 Atezolizumab with nabpaclitaxel for untreated PDL1-positive, locally advanced or metastatic, triple-negative breast cancer – classified as **RED** (as per NICE TA639)	
16.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
a.	• Sheffield Area Prescribing Group 20/02/2020	
17.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Danazol – RED discontinuation of licensed drug as per CAS alert. Prescribing for off-label and licenced indications to remain with the specialist. Roflumilast – BROWN after respiratory consultant/specialist initiation. NICE TA461: (replaces TA244 - negative appraisal) Roflumilast for treating chronic obstructive pulmonary disease. Patients care to be transferred to primary care after 3 months under the respiratory consultant/specialist when the patient is stable and free from adverse effects. Oxybutynin IR – GREEN 1st line standard/immediate release (IR) preparation for urinary incontinence. Oxybutynin MR – BROWN Modified Release (MR) preparation. The MR preparation should only be used if the IR is unsuitable (i.e. for those who may be at higher risk of sudden deterioration in their physical or mental health). Solifenacin – GREEN 2nd line for urinary incontinence. Trospium IR – GREEN 3rd line for urinary incontinence. *Trospium MR – BROWN Modified Release (MR) preparation. Tolterodine IR – GREEN 3rd line: Immediate Release (IR) for urinary incontinence. Tolterodine MR – BROWN Modified Release (MR) preparation, significantly more expensive than IR preparation. (Neditol XL® is the preferred branded generic of tolterodine MR across Derbyshire). Propiverine IR/MR – BROWN Immediate Release (IR)/Modified Release (MR) preparations alternate options for urinary incontinence. Darifenacin MR – BROWN alternate option for urinary incontinence. Fesoterodine MR – BROWN alternate option for urinary incontinence. Mirabegron – BROWN NICE TA290: an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects. Atezolizumab – RED NICE TA638: with carboplatin and etoposide for untreated extensive stage small cell lung cancer. NHS England commissioned. Atezolizumab – RED NICE TA639: with nabpaclitaxel for untreated PDL1-positive, locally advanced or metastatic, triple-negative breast cancer. NHS England commissioned. ***Post meeting note**	
18.	**ANY OTHER BUSINESS**	
a.	**PSD/Flu vaccinations** Mr Dhadli reported that he has received an email from Ms Braithwaite to say	

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Item		Action
	that DCHSFT nurses will administer flu vaccines for 2020/2021 for housebound patients who are age 65 years and over, against a Patient Specific Direction (PSD). This information will be communicated to GP's in the JAPC bulletin.	**SQ**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 8th September 2020 at 1.30pm to be held virtually via Microsoft Teams.	