# JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Thursday 26th November 2015  
Room 6LM1, Stephenson House, 75 Hampstead Rd

**Present:**
- Prof R MacAllister  
  NCL JFC Chair (Chair)
- Ms R Clark  
  NHS Camden, Head of Medicines Management
- Mr P Gouldstone  
  NHS Enfield, Head of Medicines Management
- Ms P Taylor  
  NHS Haringey, Head of Medicines Management
- Mr J Paszkiewicz  
  NEL CSU, Senior Prescribing Advisor
- Dr A Stuart  
  NHS Camden, GP Clinical Lead Medicines Management
- Dr M Kelsey  
  Whittington, DTC Chair
- Dr V Thigiarasah  
  NHS Enfield, Medicines Management GP
- Ms W Spicer  
  RFH, Chief Pharmacist
- Dr A Stuart  
  Whittington, DTC Chair
- Mr A Shah  
  RNOH, Chief Pharmacist
- Ms H Taylor  
  WH, Chief Pharmacist

**In attendance:**
- Mr J Minshull  
  NCL JFC, Support Pharmacist
- Ms I Samuel  
  RFH, Formulary Pharmacist
- Mr P Bodalia  
  UCLH, Principal Pharmacist
- Mr A Barron  
  NCL JFC, Support Pharmacist
- Mr E Hindle  
  MEH, Formulary Pharmacist
- Ms S Sanghvi  
  UCLH, Formulary Pharmacist
- Mr K Thakrar  
  UCLH, Formulary Pharmacist
- Dr A Shah  
  UCLH, Registrar, Clinical Pharmacology
- Mr G Purohit  
  RNOH, Deputy Chief Pharmacist
- Ms H Mehta  
  NMUH, Formulary Pharmacist
- Ms S Dhall  
  RFH, Cardiology Pharmacist
- Mr E Saridogan  
  UCLH, Consultant Gynaecologist
- Dr D Nair  
  RFH, Consultant Chemical Pathologist
- Ms P Chambers  
  UCLH, Oncology Pharmacist
- Dr R Roylance  
  UCLH, Consultant Oncologist
- Dr C McGuiness  
  NHS Islington Patient Representative

**Apologies:**
- Dr R Kapoor  
  UCLH, Consultant Neurologist
- Mr T James  
  MEH, Chief Pharmacist
- Dr R Urquhart  
  UCLH, Chief Pharmacist
- Mr A Dutt  
  NHS Islington, Head of Medicines Management
- Dr R Sofat  
  UCLH, Consultant Clinical Pharmacologist
- Prof L Smeeth  
  NCL JFC Vice-Chair
- Mr B Sandhu  
  NEL CSU, Assistant Director Acute Services
- Mr C Daff  
  NHS Barnet, Head of Medicines Management
- Dr E Boleti  
  RFH, Consultant Medical Oncologist
- Dr R Breckenridge  
  UCLH, DTC Chair
2. **Meeting observers**

Prof MacAllister welcomed Dr Carol McGuinness as an observer to the meeting. Dr McGuinness is currently the Patient Representative for NHS Islington CCG Medicines Optimisation Group.

3. **Minutes of the last meeting**

The following amendments were made to the October 2015 minutes:

- The title for Ms S Naidu in attendance was amended to “Camden Diabetes IPU, Consultant Nurse”
- The final sentences of item 8.1 was amended to “Nebido is commonly prescribed in NCL with approximately 73% of patients who require intramuscular testosterone already treated with Nebido; of these, 90% of prescriptions are in primary care. The Committee was satisfied that testosterone undecanoate was an established treatment in both primary and secondary care and agreed to add testosterone undecanoate to the NCL Joint Formulary for haematology and for adolescent endocrinology.”
- The last sentence of item 8.2 was amended to “For insomnia, it was agreed that melatonin should be used second line for up to 13 weeks, after zopiclone, zolpidem, or a benzodiazepine, and prescribing should not be transferred to primary care to avoid a change in practice of this common condition.”
- The last sentence of the 1st paragraph for item 9 was amended to “Dr Dipesh Patel (RFH), Dr Sarita Naik (UCLH) and Ms Shantell Naidu (Camden IPU) attended on behalf of the diabetology clinical team.”

4. **Matters arising**

4.1 **Tolvaptan for autosomal dominant polycystic kidney disease in adults**

In June 2015, this Committee reviewed an application for tolvaptan for autosomal dominant polycystic kidney disease and agreed to defer their decision pending the anticipated NICE Technology Appraisal. Ms Sanghvi informed the Committee that tolvaptan had been approved by NICE (TA 358) for this indication.

