North Central London
Joint Formulary Committee

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Thursday 27 April 2017
Room 6LM1, Stephenson House, 75 Hampstead Rd

Present:	Dr R MacAllister	NCL JFC Chair	**(Chair)**
	Ms W Spicer	RFL, Chief Pharmacist	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Dr R Sofat	UCLH, DTC Chair	
	Mr T James	MEH, Chief Pharmacist	
	Ms L Reeves	C&I, Chief Pharmacist	
	Dr M Kelsey	WH, Chair DTC	
	Mr B Sandhu	NEL CSU, Assistant Director Acute Services	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Dr R Fox	RNOH, DTC Chair	
In attendance:	Ms S Ceci	WH, Formulary Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr P Bodalia	UCLH, Principal Pharmacist	
	Mr J Minshull	NCL JFC, Support Pharmacist	
	Ms A Fakoya	NEL CSU, Senior Prescribing Advisor	
	Mr K Thakrar	UCLH, Formulary Pharmacist	
	Ms M Kassam	MEH, Formulary Pharmacist	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
	Ms L Morgan	NMUH, Lead E&T Pharmacist	
	Dr J Fullerton	UCLH, Clinical Pharmacology SpR	
	Dr H Amer	UCLH, Clinical Pharmacology SpR	
Apologies:	Prof L Smeeth	NCL JFC Vice-Chair	
	Ms K Landeryou	Patient Partner	
	Mr A Barron	NCL JFC, Support Pharmacist	
	Mr S Richardson	WH, Chief Pharmacist	
	Ms R Clark	Camden CCG, Head of Medicines Management	
	Mr A Shah	RNOH, Chief Pharmacist	
	Dr V Thiagarasah	Enfield CCG, GP	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Dr E Boleti	RFL, Consultant Medical Oncologist	
	Mr G Kotey	NMUH, Chief Pharmacist	
	Dr P Hyatt	NMUH, DTC Chair	
	Dr S Shaw	RFL, DTC Chair	
	Dr R Kapoor	UCLH, Consultant Neurologist	
	Prof D Robinson	UCLH, Consultant in Respiratory Medicine	
	Prof A Tufail	MEH, DTC Chair	
	Mr C Daff	Barnet CCG, Head of Medicines Management	
	Ms H Mehta	NMUH, Formulary Pharmacist	

2. Meeting observers

Dr Amer and Dr Fullerton (Clinical Pharmacology Registrars) were welcomed to the meeting to present drug applications.

3. Minutes of the last meeting

The minutes were accepted as accurate.

3.1 Actions from the last meeting

Item 8.2: Mr Bodalia had received response from the Principal Investigator of the CANNA-TICS study looking at Sativex® in Tourette's syndrome that the study was only open to German-speaking participants at the primary centre, therefore it would not be possible to setup NHNN as a trial site. Mr Minshull reported that he has met with Prof Joyce, who has agreed to conduct an evaluation of THC in Tourette's syndrome using Sativex® rather than nabilone. Prof Joyce is currently working on the evaluation paperwork, which will be presented back to the JFC.

Item 8.3: Mr Minshull updated the Committee that he had been working with Dr Kriesels to identify an association between endogenous levels of melatonin and impact on sleep in order to estimate a dose of melatonin above which it is not sensible to increase melatonin doses in children. Mr Minshull will keep looking into this and report back to the Committee when this information has been found.

4. Matters arising

4.1 NCL Ocular Lubricants guideline

Mr James asked the Committee for an update on approval for the MEH Ocular Lubricants guideline. Mr Minshull noted that the CCGs had not yet endorsed the guideline because a specific brand of hypromellose 0.3% eye drops preservative free was recommended first line, which is a departure from current practice of using a generic preserved product. This difference had a potentially significant cost impact to primary care.

Action: Mr James to liaise with CCGs and the guideline author in order to seek resolution. Mr Minshull to seek Chair's action when finalised.

5. Declarations of relevant conflicts of interest

There were no declarations of interest.

