City and Hackney Clinical Commissioning Group
Homerton University Hospital Foundation Trust

Joint Prescribing & Medicines Management Group (JPG) Minutes

Date:	**Monday 11th January 2016**
Time:	**12.30pm – 2.00pm**
Venue:	**Trust Offices Meeting Room, HUHFT**
Chair:	**Haren Patel**

Present:

Dr Haren Patel, Prescribing Lead GP, Joint Chairperson; City and Hackney CCG (HaP)
Dr Richard Bull, Consultant Dermatologist, Joint Chairperson, HUHFT – (RB)
Michael Vidal, Patient & Public Involvement Representative (MV)
Rozalia Enti, Medicines Management Lead City and Hackney CCG – (RE)
Iola Williams, Homerton Chief Pharmacist, HUHFT – (IW)
Dr Lewis Caplin, Prescribing Lead GP, City & Hackney CCG - (LC)
Rhian Holland, Lead Pharmacist for Clinical Services, HUHFT – (RH)
Sagal Hashi, Joint Formulary Pharmacist HUHFT & City & Hackney CCG, JPG Secretary- (SaH)
Katti Nwosu, Prescribing Advisor for City and Hackney CCG – (KN)
Dr Francesco Medici, Consultant Endocrinologist, HUHFT – (FM)
Dr Tammy Rothenberg, Consultant Pediatrician HUHFT- (TR)
Dr Lawrence Blumberg, Prescribing Lead GP, GP City & Hackney CCG - (LB)
Dr Clare Gorman (CG), Consultant Rheumatologist HUHFT- (CG)
Maddy Woods, Nurse Consultant and Medicines Management Lead, HUHFT - (MW)
Shena Chauhan, Senior Prescribing Advisor for City and Hackney CCG -(SC)
Hitesh Patel, Pharmacist CEO City and Hackney LPC – (HiP)

1.0	**Minutes & Matters Arising**
1.1 12/2015	**Apologies, welcome and introductions**
1.2 12/2015	**Declaration of Interests (DOI)** **A**ll members to ensure their DOI were up to date.
1.3 11/2016	**Minutes** Minutes from December 2015 were reviewed. Three points on accuracy were noted • Meeting date stated November agreed to change to December • Initials in section 2.1 initials to be corrected • In section 2.2 of the minutes the Lead Gynaecology consultant's name to be amended • The rest of the minutes were agreed as accurate. Redacted minutes from December reviewed and agreed as accurate.
	Agenda Items
2.1 11/2016	**NICE update:** The group was informed of the NICE TAs that had been released since the last meeting. **Idelalisib for treating chronic lymphocytic leukaemia TA359** Idelalisib (Zydelig), given with a drug called rituximab, is recommended as a possible treatment

	for adults with:untreated chronic lymphocytic leukaemia, only if they have certain genetic chatacteristics chronic lymphocytic leukaemia, only if it has been treated but has come back within 2 years. **The JPG agreed not to approve this medicine for use at the Homerton University Hospital, Foundation Trust as the trust does not provide this specialist service. The JPG recommends the funding of this medicine to be prescribed or initiated at specialist hospitals accredited to provide this medicine, provided it is used in accordance with NICE TA359. Hospital only prescribing (formulary status BLUE)** **Ledipasvir–sofosbuvir for treating chronic hepatitis C TA363** Ledipasvir-sofosbuvir (Harvoni) is recommended as a possible treatment for adults with some types (called genotypes) of chronic hepatitis **C.** **The JPG agreed to approve this medicine for use at HUHFT provided it is used in accordance with NICE TA 363 (BLUE – Hospital Only)** **Daclatasvir for treating chronic hepatitis C TA364** Daclatasvir (Daklinza) is recommended as a possible treatment for adults with some types (called genotypes) of chronic hepatitis C, depending on their level of fibrosis. It is taken with sofosbuvir or peginteron alfa, and sometimes with a drug called ribavirin. **The JPG agreed to approve this medicine for use at HUHFT provided it is used in accordance with NICE TA 364 (BLUE – Hospital Only)** **Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C TA365** Ombitasvir–paritaprevir–ritonavir with or without dasabuvir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in table 1, only if the company provides ombitasvir–paritaprevir–ritonavir and dasabuvir at the same price or lower than that agreed with the Commercial Medicines Unit. **The JPG agreed to approve this medicine for use at HUHFT provided it is used in accordance with NICE TA 365 (BLUE – Hospital Only)** **Pembrolizumab for advanced melanoma not previously treated with ipilimumab TA366** Pembrolizumab (Keytruda) is recommended. This drug is a possible treatment for adults with melanoma that: can't be completely removed by surgery or has spread to other parts of the body has not been treated with ipilimumab before. **The JPG agreed not to approve this medicine for use at the Homerton University Hospital, Foundation Trust as the trust does not provide this specialist service. The JPG recommends the funding of this medicine to be prescribed or initiated at specialist hospitals accredited to provide this medicine, provided it is used in accordance with NICE TA366. Hospital only prescribing (formulary status BLUE)** **Vortioxetine for treating major depressive episodes TA367**