5. **Declarations of relevant conflicts of interest**

Dr D Nair declared she had attended Advisory Boards for both evolocumab and alirocumab (item 7.3). Mr P Gouldstone declared he had attended an Advisory Board for alirocumab (Item 7.4).

6. **Local DRT recommendations / minutes**

<table>
<thead>
<tr>
<th>Month</th>
<th>DTC site</th>
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<th>JFC outcome</th>
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<tr>
<td>Oct-15</td>
<td>UCLH</td>
<td>Nintedanib (compassionate use, appeal)</td>
<td>Idiopathic pulmonary fibrosis (IPF), second line to pirfenidone</td>
<td>UCLH only</td>
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<tr>
<td>Oct-15</td>
<td>UCLH</td>
<td>Citrate (Prismaflex®; Gambro)</td>
<td>Regional Citrate Anticoagulation during CRRT</td>
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<td>Oct-15</td>
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<td>Dinoprostone</td>
<td>Maintain Patency of Ductus Arteriosus in neonates</td>
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<td>Oct-15</td>
<td>RFH</td>
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<tr>
<td>Oct-15</td>
<td>RFH</td>
<td>Artesunate</td>
<td>Severe falciparum malaria</td>
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<td>Oct-15</td>
<td>RFH</td>
<td>Raltitrexed</td>
<td>Advanced colorectal cancer who are intolerant to or develop cardiotoxicity to 5-FU</td>
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<td>Oct-15</td>
<td>MEH</td>
<td>Bevacizumab intravitreal</td>
<td>Coats’ disease and familial exudative vitreoretinopathy (FEVR)</td>
<td>Added to NCL Joint Formulary</td>
</tr>
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6.1 **Citrate regional anticoagulation in ICU (UCLH)**

Ms Sanghvi informed the Committee that citrate (Prismaflex®; Gambro) for regional anticoagulation during continuous renal replacement therapy on ICT has been approved by the UCLH DTC. The citrate system allows regional anticoagulation rather than the current systemic anticoagulation with heparin. This reduces bleeding risk and is more appropriate for patients with heparin induced thrombocytopenia.
or other coagulopathies. The Committee heard that regional citrate anticoagulation is a very complex system which requires risk avoidance measures to be in place. Several different systems are available, each with different machines and accompanying fluids. At UCLH implementation has included a detailed protocol, use of inbuilt decision support software, extensive training and input from other London ICUs where regional citrate anticoagulation is currently used. Whilst the citrate system introduced at UCLH had a higher upfront cost, the system was expected to be cost-neutral due to longer filter life, reduced transfusions and fewer complications. In summary, the Committee agreed to add citrate for regional anticoagulation during haemofiltration to the NCL Joint Formulary. It was imperative that local DTCs managed local implementation closely to ensure adequate training and risk avoidance measures are in place.

7. New Medicine Reviews

7.1 Ulipristal acetate for uterine fibroids (Applicant: Mr Saridogan, UCLH; Presentation: Mr Minshull)

An application was reviewed to use ulipristal acetate for the repeated, intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, who are not suitable for surgery, have had previous surgery or are approaching menopause. The application was in line with the Marketing Authorisation for the drug. In November 2012 the JFC had approved the use of ulipristal acetate 5 mg daily for a three month pre-operative treatment course.

PEARL III was a multicentre, open-label study of 209 pre-menopausal women with symptomatic uterine fibroids and heavy bleeding. In this study, women were treated for 90 days with ulipristal acetate 10 mg daily (higher dose than that licensed in the UK), with half randomised in a double-blind manner to subsequently receive norethisterone acetate 10 mg daily or placebo for 10 days. Amenorrhoea was reported by 164 of the 209 women (78.5%, 95% CI: 72.4 to 83.5%, median time to amenorrhoea 3.5 days) after the first course of treatment.

One hundred and thirty two patients then continued on to the extension study (PEARL III Extension) to receive up to a further 3 courses of ulipristal acetate. There was no difference in amenorrhoea rates after course one between those consenting to enter the extension study and drop-outs, though there had been a greater reduction in fibroid volume (-49.9% vs. -38.5%) and QOL improvement (least square mean change 31.2 vs. 25.3). Amenorrhoea rate increased to between 88.5% and 89.7% in women who received two to four courses of ulipristal acetate. The median change in combined-volume of the three largest fibroids from baseline to end of the first treatment course was -45.1% (IQE: -66.1 to -24.9%). This volume reduction continued for patients receiving multiple courses, plateauing at about 72%.

