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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 12 May 2015

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Rivaroxaban 2.5mg	**RED** according to NICE TA 335
Matoride XL	**AMBER** (added to ADHD shared care guideline)
Aclidinium plus formoterol inhaler (Duaklir Genuair)	**BROWN**
Apremilast	**RED**
Bromelain (Nexbrid)	**RED** (specialist tertiary burn centres)
Filgrastim biosimilar (Accofil)	**RED** (NHS England drug)
Follicle stimulating hormone biosimilar (Bemfola)	**RED**

Clinical Guidelines

Children's Asthma Guidance
Adult Asthma Guidance
Bowel Cleansing Products (DTHFT)
Familial Hypercholesterolemia
NSTEMI dual antiplatelet in ACS (CRHFT)
Gastro oesophageal reflux disease in children and young adults

Shared Care Guidelines

Denosumab for the prevention of osteoporotic fractures in men and women with osteoporosis

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
North Derbyshire CCG	
Dr D Fitzsimons	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Ms J Town	Head of Finance
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair - Drugs and Therapeutic Committee
Derbyshire Healthcare NHS Foundation Trust	
Dr S Taylor	Chair – Drugs and Therapeutic Committee
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Mr M Steward	Head of Medicines Management
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Dr R Dewis, Dr C Emslie and Mrs L Hunter.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No relevant declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	No declarations of any other business were made.	
4.	**MINUTES OF JAPC MEETING HELD ON 14 APRIL 2015**	
	The minutes of the meeting held on 14th April 2015 were agreed as a correct record after the following amendments: Dementia: Amend to ' Ms Bassi advised JAPC that the shared care agreements acetylcholinesterase inhibitors donepezil, rivastigmine and galantamine were due to expire in June 2015 and memantine for Alzheimer's disease was due to expire in May 2015.' Escitalopram – Amend point 2 to read 'For patients who have had a good response to escitalopram for a previous episode after trying formulary choices or now require anti-depressant following recommendation from a tertiary centre.' New Oral Anticoagulants - East Midlands Strategic Clinical Network (EMSCN) Guideline – Amend to: ' A clear statement is included in the algorithm to make it clear that no head to head studies have taken place and all anticoagulants in the algorithm are recommended as options by NICE and commissioners may only recommend an individual drug after a patient and prescriber have discussed all the treatment options and only if they have no preference about which medicine they wanted to use.' Traffic Lights – Any Changes? Amend to 'Lamotrigine – GREEN after consultant/specialist initiation.	
5.	**MATTERS ARISING**	
a.	**Rivaroxaban for ACS** Mr Dhadli reported that an email had been received from Dr Justin Cooke, CRH Consultant Cardiologist, who had indicated that they have no plans to use rivaroxaban 2.5mg for acute coronary syndrome at this time, and consequently they intend to continue with dual anti-platelet medication. Dr Goddard stated that the cardiologists at RDH were unclear how it should be used for high risk patients in the absence of any head to head studies, but would like to retain its use as an option. Its place in treatment was being discussed. It was agreed that Rivaroxaban for ACS should be classified as a **RED** drug until CRH and RDH had brought forward a pathway to JAPC for agreement, and the communication with GPs about the length of treatment up to twelve months as referred to in the NICE TAG had been resolved. The traffic light classification would probably be changed to GREEN specialist initiation once an agreed pathway had been developed.	**WG/MS**