6. Local DTC recommendations / minutes

6.1 Approved by local DTC

DTC site	Month	Drug	Indication	JFC outcome
MEH	Jan-17	Bevacizumab	Pre-operative adjunct to diabetic vitrectomy	MEH only
RFL	Mar-17	Dupilumab (EAMS)	Severe atopic dermatitis (eczema) refractory to corticosteroids and ciclosporin and methotrexate	RFL only
RFL	Mar-17	Patisiran (compassionate access)	Familial Amyloid Polyneuropathy	RFL only
UCLH	Dec-05	Eplerenone	Heart failure in patients unable to tolerate spironolactone due to gynacomastia	Added to NCL Joint Formulary

6.2 Approved Under evaluation by local DTC

DTC site	Month	Drug	Indication	JFC outcome
MEH	Jan-17	Mydrane	Obtain intraoperative pupil dilatation and intracamerular anaesthesia during topical anaesthesia cataract surgery	Under evaluation at MEH only (6 months)

MEH	Jan-17	Cacicol	Non-healing corneal ulcers/ persistent epithelial defects	Under evaluation at MEH only (restricted to corneal eye disease service only)

6.3 Deferred by local DTC

DTC site	Month	Drug	Indication	JFC outcome
RFL	Mar-17	Mepivacaine	Intracervical block during intrauterine device and intrauterine system fitting (IUD/ IUS)	Deferred
RFL	Mar-17	Bortezomib	Severe resistant Systemic lupus erythematosus (post steroids, rituximab, cyclophosphamide and ofatumumab)	Deferred[†]

[†] Bortezomib had been discussed further at the RFL April 2017 DTC, where it was acknowledged that the data was being extrapolated, but it would be used in a limited group under evaluation. RFL DTC is anticipating very low patient numbers and has requested feedback after each patient is treated.

7. New Medicine Reviews

7.1 Methenamine hippurate for recurrent UTIs (Applicants: Dr A Kupelian, Ms M Pakzad, Dr S Logan)

The Committee reviewed an application for the use of methenamine hippurate to be used in the prevention of urinary tract infections. Dr A Kupelian was welcomed to the meeting to support the discussion and clarify any points unclear in the application or evaluation.

Evidence on the clinical effectiveness of methenamine hippurate was taken from the Cochrane Review (Lee et al 2012) which included 2,032 patients from 13 studies. Methenamine hippurate was found to have a role in the short-term prophylaxis against UTI in people without renal tract abnormality. The Committee noted that there was significant heterogeneity between the studies, caused by different doses used, acidification of the urine used in two studies, and different ways of defining UTI. In the pooled analysis, methenamine was shown to be effective at preventing symptomatic UTI in patients without renal tract abnormalities (RR 0.24, 95% CI 0.07 to 0.89, p=0.02), whereas for patients with renal tract abnormality it was likely ineffective (RR 1.54, 95% CI 0.38 to 6.20, p=0.14). The Committee could not see a reason why renal tract abnormalities would prevent methenamine hippurate from being effective. Dr Kupelian explained that minor renal tract abnormalities are unlikely to have a negative impact on efficacy, whereas major renal tract abnormalities are likely to make the drug ineffective.

As methenamine hippurate exerts its effect through its conversion to formaldehyde in acidic urine, the Committee questioned whether acidification regimens are necessary when methenamine is used. It was noted that only two of the studies in the Cochrane Review involved an acidification regimen and the UK product information, unlike US product information, does not recommend acidification of the urine. Acidification of the urine cannot be continued long term due to the kidneys physiological response to maintain normal buffering action to maintain acid-base balance. However, methenamine should be used where people already have acidic urine. The Committee acknowledged that, although resistance to methenamine hippurate is not yet considered to be a concern, it was highlighted that some gut bacteria already produce aldehyde dehydrogenase therefore there is a theoretical potential for resistance.

The Committee noted that there is national guidance from Public Health England (PHE) advocating use of methenamine hippurate as a 3rd line option (after first-line hydration and analgesia, and second-line stand-by or post-coital antibiotics). An alternative third-line option is for prophylaxis with a conventional antibiotic (e.g. nitrofurantoin, pivmecillinam or trimethoprim). Dr Kupelian explained that there is a drive to find an alternative to antibiotics to help prevent recurrent urinary tract infections. Of the antibiotics recommended by PHE, resistance rates to trimethoprim are high within London and clinicians want to reserve pivmecillinam for ESBLs. Traditional antibiotics already have a risk of developing Clostridium difficile infection; Dr Kupelian stated that Department of Health estimates that each case of CDI costs approximately £10,000.