Considering important secondary end-points, women reported substantial improvements in pain and QoL scores during treatment, though improvements seen after the first course were larger than those seen after subsequent courses.

PEARL IV (a randomised, double-blind study of 451 women) evaluated the efficacy of ulipristal 5 mg or 10 mg daily. In part 1 of the study, assessment of ulipristal efficacy was measured after two courses of twelve weeks of treatment. In part 2 of the study, assessment was after four courses of treatment. Patient numbers decreased after the first course as patients were allowed to leave the study to have surgery. The primary efficacy end-point, percentage of patients with amenorrhoea at the end of treatment courses one and two, was 62% on 5 mg, 73% on 10 mg, and at the end of each of the four treatment courses was 49% on 5 mg and 61% on 10 mg.

PEARL IV demonstrated similar efficacy of ulipristal acetate to PEARL III and PEARL III Extension. Long term, intermittent treatment with ulipristal 5 mg or 10 mg daily led to amenorrhoea after each treatment course and controlled bleeding after all four treatment courses in a significant proportion of patients. Median fibroid volume (3 largest fibroids) decreased during the study (-54.1% to -71.8% after two and four courses of ulipristal acetate 5 mg respectively).

The most frequent adverse effects associated with ulipristal acetate included endometrial thickening, affecting up to 15% of women. For this reason, women should undergo a two-bleed treatment holiday after three months of therapy, and monitoring of the endometrium with annual ultrasound. Results from PEARL III and IV studies showed that repetition of treatment courses did not increase PAEC (PRM-associated endometrial change) appearance, frequency or reversibility. Hyperplasia incidence was reported to be low in PEARL III and PEARL IV, and did not increase with four courses. Hot flushes affected up to 24% of patients in active comparator studies (compared to 60% with leuprolelin).
As part of its intended use is to maintain fertility in women, the Committee was reassured by reports that pregnancies have occurred after uterine fibroid treatment with ulipristal acetate. Of twenty one women wishing to conceive, fifteen women became pregnant (18 pregnancies), with 12 resulting in delivery of 13 healthy babies and 6 ending in early miscarriage.

Ulipristal acetate 5 mg costs £114 for 28 days (£342 for 3 months, £1,370 for four courses). Drug treatment should reduce the requirement for surgical treatments of uterine fibroids. The applicant proposed that 40 patients have been identified for treatment with ulipristal; in the event that this treatment is not supported by the JFC, 20 patients will require myomectomy (£3,213/procedure), 12 patients will require hysterectomy (£2,200 to £3,300/procedure), 6 patients will require embolization (£2,458/procedure) and 2 patients will require endometrial ablation/fibroid resection (ablation £905/procedure). Ulipristal is therefore likely to be cost-neutral compared with surgical intervention when used at a maximum of 8 courses of treatment. The applicant did not support use of this treatment if all prescribing were to be restricted to secondary care as the cost of the drug is outwith of the associated HRG income tariff. The Committee noted the applicants’ opinion that it would be clinically appropriate for prescribing to be undertaken by a GP.

Although the Marketing Authorisation does not limit the number of courses of ulipristal acetate that a patient can receive, there are currently no data beyond eighteen months (four courses). Data reporting on use of ulipristal acetate for up to five years (eight courses) are expected imminently; therefore longer term use should be evaluated when these data are available.

In summary, the Committee agreed that the extended use of ulipristal would add value in the treatment options for the target population whilst offering the opportunity for a saving in CCG commissioning budgets (avoidance of surgery). This saving however would come at the cost of an increase in drug spend; therefore further discussion would be needed between the relevant CCG and provider leads to explore local commissioning arrangements to introduce this treatment into practice. The final decision was thus deferred pending outcome of this discussion.

**Actions:** Mr Minshull to provide the Medicines Optimisation Network with information on anticipated patient numbers, costs avoided and monitoring requirements.