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6.	**NEW DRUG ASSESSMENTS**	
a.	**Matoride XL** Dr Taylor reported that Matoride XL was a 12 hour methylphenidate, osmotic controlled, extended release tablet used as part of a comprehensive treatment programme for Attention Deficit Hyperactivity Disorder (ADHD) licensed in children from the age of 6 years and adolescents. Dr Taylor highlighted that Matoride XL was bioequivalent to Concerta XL and it had been discussed by the DHcFT Drugs and Therapeutic Committee which had agreed that GPs could switch from Concerta XL to Matoride XL following a face to face review involving carers and parents in the decision. It had been noted that patients and carers often became anxious when the names and packaging of drugs was changed. During discussion Mr Dhadli commented that Matoride XL was directly comparable to Concerta XL and was more cost effective. It should be placed on the formulary and a decision made about implementation by the CCGs. Mrs Needham highlighted that a switch would probably be a significant amount of work, and this may offset any potential savings. Dr Henn commented that only a minority of patients would be anxious about switching from one branded generic drug to another and therefore there may not be a need for face to face reviews for any switching; this should be a clinical decision. Dr Mott stated that all patients concerned came under shared care and the process of discussing switching could therefore become the responsibility of the clinician in DHcFT as well as in primary care. It was agreed that new patients requiring this medication should be given Matoride XL. **Agreed:** Matoride XL classified as an **AMBER** drug and would be added to the formulary as an alternative to Concerta XL. **Action:** The shared care guideline would be amended to include Matoride XL alongside Concerta XL **Action:** The CCG Prescribing Groups to determine the extent to which a switch of existing patients to Matoride XL should be promoted.	**SD** **SD** **SD**
b.	**Aclidinium + Formoterol (Duaklir Genuair)** Mr Dhadli reported that the combination inhaler of aclidinium and formoterol (Duaklir Genuair) was licensed as a maintenance bronchodilator treatment containing a long-acting muscarinic antagonist (LAMA) and long-acting beta-2 agonist (LABA) to relieve symptoms in adults with COPD. Mr Dhadli commented on past decisions of LABA/LAMA combinations: umeclidinium/vilanterol had previously been classified as BLACK in October 2014 as vilanterol was not available as monotherapy and vilanterol was unclassified. Indacaterol/glycopyrronium had been classified as a BROWN drug in May 2014. The Guideline Group had therefore recommended that Duaklir Genuair be assigned a traffic light classification of brown. NICE had produced a New Medicine Evidence Summary and this had been based on two RCTs (ACLIFORM-COPD and AUGMENT-COPD) which	

Item		Action
	evaluated the efficacy of aclidinium/formoterol compared with placebo and aclidinium and formoterol monotherapies in people with moderate or severe stable COPD over 24 weeks. The summary had included pooled analyses of data from ACLIFORM and AUGMENT taken from the European Public Assessment Report for aclidinium/formoterol. Aclidinium/formoterol had been shown to statistically significantly improve lung function and breathlessness over 24 weeks compared with placebo and aclidinium and formoterol monotherapies. However not all of the comparisons with aclidinium or formoterol monotherapy had been considered to be clinically important using conventional criteria but, according to the European Public Assessment Report for aclidinium/formoterol, improvements in lung function and breathlessness were similar to those seen with the other LAMA/LABA combinations of umeclidinium/vilanterol and indacaterol/glycopyrronium. It was highlighted that significant savings could be made by the use of a combination product over prescribing individual inhalers, where both LAMA and LABA are beneficial to the individual patient. Dr Henn commented that the evidence was quite weak in relation to reduction in exacerbations, whereas the evidence was stronger in this regard for the use of tiotropium. More evidence was needed before a different traffic light classification to the other LABA/LAMA products could be given. **Agreed:** Duaklir Genuair classified as a **BROWN** drug, it is a cost effective option where patients are deriving benefit from both inhalers individually.	
7.	**CLINICAL GUIDELINES**	
a.	**<u>Children's Asthma Guidance</u>** Mrs Qureshi advised JAPC that the Guideline Group had made the following changes to the children's asthma management guidance: Step 3(a) - Move to Seretide 50 MDI 1 puff BD or Symbicort turbohaler 100/6, 1 puff BD. Patients would therefore only receive 100mcg of fluticasone or 200mcg of budesonide. Step 3(b) - Continue LABA and increase ICS dose to a maximum of 400mcg/day BPD or equivalent, either: Seretide 50 MDI 2 puffs BD or Seretide 100 Accuhaler 1 puff BD or Symbicort turbohaler 100/6, 2 puffs BD. Step 3(c) - Stop LABA and increase ICS dose (400mcg/day) if not already at this dose preferred formulary choice would be Clenil 100mcg 2 puff bd. Mr Shepherd queried whether the guidance had been sent to the paediatricians for comment. Mrs Qureshi would let Mr Shepherd have details of the clinicians who had been consulted with. Mr Dhadli highlighted the need for the arrows in the guidance to indicate that children could be stepped up as well as down and that the reference to check inhaler technique and adherence to treatment in step two should apply to all of the steps. Dr Henn requested that the reference in step 3(a) to separate inhaler combinations to allow assessment of the LABA and, in the event that good asthma control was achieved after one month, the move to an appropriate combination inhaler should be promoted due to the risk that children could continue on separate inhalers and therefore not take the inhaled steroid. This was a major risk factor for exacerbations and asthma deaths.	**SQ**