Vortioxetine (Brintellix) is recommended as a possible treatment for adults having a first or recurrent major depressive episode, if the current episode has not responded to 2 antidepressants.

The JPG agreed to approve this medicine for use at HUHFT provided it is used in accordance with NICE TA 367 (BLUE – Hospital Only). Pathway to be confirmed with ELFT

Apremilast for treating moderate to severe plaque psoriasis TA368

Apremilast (Otezla) is not recommended for treating moderate to severe chronic plaque psoriasis in adults whose psoriasis has not improved with other treatments, or they have had side effects with these treatments in the past or there is a reason why they cannot have them.

The JPG agreed not to approve this medicine as currently NICE cannot recommend its use.

2.2 11/2016

Clipper®: Beclometasone dipropionate (BDP) 5mg SR tablets Fast Track Application

Applicant	Presented By	Decision	Responsibility for Prescribing
		Approved: pending Pathway Second line (prednisolone first line) for patients with mild-moderate acute flares of left-sided or extensive UC who do not tolerate prednisolone (and do not respond to 5-ASA). 4 week course	Blue Hospital Only

Beclometasone dipropionate (BDP) is licenced to be used as an adjunct to aminosalicylates in acute mild to moderate ulcerative colitis, more specifically to induce remission in adults with left-sided or extensive UC, with a mild to moderate first presentation or inflammatory exacerbation.

NICE Clinical Guidance 166 Ulcerative Colitis: management states that clinicians can consider adding beclometasone dipropionate taking into account patients' preferences.

The application for BDP reviewed evidence from 5 trials.

- **Rizzello et al** (2002; n=119) conducted a 4-week, double blind, randomised, placebo controlled study of oral BDP. The ITT analysis (n-119) demonstrated that both treatment groups reached a significant reduction (p=0.001) in UCDAI score, with a mean absolute reduction of 3.7 in the BDP + 5-ASA group, and 3.0 in the placebo + 5-ASA group. Although the authors reported the results as being statistically significant (p=0.014 between treatments), the absolute difference between the treatments was small (0.7 on a 12-point scale). The trial was company sponsored, and the clinical significance of a 0.7 point difference is questionable when BDP+5-ASA compared to 5-ASA alone.
- Campieri et al (2003, n=177) undertook was a randomised, parallel-group, single-blind study in patients with active mild to moderate UC (UCDAI score 3 - 10) comparing BDP (5mg daily) with 5-ASA (2.4g daily) for 4 weeks. In the ITT analysis

(n=133), the mean UCDAI score was significantly reduced in both groups. The BDP group had a higher percentage of patients with extensive ulcerative colitis (35.6% vs 20.7%; p<0.05) and a higher mean UCDAI score (6.06 vs 5.30; p<0.05) compared to the 5-ASA group, therefore may show a higher response rate. The percentages of patients in clinical remission (63% vs 62.5%) and with a significant clinical improvement (15.1% vs 11.3%) did not significantly differ between the BDP and 5-ASA treatment groups.