**Decision:** Approved subject to funding

Prescribing: Initiation in Secondary care and then transfer to Primary care (to be confirmed)

Tariff status: Included

Funding: To be confirmed

Fact sheet or shared care required: To be confirmed when prescribing status agreed

Audit required: No

### 7.2 Prucalopride for constipation in men (Applicant: Dr Emmanuel, UCLH; Presentation: Mr Minshull)

The Committee heard that NICE TA211 had recommended prucalopride for women with chronic constipation who had failed at least two laxatives at full doses, for 6 months, and invasive treatment for constipation is being considered. The restriction to women was secondary to the EMA restricting the licensed indication to female patients. Prucalopride is now licensed in men, with evidence available supporting its efficacy, therefore on the grounds of gender equality, the Committee agreed to remove the gender restriction in NCL.

In summary, the Committee agreed that prucalopride should be added to the NCL Joint Formulary for men with chronic constipation who had failed at least two laxatives at full doses, for 6 months, and invasive treatment for constipation is being considered.

**Decision:** Approved

Prescribing: Secondary care initiation with continuation by GP

Tariff status: Included

Funding: Hospital and GP budgets

Fact sheet or shared care required: No

Audit required: No

### 7.3 PCSK9 inhibitors (evolocumab or alirocumab) for lipid clinic (Applicants: Dr Lunken, UCLH [evolocumab] and Dr Nair, RFH [alirocumab]; Presentation: Mr Barron)

The Committee reviewed two applications for the use of evolocumab and alirocumab for patients with heterozygous familial hypercholesterolaemia and high cardiovascular risk.
The Committee were informed that heterozygous-familial hypercholesterolaemia (HeFH) is a genetic condition associated with high LDL-C levels and increased risk of cardiovascular (CV) disease. NICE guidelines recommend reducing CV risk with a high intensity statin and NICE TA132 recommends ezetimibe as monotherapy when statins are not tolerated, and in combination with statins when initial statin therapy does not provide appropriate control of LDL-C. PCSK9 inhibitors offer a new mechanism of action which prevents degradation of LDL receptors in the liver, thereby facilitating LDL-C clearance from circulation and lowering LDL-C levels in the blood. The Committee reviewed the published evidence for each drug in turn.

RUTHERFORD-2 was a 12 week multinational, double-blind, placebo-controlled RCT to investigate the safety and efficacy of evolocumab in patients with HeFH (n=329). Adult patients with a clinical diagnosis of HeFH taking a statin ± other lipid lowering therapies (including ezetimibe) were included. Patients were randomised 2:2:1:1 to receive evolocumab 140mg every 2 weeks (evoQ2W), evolocumab 420mg every month (evoQ4W), placebo every 2 weeks or placebo every 4 weeks. Primary endpoints included % change in LDL-C from baseline weeks 10 & 12. Completion rates were high (99%) and did not differ significantly between groups. Baseline characteristics were relatively well balanced across groups; on average patients were 51 years old, 31% had coronary artery disease, LDL-C was 4mmol/L, all were taking a statin (87% taking high intensity statin) and 62% were taking ezetimibe. Results demonstrated that compared with placebo, evolocumab achieved a mean reduction in LDL-C of 60.2% (95%CI: 54.5–65.8%) and 65.6% (95%CI: 59.8–71.3%) for evoQ2W and evoQ4W respectively. A second study, GAUSS-2, recruited patients with statin intolerance and demonstrated that evolocumab reduced LDL-C from baseline by 56.1% (95%CI: 59.7–52.5%) and 55.3% (95%CI: 58.3–52.3%) for evoQ2W and evoQ4W respectively.

ODYSSEY FH I (primarily US) and FH II (primarily EU) were 24+54 week multicentre, multinational, randomized, double-blind, placebo controlled studies to investigate the safety and efficacy of alirocumab in patients with HeFH (n=486+249=735). Adult patients with a clinical diagnosis of HeFH taking a statin ± other lipid lowering therapies (including ezetimibe) with LDL-C ≥2.6mmol/L (for secondary prevention) or ≥1.8mmol (primary prevention) were included. Patients were randomised 2:1 to receive alirocumab 75mg every 2 weeks or placebo every 2 weeks; the dose of alirocumab was increased in a blinded fashion to 150mg if LDL-C at week 8 was ≥1.8mmol/L. Primary endpoint was % change in LDL-C from baseline to week 24. Completion rates at 24 weeks were not reported, however at 76 weeks discontinuation was 19% and 18% for alirocumab and placebo respectively. Baseline characteristics were well balanced across groups in the studies although characteristics were different between studies; FH I had a higher prevalence of CHD, slightly higher baseline LDL-C but slightly lower high-intensity statin and ezetimibe use. Dose increases from alirocumab 75 to 150mg were required for 43% & 39% of patients in FH I & FH II respectively. FH I results demonstrated that compared with placebo, alirocumab achieved a week 24 reduction in LDL-C of 57.9% (95%CI: 52.6–63.3). FH II results demonstrated that compared with placebo, alirocumab achieved a week 24 reduction in LDL-C of 51.4% (95%CI: 44.8–58.1). A second study, ODYSSEY ALTERNATIVE, recruited patients with statin intolerance and demonstrated that alirocumab reduced LDL-C from baseline by 45.0%.