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Item		Action
	Dr Parkin suggested that a copy of the guidance should be sent to the Local Pharmaceutical Committee, who have been active recently with asthma/inhaler use.	**SQ**
	Agreed: JAPC ratified the children's asthma guidance with the agreed amendments. The guidance would be reviewed in July 2017.	**SQ**
b.	**Adult Asthma Guidance** Mrs Qureshi advised JAPC that the Guideline Group had made the following changes to the Adult Asthma Guidance: • Budesonide Easyhaler included throughout steps 1 to 4, to allow another ICS in addition to beclomethasone, and to be consistent with our recommended combination inhalers.	
	Dr Henn highlighted that there was a sub-group of patients who would achieve better control from the use of QVAR beclomethasone inhaler and also requested that a clearer indication of maximum doses be given in the section concerning the flexible dosing regimens of Fostair MART and Symbicort SMART.	**SQ**
	Mrs Needham queried whether the reference to consideration of Tiotropium (Spiriva Respimat) in step 4 for use in patients with airflow obstruction under the supervision of a specialist should be included on the front sheet as this would only affect a minority of patients.	**SQ**
	Agreed: JAPC ratified the adult asthma guidance with the agreed amendments. The guidance would be reviewed in July 2017 to coincide with the NICE asthma guidance.	**SQ**
c.	**<u>Bowel Cleansing Products</u>** Dr Goddard referred to the RDH form used for the supply of bowel cleansing products and queried why the use of home self administered phosphate enemas had been removed from the bowel products section. This was of concern as the use of self- administered enema products was now being encouraged with the introduction of flexible sigmoidoscopy. Mr Dhadli would contact Shane Artis to clarify this point.	**SD**
	Agreed: JAPC ratified the bowel cleansing products guidance.	**SD**
d.	**<u>Familial Hypercholesterolemia</u>** Mr Dhadli reported that the identification and management of familial hypercholesterolemia (FH) guidance had been updated based on the lipid guidance which allowed wider use of atorvastatin 10-20 mg in consultation with Dr Paul Masters and Dr Roger Stanworth. Mr Dhadli highlighted that FH would continue to be diagnosed and monitored by reference to LDL-C and not the non-HDL cholesterol which applied to other patient groups. LDL-C can only be calculated from a fasting sample and the labs will continue to provide it when a full fasting lipid profile is requested.	

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Item		Action
	Mrs Needham queried why a decision had been made to start patients on atorvastatin 10mg and the risk that patients would remain on this strength if primary care did not titrate up to 20mg. However, as long as the necessary reduction in cholesterol level is achieved, the starting dose is less relevant. **Agreed:** JAPC ratified the identification and management of familial hypercholesterolemia guidance.	
e.	**<u>ACS Dual Antiplatelet (DAPT) Guideline NSTEMI</u>** Mr Dhadli tabled the updated ACS dual antiplatelet (DAPT) guideline NSTEMI relevant to Chesterfield Royal Hospital Foundation Trust which now included the use of aspirin for clarity. It was highlighted that the guidance from the North Trent Network should now be badged from Chesterfield Royal Hospital. Dr Mott queries why CRHFT and DTHFT differed and if a Derbyshire wide one could be agreed. Mr Dhadli recalled that there were some significant differences between the versions used by the two acute hospitals in Derbyshire. It was agreed that the CRH and RDH guidelines should be discussed by the Guideline Group in order to ascertain the extent of the variation between them.	**SD**
f.	**<u>GOR(D) Diagnosis and Management in Children and Young People</u>** Mr Dhadli reported that this guidance was broadly based on NICE NG1 'Gastro-oesophageal reflux disease (GORD): recognition, diagnosis and management in children and young people' which had been published in January 2015. This is a new guideline that offers management strategies to treat reflux in primary care and guidance on when referrals to secondary care were appropriate. The guidance had been produced in liaison with Dr Julia Surridge, Paediatric Emergency Department Consultant, and Dr Aiwyne Foo, Consultant Paediatrician and had been sent out for consultation and comment. Mr Dhadli highlighted further changes to the draft which had been suggested: • Clarification on the definition of GORD. • Removal of Gastrocote which had been discontinued • Inclusion of dose of Gaviscon advance for children • Proton pump inhibitors – statement included to indicate that special suspensions were usually more expensive, have a short half-life and questionable stability when compared to licensed medicines. • Addition of dosage information for omeprazole • Appendix 1 – addition of information about powdered anti-regurgitation formulas and alternatives to commercial anti-regurgitation formulas of a thickening agent to formula milk including Carobel. Dr Mott advised that a section in the pharmacological treatment of GORD should be amended to read: 'For those unable to tell you about their symptoms consider a 4-week trial of H2RA (ranitidine 1st line) or PPI if any one of the following; unexplained feeding difficulties, distressed behaviour and faltering growth.'	**SD**
	Action: The guidelines would be circulated with a request that any comments/amendments be conveyed to Mr Dhadli by 26th May. In the event that no major changes were made the guideline would be adopted for use.	**SD**