- Nunes et al (2010, n=394) conducted a retrospective, multi-centre study assessing the efficacy and safety of oral BDP for active UC from post-marketing experience in clinical practice in Spain. Most patients in the study had left-sided or extensive colitis and were on maintenance therapy with oral /rectal 5-ASA when BDP was started. The results showed that BDP was associated with remission in 44.4% of patients, response in 22.3% of patients and failure in 33.2% of patients. Patients treated with BDP for more than 4 weeks had lower failure rates than those treated for less than 4 weeks (p<0.02), however, this is outside of marketing authorisation
- Papi et al (2010, n=64) undertook a single-arm study assessing whether oral BDP would be a useful alternative to oral prednisolone as a second-line treatment Overall after 8 weeks of treatment with BDP, mean CAI score decreased from 7.4 points (95% CI 6.9-7.8) to 3.0 points (95% CI 2.3-3.7) (p<0.0001). Patients with moderate disease had a lower remission rate than those with mild disease (47% vs 87% respectively; p=0.003; OR = 0.13). The percentage of patients maintaining steroid-free remission for 12 months post BDP therapy were: 37 patients remained in remission (58%; 95% CI 44.8-70.0%) and 48 patients (75%; 95% CI 62.6-84.9%) avoided systemic corticosteroids for one year. There are a number of study limitations including the lack of a control or active comparator (e.g. prednisolone), the lack of endoscopic outcomes, and the use of higher doses / longer treatment duration compared to the licensed dose.
- Balzano et al (2015, n =277 abstract only) compared the efficacy and safety of BDP with oral prednisolone in patients receiving 5-ASA therapy (up to 3g/day). Subjects were randomised in a double-blind manner to an 8-week non-inferiority study to receive either (Group 1) BDP 5mg daily for 4 weeks then 5mg on alternate days for 4 weeks, or (Group 2) prednisolone 40mg daily for 2 weeks with tapering dose of 10mg every 2 weeks thereafter. Although the non-inferiority limit of 20% was set fairly high, the results demonstrated comparable efficacy of the two treatments, however, the dosing of BDP was outside of license. The authors concluded that BDP was non-inferior to prednisolone in the treatment of active UC, with a good safety profile in both the groups.

<u>JPG reviewed the safety profile of BDP</u>

It was noted that BDP was generally well tolerated in all studies with no serious adverse events noted. Common side effects of steroids would be applicable to BDP.

<u>General Discussion</u>

The JPG were informed that BDP does not offer any flexibility in dosing. The group were also informed that there was a cost difference with BDP: 5mg once daily costing £56.56/course and prednisolone: 40mg once daily, reducing by 5mg weekly costing £12.60/course. It was recommended that BDP is placed as 2nd line therapy in patients who can't tolerate prednisolone.

The applicant was asked to inform the group where she would see BDP's place in therapy. She explained that she would very rarely recommend the use of BDP, but for some patients

	she believed it would be a valuable option. The applicant informed the JPG of a current patient, who is unsuitable for prednisolone but needs something to bridge the gap before surgery. Having BDP as an option would prevent her from going onto escalating therapy. The applicant also informed the JPG that she believed the cohort of patients that would require BDP would be a very small group of patients around 2/3 a year. A JPG member asked if there were any other scenarios when BDP would be used as first line option. The applicant informed the group that this would only be first line in patients who can't tolerate prednisolone. A JPG member stated that given the limited clinical evidence for efficacy it is important to prevent over prescribing of BDP over prednisolone, and suggested that a pathway be produced defining the exact place in therapy of BDP. The applicant agreed to produce a pathway. The JPG agreed to add beclomethasone diproprionate 5mg onto the joint formulary as Blue, Hospital only.
2.5 11/2016	**Guideline for the use of Intravenous Unfractionated Heparin for Adults** A JPG member presented the intravenous unfractionated heparin guidelines to the group and explained that the document would also be submitted to the Improving Clinical Effectiveness Committee. The group were informed that SaH had provided comments on the document prior to the meeting. It was agreed that these comments and the document would be re-circulated to the group following amendments.
2.6-2.7 11/2016	**Proposal for S/C methotrexate in primary care** Methotrexate given orally is the first line treatment for rheumatoid arthritis and is also used in other inflammatory rheumatic conditions, inflammatory bowel disease and psoriasis. However, poorer bioavailability at higher doses (more than 15mg per week) can limit efficacy. In addition, side effects (especially gastrointestinal) can also limit patients taking higher doses of oral Methotrexate. Thus, Methotrexate given parenterally (subcutaneously) is used increasingly in clinical practice, especially in rheumatology, to overcome these problems. The applicant explained that the rheumatology department at the Homerton have developed a methotrexate injection service. The applicant informed the group that seven years ago (2008), this comprised of 20 patients attending a specific clinic at the Homerton to receive a weekly subcutaneous (s/c) methotrexate injection administered by a rheumatology clinical nurse specialist (CNS). Due to demand, this was increased to 60 patients and a homecare service was offered to the few patients that preferred to administer at home (after being taught how to administer and their competency assessed). This homecare service is provided by Healthcare at Home (HAH) and was initially taken up by four patients (in 2010). At the time, methotrexate was available only as a standard needle and syringe. The JPG were informed that over the last five years, this delivery of methotrexate at home has increased exponentially: 4 patients in 2010, 16 in 2013 to 104 in 2015. The applicant also informed the group the reasons behind this increase: a) The introduction of Metoject® as an autoinjector pen has made self-administration more acceptable to many patients. b) The advantage of the pre-filled pens is that minimal handling and no assembly of syringes is required, facilitating safety and usability. It was clarified that if this transfer was agreed then teaching of the patients/carers in