The Committee queried how long methenamine hippurate should be continued for. Dr Kupelian explained that data for most drugs used in UTI prophylaxis is for 12 months, whereas data for methenamine hippurate is limited to 6 months. Many patients are likely to experience UTI as soon as suppression is stopped, but there is uncertainty about who these patients will be. Dr Kupelian agreed that it would be reasonable to review patients every six months; it will be possible to provide information to GPs to empower them to stop and evaluate response to treatment.

In camera, it was acknowledged that an additional treatment option to avoid use of antibiotics would be valued. The significant potential cost impact of methenamine use was considered by the Committee, emphasising the importance of careful management of who receives the drug and for how long. The uncertainty around duration of treatment and stopping criteria will require clear communication to the GP and patient if the drug is initiated by a specialist. It was also highlighted that methenamine hippurate will be ineffective against infections caused by Proteus sp. None of the papers evaluated included patients who received methenamine hippurate in addition to other antibiotics; PHE is advocating use of methenamine hippurate as an alternative to antibiotics, not in addition to. Although methenamine is more likely to be effective in the presence of acidic urine, an acidification regiment (for example using vitamin C) was not advocated by the Committee.

In summary, the Committee supported the use of methenamine hippurate for recurrent UTIs in adults who have experienced ≥ 2 UTIs in the last 6 months, or ≥ 3 in the last 12 months. Initiation will be by the GP or in secondary care, in line with Public Health England guidelines. Treatment should be reviewed every six months. Communication from specialists to the GP and patient should include details of stopping criteria and markers of success or failure.

Decision: Approved
Prescribing: Primary and secondary care initiation
Tariff status: In tariff
Funding: GP or hospital budgets
Fact sheet or shared care required: No
Audit required: No

7.2 Dalbavancin for skin and soft tissue infections (Applicant: Dr S Mepham, RFL)

Dr Fullerton presented an application to use dalbavancin, a semi-synthetic, lipglycopeptide analogue antibiotic, proposed as an option for the treatment of acute bacterial skin and soft tissue infections (SSSIs). The Committee heard how dalbavacin has a long terminal half-life (372 hours), resulting in serum concentrations above the minimum inhibitory concentration (MIC) for > 7 days. This feature allows the drug to be administered once-only, or once weekly (depending on the regimen required). The proposal is to use the agent 3rd line for patients presenting in secondary care, where adherence to oral treatment regimens is not possible, and currently available treatment pathways for IV antibiotics are unsuitable (e.g. chaotic lifestyle, immobility, poor venous access). The Committee welcomed Dr Mepham to support the discussion and clarify any points unclear in the application or evaluation.

Evidence on the clinical effectiveness of dalbavancin was taken from three phase III, double-blind, double-dummy, active comparator controlled trials. An additional double-blind study comparing single dose dalbavancin (1500 mg STAT) to split dose dalbavancin (1000 mg followed by 500 mg a week later) was discussed.

Jaurequi *et al* (2005, n=660/845 evaluable patients) saw patients receive either linezolid 600 mg twice daily for 14 days, or dalbavancin 1000 mg IV on day 1, followed by dalbavancin 500 mg IV on day 8. All participants were suffering from (suspected) skin or soft tissue infection caused by a gram positive organism that warranted initial parenteral therapy. Metronidazole and or aztreonam were permitted if suspected anaerobic/Gram negative infection. The primary end point considered was “clinical success” (signs and symptoms of SSSI had improved) at the “test of cure” visit 14 ± 2 days following treatment cessation. 23% of randomised patients were not included in the primary efficacy analysis. “Clinical success” was achieved in 91.2% of linezolid-treated patients, and 88.9% in the dalbavancin arm. The Committee discussed the limitations inherent in non-inferiority studies i.e. in this case the trial design permitted up to 12.5% fewer patients to achieve “clinical success” with dalbavancin compared to linezolid and still be considered equally effective. It was noted that the result was within this margin (lower limit of the 95% CI was -7.28%) and that fewer than 1% of patients in both arms were considered to have relapsed.