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8.	**SHARED CARE GUIDELINES**	
a.	**Denosumab** Dr Goddard reported that the existing shared care agreement for the use of denosumab in the prevention of osteoporotic fractures in post-menopausal women as per NICE TA 204 should be expanded to include for use in an equivalent group of men to prevent osteoporosis including a specific subset with prostate cancer treated with androgen deprivation therapy. Mr Dhadli referred to the supporting evidence from two main studies one of which included a key bridging study for the use of denosumab in men to widen its licence. This had involved 242 patients treated for twelve months (Orwoll1 et al) and a study in the New England Journal of Medicine for men who received androgen deprivation therapy in prostate cancer. Data was limited in terms of fractures but both studies showed an increase in BMD consistent with studies seen in women. The increase in the number of male patients was estimated as thirty for DTHFT and ten for CRHFT and it was highlighted that this would be a cost pressure for the CCGs. **Agreed:** The inclusion of denosumab in the shared care agreement for the prevention of osteoporotic fractures in an equivalent group of men with osteoporosis was ratified by JAPC.	
10.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations and drug discontinuations: New drug launches: Apremilast (Otezla) – Classified as RED and await NICE guidance expected in August 2015. Bromelain (NexoBrid) – Classified as RED. Filgrastim biosimilar (Accofil) – Classified as RED (NHS England drug). Follicle stimulating hormone biosimilar (Bemfola) – Classified as RED. Licence extensions: Paclitaxel albumin-bound (Abraxane) Ruxolitinib (Jakavi) Drug discontinuations: Brochlor Drops (chloramphenicol) HumaPen Memoir Mucodyne Paediatric (carbocisteine) Novasource GI Control Piportil Depot (pipotiazine palmitate) Resource Dessert Fruit Rupafin (rupatadine) Ursogal (ursodeoxycholic acid) NICE New evidence Reviews with Proposed Actions: Aclidinium/ formoterol for COPD - For guideline group in June (COPD) Brinzolamide/brimonidine for glaucoma - No decision – await clinician request from provider Drugs and Therapeutic Committee	

Item		Action
	Budesonide for Induction of remission in patients with mild to moderate active ulcerative colitis – July JAPC Degludec/ liraglutide for type 2 diabetes - No action await NICE guideline Dulaglutide for type 2 diabetes – July JAPC Nab-paclitaxel for non-small cell lung cancer - No action required	
11.	**MISCELLANEOUS**	
a.	**Olodaterol** Olodaterol had been assigned a traffic light classification of BLACK due to lack of data on effectiveness compared with standard therapy and less cost-effective than current standard therapy. A similar view was seen by a recent DTB review.	
b.	**Never Events** Mr Dhadli advised JAPC that Never Events were serious incidents that were wholly preventable and result as a failure from strong systemic protective barriers. They had the potential to highlight weaknesses in how an organisation manages fundamental safety processes. A revised Never Events Policy and Framework had been published in March 2015 and this had included changes to the definition of what a Never Event is and adjustments to the types of incident that were included on the Never Events list, reducing the list from 25 to 14 incident types. Mr Dhadli added that the prescribing elements in the revised document had been the subject of a risk assessment process by DHcFT Drugs and Therapeutic Committee. Dr Goddard confirmed that the Never Events guidelines were considered both by the DTHFT Drugs and Therapeutic Committee and the Trust Safety Group. MS confirmed that this is also the case at CRHFT.	
c.	**JAPC Annual Report** Dr Mott stated that an introduction would be written for the JAPC Annual Report in order to highlight any issues. A revised version would therefore be brought to the June JAPC meeting for further discussion. Members were requested to convey any comments on the Annual Report to Mrs Qureshi.	**SQ All members**
12.	**JAPC BULLETIN**	
	The April JAPC bulletin was ratified.	
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Update for April 2015 was noted. Mr Dhadli highlighted the following: • Hydroxyzine (Atarax, Ucerax): Maximum daily dose has been reduced to 100mg due the risk of QT interval prolongation and Torsade de Pointes. • Codeine for cough and cold: Restricted in children under 12 years • High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error – Healthcare professionals and patients needed to understand the insulin strength of the new products and how they should be use correctly in order to minimise the risk of medication errors such as the wrong insulin dose being administered.	