	administering Metoject® would be undertaken by the rheumatology (or gastroenterology) CNS at the Homerton Hospital and only patients assessed as competent to self-inject would be placed on a shared care pathway. Patients not suitable to self-inject would continue to be seen at the HUHFT injection clinic. The applicant informed the group that she believed this model would enhance patient satisfaction and that this was starting to become standard practice in many areas around the country. The applicant also stated that this shared care protocol was applicable for rheumatology, dermatology and gastroenterology, but the patient numbers for dermatology and gastroenterology at HUHFT were very small. A JPG member asked if the dosing regimens (i.e. maximum dosing for S/C methotrexate) would be the same for all specialities, another JPG member stated that dermatology would not use more than 25mg a week. The applicant informed the group that she would have to get confirmation from gastroenterology. The group were also informed that the increased numbers of patients receiving this service have inevitably led to increased cost pressure for the trust. Currently, the Metoject® service via Healthcare at Home costs £46,500 compared to a cost price of £26,000 for the drug alone (due to delivery charges, nurse visits and the additional premium that HAH charges for the service). It was stated that the monitoring and prescribing of methotrexate is the same for the oral & injection, therefore the guidelines for GP were the same. The group were informed that the transfer of prescribing into primary care would be an additional cost pressure for primary care. The applicant was asked if a contact number for both in and out of hours could be added to the guideline. The applicant informed the group that the main problem encountered by patients was misfiring of the autoinjecter but she would be happy to add the contact details onto the shared care guidelines as requested. It was noted that the SCG mentioned that the competency assessment would be done by HAH, CG informed the group that this was an error and she would remove this from the document. CG stated that all competency assessments would be done by the CNS's at HUHFT. A JPG member asked about the impact for GPs and if this transfer of prescribing would result in 104 new patients that GP's would now have to prescribe for and monitor. Another JPG member explained that all patients are on the DAWN system. It was suggested that a 'face to face' training session is organised for local GPs. The applicant agreed to this. RE suggested that the CNS's are involved in delivering the GP educational event. CG agreed and stated she was very keen that the GPs are fully informed and engaged with the transfer of prescribing. It was requested that HAH are asked to provide the date that the prescriptions need to be reissued for each patient and that the transfer of patients into primary care is staggered. The JPG were informed that it would be useful if a factsheet could be produced for community pharmacists as they are often approached by patients with queries about their medication. The applicant stated that they currently have a 9-5 helpline manned by 3 nurses. A JPG member asked who would dispose of the sharps bin. Another JPG member explained

	that the local authority have to collect these and suggested that this number is added to the document. The group were asked if they were aware if the purple sharps bin could be prescribed on an FP10. The group agreed that City and Hackney's finance team would have to review this proposal before a decision can be made. The group were also informed that the primary care prescribing budget also faces significant cost pressure so this decision to shift prescribing responsibility and costs will have to be reviewed carefully.
2.7 11/2016	**Colecalciferol Proposal** Background information was provided to the JPG on the importance of using licenced medicines and also the summarised occasions when deviation from a licenced product might be necessary. The JPG were informed of UKMI's risk rating of vitamin D products. The group were also told that Pro-D3® (£7.38) is currently first line at HUHFT, but it is an unlicensed food supplement. It was proposed that a switch is made to Stexerol-D3® (£1.20) a licenced product. The second proposal was to switch from Thame Lab to Birchwood Pharma for colecalciferol 3000units/ml liquid. Thame Lab (£143/100ml) is a licenced product but is not suitable for patients with a nut allergy. The Birchwood product (£35.40/100 ml) is unlicensed but is suitable for patients with nut allergy. The applicant informed the group that savings for switching both products would result in savings in secondary care of approximately £10k per annum for HUHFT. The applicant informed the group that the manufacturer had advised that primary care would also benefit from savings in switching to Stexerol-D3®, although this would require further investigation. A JPG member clarified that the Stexerol® price stated was not a primary care price. It was highlighted to the group that in order to make a fully informed decision all available licensed products should have been included in the proposal and explained to the group. The UKMI list should have also been made available fully to the JPG. A group member stated that it was of high importance to have a unified formulary as vitamin D products will need to be continued in primary care. It was noted that the vitamin D guidelines will need to be updated. The JPG members discussed the appropriateness of only reviewing some of the available colecalciferol products. On this occasion the JPG agreed to the proposed switches for secondary care, SaH to review options in primary care and report back to the JPG. Stexerol-D3® to replace Pro-D3® as first line 1000 unit colecalciferol product at HUHFT and Birchwood product to replace Thame Lab colecalciferol product as first line liquid colecalciferol.
2.8 11/2016	**Sirdupla® Fast track drug application**