With regards to safety, both drugs report similar overall adverse events to placebo. A recent meta-analysis identified PCSK9 inhibitors to be associated with a higher incidence of neurocognitive adverse events compared with placebo (OR = 2.35 [95%CI: 1.11-4.93]) although the clinical implications of this are unclear.

With regards to cost, both companies have provided confidential Patient Access Schemes. It is anticipated that PCSK9 inhibitors will be excluded from tariff in April 2016 therefore all prescribing will remain in secondary care. The NICE Appraisal Consultation Document for evolocumab published in November 2015 made a negative recommendation due to methodological weaknesses in the cost-effectiveness evaluation. Despite this the Committee were minded that the NICE Final Appraisal Document for the PCSK9 inhibitors would likely be positive given the novel mechanism of action, the significant treatment effect and the high unmet need for the population proposed in the applications.

Dr Nair informed the Committee that none of the studies included CV events as a primary endpoint however such studies were underway with results expected in 2 to 3 years. Ezetimibe was approved by NICE for HeFH before the CV outcome studies had been published and furthermore, recently published meta-analyses for both drugs suggested PCSK9 inhibitors reduced CV events by approximately 50%.

The Committee agreed that early use of PCSK9 inhibitors should be prioritised for patients with the highest baseline CV risk. The inclusion criteria proposed under both applications were reviewed and the criteria set out by the RFH was preferred. It was questioned why the Committee were reviewing these application given pending NICE TAs, however it was agreed that the nine month lag between product
launch and funding agreement was too long to wait for access to these class of medicines in such high risk patients.

The Committee and applicant agreed that access to only one PSCK9 inhibitor would be necessary. On this basis, it was agreed that the most cost-effective PCSK9 inhibitor, evolocumab 140mg every two weeks, should be made available on the NCL Joint Formulary with a restriction to specialist use at UCLH and RFH lipid clinics and subject to internal funding approval. Prescribing should be restricted to patients with a clinical diagnosis of HeFH who have an LDL ≥4.5mmol/L and:

- Have CVD and on maximum tolerated therapy (statin + ezetimibe)
- or
- Are intolerant to a statin ± ezetimibe (± other lipid lowering drugs) and have two other CHD risk factors (including smoking, hypertension, low HDL and lipoprotein a).

Patients must have tried to quit smoking using established smoking cessation programme. Statin intolerance is defined as having tried at least 3 statins or had a documented episode of rhabdomyolysis.

Decision: Approved (pending funding confirmation)
Prescribing: Hospital only
Tariff status: Included until April 2016, expected to be excluded after this time.
Funding: Hospital funding until 90 days post positive NICE TA, CCG funding after this time.
Fact sheet or shared care required: No
Audit required: Yes, in 1 year

7.4 Pivmecillinam in uncomplicated UTI

An application was heard for the use of pivmecillinam for urinary tract infections (UTI) due to suspected extended-spectrum beta-lactamases (ESBL) producing organisms in primary and secondary care. Dr Kelsey informed the Committee that pivmecillinam, an oral pro-drug of mecillinam (a penicillin), was launched in 1980 and is widely used in Scandinavia. Public Health England (PHE) now recommends pivmecillinam as an option for uncomplicated UTIs in adults due to the increasing rates of ESBL producing organisms. Pivmecillinam is not restricted to Microbiology approval in primary or secondary care and will be included as part of second-line sensitivity pattern assessment in secondary care.