Item		Action
	Mr Dhadli raised concern of the new or yet to be launched insulin products. For example one of the products Toujeo was not bioequivalent to another new product Lantus and dose adjustment would need to be made when patients were switched from Lantus or other basal insulins to Toujeo or vice versa. In addition, for Tresiba one dose step on the 100 units/mL pen was equivalent to one unit of Tresiba but one dose step on the 200 units/mL pen was equivalent to two units of Tresiba. The potential for significant medication error was highlighted to JAPC. Mr Dhadli advised that high strength insulin degludec had previously been assigned a BROWN traffic light but it was agreed that the other high strength combinations should not be used until a plan for implementation had been developed. The advice of the diabetologists would be obtained about the use of the biosimilar product insulin glargine and Mr Dhadli would develop a list of questions to be put to them.	**SD**
14.	**NICE SUMMARY**	
	It was noted that no NICE guidance had been published in April due to the General Election.	
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Rivaroxaban 2.5mg – RED according to NICE TA 335 Matoride XL – added to the AMBER ADHD shared care list Aclidinium plus formoterol (Duaklir Genuair) – BROWN Apremilast – RED Bromelain – RED Filgrastim biosimilar - RED (NHS England drug). Follicle stimulating hormone biosimilar - RED	
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Hyperprolactinaemia - Shared care to be updated by Dr Stanworth Aripiprazole and pregabalin – Legal case expected in June/July 2015 Lithium monitoring – To be brought to the August JAPC meeting PGDs - PGDs extended by six months from April 2015 to October 2015 Rivaroxaban – To be taken off the list NICE CG 28 depression in children and young people – To be brought to the June JAPC meeting. Reflux Guidance – May be re-considered in the light of comments received JAPC Annual Report – To be brought to the June JAPC meeting.	
17.	**GUIDELINE GROUP**	
	The summary of key messages was noted. Dr Goddard highlighted the following: • Management of dyspepsia and the update by NICE of the referral guidelines for all suspected cancers which included upper GI. The updated guidelines would change the current red flag list of symptoms and has the potential to alter the guidelines. Mr Dhadli would look at the draft NICE consultation document.	**SD**

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Item		Action
	Dr Mott highlighted the following; • Out of date general prescribing guidance for GPs. Mrs Needham reported that a member of the Medicines Management Team was in the process of updating these.	
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Nottinghamshire Area Prescribing Committee 15/1/15 • Sheffield Area Prescribing Group 12/2/15 • DHcFT Drugs and Therapeutic Committee 26.3.15 • DTHFT Drugs and Therapeutic Committee 17.3.15 • DCHS MOST Minutes 18.3.15 Mr Dhadli highlighted the following: • Nottinghamshire Area Prescribing Committee meeting – One of the Nottinghamshire CCGs had confirmed that they did not support shared cared for ADHD medications in any patient group. • Sheffield Area Prescribing Group meeting - It had been reported that a copy of the letter from the rheumatologists was sent to GPs when patients were commenced on biologics. Mr Dhadli stated that a copy of this letter would be obtained and shared with RDH and CRH.	**SD**
19.	**ANY OTHER BUSINESS**	
	There were no other items of business.	
20.	**DATE OF NEXT MEETING**	
	Tuesday, 9th June 2015 at 1.30pm in the Post Mill Centre, South Normanton.	