Applicant	Presented By	Decision	Responsibility for Prescribing
		Approved Green Joint Formulary Choice	Primary and Secondary care

		Respiratory consultants to inform group if there are any contraindications to be aware of before switching from Seretide® to Sirdupla®	

Fluticasone/Salmeterol (Sirdupla®) is a combination inhaler containing an inhaled corticosteroid (ICS) and a long-acting beta2 agonist (LABA). As a branded generic, Marketing Authorisation (MA) has been granted by the European Medicines Agency (EMA) on the basis of demonstrating pharmacokinetic equivalence to Seretide® (Fluticasone/Salmeterol). As such, it is indicated for the same patient groups as Seretide®.

In Asthma:

- For the regular treatment of asthma, where use of a combination (ICS/LABA) is appropriate: in patients not adequately controlled with ICS and "as needed" inhaled short-acting β2 adrenoceptor agonists, i.e. indicated at Steps 3-4 of the BTS/SIGN Asthma Guidelines
- Or in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists, i.e. indicated at Steps 3-4 of the BTS/SIGN Asthma Guidelines.

In COPD:

- Symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators

However, the following are the exceptions of where Sirdupla® does **not** have the same licence as Seretide®:

- Not indicated in patients under 18 years of age
- Pharmacokinetic equivalence was not proved in the lowest ICS/LABA combination that is equivalent to Seretide® 50/25

The group were informed that cost savings can be realised if patients are switched to this device. It was also explained that the device is the same as the Seretide® device but there is a slight difference in colour.

The group were asked if it was appropriate to switch patients' brand of inhaler purely on a cost basis. The consensus from the JPG was that it was important to make cost savings when clinically appropriate. RH stated that it was also very important that patients are reviewed and informed before switching. It was suggested that the respiratory consultants should inform the JPG if there are any scenarios in which switching brands for this preparation may not be advisable.

The JPG agreed to add Sirdupla® onto the formulary as Green joint formulary choice as 1st line to be used in accordance to its marketing authorisation. i.e. in patients at Steps 3-4 of the BTS/SIGN Asthma Guidelines and symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

3.0 12/2015	**Standing Items**
3.1 12/2015	**MHRA Drug Safety Update** For information only December 2015
3.2 12/2015	**Update on Electronic Formulary/ Review** No updates
3.3 12/2015	**NELMMN Update** No update
4.0	**Any Other Business Not on the Agenda**
4.1 12/2015	**Chairman's action: Short chain Fatty Acids: DECLINED** The JPG were informed that an informal JPG application for Chairman's action for the use of Short Chain Fatty Acids (SCFA) for two patients with symptomatic diversion colitis had been received. The JPG were informed that a request was made by a consultant colorectal surgeon at HUHFT to use SCFA for two patients at HUHFT. The colorectal surgeon anticipated that they would want to use this treatment in about 5 or 6 patients a year. The clinical evidence available was summarised: Remission was maintained for up to 14 months (in one patient only) and undiversion or rectal excision was ultimately carried in some patients. The results of another larger study included 91 patients with distal ulcerative colitis who entered a six week, double-blind, placebo controlled trial of rectal SCFA demonstrated improvement in symptoms, clinical and histological scores in the patients treated with SCFA compared to the placebo, but none of the results were statistically significant. The only group of patients for whom improvement was statistically significant was those with a relatively short current episode of colitis (< 6 months). The group was also informed that SCFA's are not used in Royal London, UCLH and St George's Hospital these are other centers that have large gastroenterology units. A trial course of 6 weeks treatment costs ~ £2800. A JPG member stated that St Marks Hospital an internationally renowned center for gastroenterology also rejected a chairman's action request for use of this of this product in diversion colitis in August 2015. Given the information above the Chairs rejected this proposal, but welcomed a full application from the applicants.
5.0 12/2015	**Information Only Items – For noting**
5.1 12/15	**ELFT Medicines bulletin** **Circulated for information**
6.1	**Next Meeting**
	Monday 08th February Trust Office Meeting Room