The Committee also discussed the results of the DISCOVER 1 and DISCOVER 2 studies, which had a pooled population size of 1,303 patients. Patients were randomised to receive either dalbavancin (same regimen

as described above) or vancomycin (1 gram or 15 mg/kg every twelve hours) for at least 3 days with the option to switch to oral linezolid to complete 10 to 14 days therapy. A double-blind, double-dummy method was used. The primary end point of cessation of spread of erythema and temperature ≤ 37.6°C at three consecutive readings was measured after 48 to 72 hours of therapy using the intention-to-treat population (the single biggest cause of treatment failure was missing temperature data). Non-inferiority between treatment arms was established if the lower limit for the 95% CI was no less than -10%. A successful outcome was achieved in 79.7% in the dalbavancin arm and 79.8% in the vancomycin-linezolid arm (difference -0.1%, 95% CI -4.5 to 4.2). Bacteraemia data were available at baseline and following treatment in 23 in the dalbavancin arm and 14 patients in the vancomycin-linezolid group; negative blood cultures were seen in 100% of the dalbavancin arm and 85.7% of the vancomycin-linezolid arm.

The single-dose dalbavancin regimen (1500 mg stat) was compared to the two-dose dalbavancin regimen (1000 mg and 500 mg a week a part) in a double-blind, active-comparator controlled non-inferiority study. Concomitant treatment with metronidazole and/or aztreonam were again acceptable if anaerobic or Gram negative infections were suspected. The primary efficacy end-point considered for non-inferiority was a combination of ≥ 20% reduction in erythema size and no need for rescue antibacterial. A non-inferiority margin of -10% effectiveness was used; clinical effectiveness was achieved in 81.4% of the single-dose arm, and 84.2% of the two-dose arm (difference -2.9%, 95% CI -8.5 to 2.8%) at 48 to 72 hours. When the window was extended to 36 to 75 hours, treatment response was 84% and 85.4% respectively (difference -1.4%, 95% CI -6.8 to 4%).

The Committee heard that the majority of adverse events were mild to moderate in intensity, most commonly nausea (5.5%), diarrhoea (4.4%) and headache (4.7%). One case of anaphylactoid reaction was reported in the dalbavancin treated patients. Elevation of liver transaminases was noted in the DISCOVER studies, with nearly all cases of ALT elevation peaking at 14 days post-dose, returning to normal at day 20 to 32. No cases of liver failure were reported. Dalbavancin was found to be safer than teicoplanin with regards to nephrotoxicity.

In camera, the Committee were conscious that this new antibiotic would need to be introduced into practice carefully as there is potential for both uncontrolled indication-creep and dose-creep. It was agreed that use should be restricted to patients approved by microbiology, and it should not be used in patients for whom there is a clinically appropriate regimen of oral antibiotics available. The Committee discussed whether the cost associated with dalbavancin therapy was likely to be off-set by reductions in the cost of inpatient stays, or of running OPAT services; the Committee did not believe that sufficient reduction would be seen. The Committee were minded not to be complacent about this drug, as its long half-life means that its concentration will be as long under the MIC as above it, which may provoke resistance to develop.

The Committee expressed some concern that evidence for efficacy was based on non-inferiority trials with large non-inferiority margins, which exposes patients to new interventions that may be less effective than the comparator. This was of particular concern in the study by Jaurequi *et al* (2005) although less so for DISCOVER 1 and DISCOVER 2.

In summary, the Committee approved the use of dalbavacin for skin and soft tissue infections in patients unable to receive oral therapy. Prescribing should be restricted to Microbiology recommendation.

Decision: Approved under evaluation
Prescribing: Secondary care
Tariff status: In tariff
Funding: Hospital budgets
Fact sheet or shared care required: No
Audit required: Yes

Post-meeting notes: To prevent inadvertent overdose with dalbavancin, Trusts should explore having an alert embedded into their electronic prescription and administration software.

7.3 Delamanid and bedaquiline for MDR-TB and XDR-TB (Applicant: Dr M Brown, WH and UCLH)

Mr Minshull presented an NHS England Commissioning Policy for delamanid (oral nitromidazole anti-mycobacterial agent) and bedaquiline (oral diarylquinoline anti-mycobacterial agent) used in the treatment of MDR-TB and XDR-TB. Both agents have novel mechanisms of action, and have been licensed and approved by NHS England following phase IIb trials due to the serious unmet need in highly resistant TB.

The Committee heard how MDR-TB requires long courses of treatment (>20 months), and success is seen in less than 50% of cases; XDR-TB has even lower success rates (33%) with current agents. Delamanid and bedaquiline are required to form part of combination therapy (minimum four drugs) for a maximum duration of 6 months each. Treatment will be guided by multidisciplinary team or the MDR-TB treatment centre.

Evidence on the clinical effectiveness of these drugs, summarised in the NHS England Clinical Commissioning Policy F04/P/a, was noted by the Committee. Data on the efficacy of delamanid has been demonstrated in one phase IIb, 8 week trial and a six-month extension study. In the phase IIb trial (mITT population n=402), culture conversion at day 57 was seen in 29.6% of the placebo arm, and 45.4% receiving 100 mg delamanid twice daily (p=0.0083); the hazard ratio for increased time to sputum culture conversion was 0.58 (95% CI 0.39, 0.89) in the 100 mg arm. The extension study showed favourable outcomes in 74.5% delamanid patients at 6 months, compared to 55% placebo patients. Mortality rate was 1% in the delamanid arm, compared to 8.3% in the placebo arm (p<0.001). Data on the efficacy of bedaquiline has been demonstrated in a phase IIb study (22 weeks) in which all patients received a 5 drug regimen in addition to bedaquiline. The primary efficacy end point considered with medium time to sputum culture conversion (83 days with bedaquiline vs. 125 days with placebo) HR=2.44 [95% CI 1.15, 3.80; p<0.0001]. Secondary end points considered with a significant outcome were culture conversion at 24 weeks (78.8% bedaquiline vs. 57.6% placebo, p=0.008); culture conversion at 120 weeks (62.1% bedaquiline vs. 43.9% placebo, p=0.035) and WHO criteria cure at week 120 (58% bedaquiline vs. 32% placebo; p=0.003).

The incidence of QT prolongation with either agent was a concern for the Committee, which endorsed NHS England's decision to implement an obligatory monitoring framework and the need for caution if other drugs are used that prolong the QT interval. Other adverse effects reported for the two drugs were not considered to be a significant concern compared to the benefit of treatment TB.

The Committee discussed how the Commissioning Policy should be interpreted with regards to patients who require treatment with both bedaquiline and delamanid. As treatment courses continue for long periods, and each drug is only licensed for use up to six months, the Committee thought it seemed likely that patients would require both drugs. The Commissioning Policy acknowledges that caution should be exercised if delamanid is used following bedaquiline due to the latter's long tissue half-life (5 months); enhanced ECG monitoring is required if this use is unavoidable. However, previous communication with NHS England has suggested that serial use of these two drugs would necessitate IFR; clarification on this point has been sought from NHS England.

In summary, the Committee supported the use of both delamanid and bedaquiline in line with the NHS England Clinical Commissioning Policy F04/P/a.

Decision: Approved
Prescribing: Secondary care
Tariff status: PbR-excluded
Funding: NHS England
Fact sheet or shared care required: No
Audit required: No

7.4 Nebulised tobramycin for non-CF bronchiectasis (Applicant: Dr J Hurst, RFL)

Dr Amer presented an application to use tobramycin in patients with non-CF bronchiectasis. The applicant was unable to attend.

The Committee considered evidence from a systematic review and meta-analysis of antibiotic prophylaxis (Cochrane 2015), and of inhaled antibiotics (Brodt et al. , 2015) as well as three randomised controlled trials of nebulised tobramycin (Barker et al., 2000; Drobnic et al., 2005; Orriols et al., 2015).

Brodt et al. showed that nebulised antibiotics are effective at improving microbiological outcomes, with a greater reduction in sputum bacterial load (log10 CFU.g-1) compared with the control group (weighted mean difference = -2.65 [95% CI: -4.38 to -0.92; p=0.003]). Furthermore, a four-fold higher chance of achieving bacterial eradication from sputum was observed (risk ratio = 4.2 [95% CI: 1.62–10.64; p=0.003]).

The Committee noted that important clinical outcomes for patient with non-CF bronchiectasis are: reducing the risk of exacerbations and unscheduled hospitalisations; improving lung function; and improving quality of life (QoL).

Brodt et al. showed inhaled antibiotics produced a reduced risk of exacerbation compared with controls (risk ratio = 0.72 [95% CI: 0.55 to 0.94; p=0.02]). There was no statistically significant incidence of hospitalisation between the antibiotic group and the control group (risk ratio = 0.59 [95% CI: 0.14 to 2.51, p=0.48]). . Results for FEV1 % predicted, a small but statistically significant mean change in favour of the control group (WMD = -0.66 [95% CI: 1.13 to -0.29], p=0.005). There was no statistical difference in the HRQoL between inhaled antibiotics and control groups in terms of improvement in 'St. George Respiratory Questionnaire' (SGRQ) score (WMD = -1.49 [95% CI: -5.79 to 2.80, p=0.50).

Barker et al. (n=74) did not report the number of exacerbations; however 5 participants in the tobramycin group and 1 participant in the placebo group had unscheduled hospitalisations. There was no significant improvement in lung function with tobramycin although there was an improvement in the physician assessment of QoL.

Drobnic et al. (n=30) found no statistically significant difference in the mean number of exacerbations (p=0.330). However, the mean number of exacerbations that required admission and the mean number of days of hospital admissions per person were significantly lower in the tobramycin period than in the placebo period (0.15 versus 0.75, p=0.038 and 2.05 versus 12.65, p=0.047 respectively). There was no significant improvement in lung function. There was no significant difference in the mean change from baseline to the end of treatment in the St George's respiratory questionnaire (SGRQ) total scores.

Orriols et al. (n=35) found that tobramycin compared with placebo significantly reduced the mean number of exacerbations (1.27 versus 2.5, p=0.04), mean number of admissions (0.06 versus 0.47, p=0.03) and mean number of days of hospital admission in (0.90 versus 13.567, p=0.04). There was no significant improvement in lung function. The mean change in the total SGRQ scores for tobramycin and placebo was −14.6 and −4.9 (p=0.31) and a non-statistical significant difference between tobramycin and placebo for the change in individual component scores.

Quality of life was reported using the St George's Respiratory Questionnaire, which failed to demonstrate a significant improvement in all three trials. In a Cochrane Review, there was a trend towards improvement, but this did not meet the minimum improvement required to be clinically relevant. The Committee questioned whether there was a need to ensure equality of treatment between those with CF and non-CF bronchiectasis. The Committee felt that as these were such different cohorts of patients, this was not necessary.

The application specified tobramycin for "long term management of chronic pulmonary infections due to *P. aeruginosa*" however it was unclear if all patients met the BTS guidelines for long-term nebulised antibiotics (patients having ≥3 exacerbations per year requiring antibiotic therapy or patients with fewer exacerbations that are causing significant morbidity; level C evidence) or the overall positioning of tobramycin against other nebulised antibiotics. The Royal Brompton recommends tobramycin as a third-line treatment for *P. aeruginosa* infections; after failure or intolerance to both nebulised colistimethate and gentamicin. The Committee considered it very unlikely that *P aeruginosa* would be sensitive to tobramycin if resistant to gentamycin; colistimethate resistance is unusual although is increasing. The only guidance available for treatment of non-CF bronchiectasis is from the British Thoracic Society; there is no guidance available in the US or Europe.

The annual cost of nebulised tobramycin (TOBI®) was significantly greater than either colistimethate or gentamicin. There was no evidence to support a claim of superiority of tobramycin over either alternative and the budget impact for 12 patients in NCL was estimated to be £238,000. It was noted that this is a high-cost drug which is not routinely commissioned and as such would be subject to business case approval.

In summary, the Committee was not convinced that nebulised tobramycin adequately reduced exacerbations and hospitalisations. Furthermore, reported improvement in QoL failed to meet the minimum improvement required to be clinically relevant. Lastly, the budget impact was considered to be both prohibitive and unjustifiable.

Decision: Not approved

8. Methotrexate Shared Care Guideline

Mr Minshull presented an update to the Methotrexate Shared Care Guideline following JFC recommendation (August 2016) that methotrexate is suitable for prescribing in primary care for off-label indications provided that the patient and dose are stabilised by a specialist. Consultation has been sought with all Trusts and CCGs in NCL.

The Committee approved the Shared Care Guideline.

9. Ulipristal Acetate Shared Care Guideline

Mr Minshull presented a new shared care guideline for Ulipristal Acetate, a medicine that had been approved by the JFC in November 2015. Consultation has been sought with all Trusts and CCGs in NCL.

The Committee approved the Shared Care Guideline.

Post meeting notes: This Shared Care Guideline has been approved following a clinical consensus on the use of ulipristal acetate having been reached. Trusts should work with Gynaecologists in their organisations to ensure funding is in place to support the first three months of prescribing.

10. JFC Work plan

This item was included for information only. Any questions should be directed to Mr Minshull.

11. Next meeting

Thursday 25 May 2017, St Pancras Hospital Conference Hall, 4 St Pancras Way, London, NW1 0PE

12. Any Other Business

Nil