It was discussed whether pivmecillinam could be adopted in NCL A&Es as CCGs are keen to reduce the prescribing rates of co-amoxiclav, quinolones and ciprofloxacin. PHE advises that routine use of broad spectrum antibiotics (e.g. co-amoxiclav, quinolones and cephalosporins) should be avoided when narrow spectrum antibiotics remain effective; the rationale being that broad spectrum antibiotics are associated with an increased risk of C. diff. The Royal College of GPs and PHE have reminded prescribers that narrow-spectrum penicillins are associated with a lower odds ratio for risk of C. diff than cephalosporins and fluoroquinolones. Dr Kelsey stated that pivmecillinam was unlikely to displace co-amoxiclav as pivmecillinam would be prioritised for ESBL producing organisms, however hospitals should explore whether the addition of pivmecillinam to treat UTI, suspected or known to be caused by an ESBL, can support A&E departments to reduce use of broad spectrum antibiotics in UTI.

In summary, the Committee was satisfied that pivmecillinam was a safe and effective treatment for UTI suspected to be caused by ESBL and should be added to the NCL Joint Formulary for primary and secondary care.

Decision: Approved
Prescribing status: Primary and Secondary care
Tariff status: Included
Funding: Hospital and GP budgets
Fact sheet or shared care required: Not applicable
Audit required: No

7.5 Temocillin for ESBL infections

An application was heard for the use of temocillin for confirmed extended-spectrum beta-lactamases (ESBL) producing organisms in secondary care. Dr Kelsey informed the Committee that temocillin is available as an intravenous preparation and the available data suggests that a dose of 2g twice-daily was effective. Temocillin would be used primarily for ESBL bacteraemia and should be used in combination with a gram positive antimicrobial agent (teicoplanin or vancomycin). The Committee agreed that
temocillin should be added to the NCL Joint Formulary to treat ESBL organisms and should be restricted to Microbiology approval only.

Decision: Approved
Prescribing status: Secondary care only, Microbiology approval required
Tariff status: Included
Funding: Secondary care budget (OPAT not discussed)
Fact sheet or shared care required: Not applicable
Audit required: No

The Committee agreed that medicines recommended within an NHS England Commissioning Policy should remain subject to the standard JFC / DTC application and review process as the DoH mandate for not duplicating the review of innovative treatment only applies to recommendations made within a NICE Technology Appraisal. It was agreed that all provider Trusts in NCL should adopt this policy to avoid regional differences in practice.

9. **Xgeva® (denosumab) for preventing skeletal related events**
Mr Minshull informed the Committee that patients with solid tumours receive treatment with bisphosphonates in their registered chemotherapy centre to prevent skeletal related events. The first-line bisphosphonate of choice is intravenous zolendronic acid as this ties in with the 3-week chemotherapy cycle and hospital admissions. Where subcutaneous denosumab (Xgeva®) is indicated, patients are required to attend hospital for a separate episode as the administration cycle for this agent is every 4 weeks. This visit is an additional cost for the CCG and an inconvenience for the patient. As part of the strategy to improve the overall patient experience London Cancer (part of UCL Partners) has put forward a proposal recommending denosumab subcutaneous administration closer to the patients home (i.e. in primary care).

The Committee heard that denosumab (Xgeva®) is NICE approved (TA265) and has the potential to be cost-saving from an NHS payer perspective as it is a subcutaneous injection and therefore does not require admission into Acute Trusts for administration, unlike intravenous zolendronic acid. Ms Chambers, a member of London Cancer, informed the Committee that although denosumab is not available in a prefilled device (and therefore not suitable for patient self-administration) there is precedence of it being administered in GP practices in other regions of the UK. A second model was discussed where Acute Trusts develop a locally agreed service model where they use a Homecare provider to supply and administer denosumab, which can be supplied in pre-filled syringe for patients to self-administer. A barrier to implementation of the first model is that funding for activity related to bisphosphonates administration in secondary care (either via block contracts or PbR tariff activity) would need to be made available to GPs. The commissioners and GPs also discussed that there are capacity issues in primary care which would need to be considered. Concern was also raised by Commissioners that this model would result in two different preparations of denosumab (Xgeva® and Prolia®) being available in some GP practices, which could contribute to administration errors.

In summary, the Committee supported the rationale for use of subcutaneous denosumab to improve patient experience, lower overall treatment costs and achieve compliance with the NICE Technology Appraisal. The Committee agreed that details on the implementation of this (specifically contractual and supply arrangements) should be co-ordinated by its sub-Committee, the NCL Medicines Optimisation Network.

Decision: Approved pending service development (TBC by NCL Medicines Optimisation Network)
Prescribing: Initiation in Secondary care and then transfer to Primary care (to be confirmed)
Tariff status: Included
Funding: To be confirmed by NCL Medicines Optimisation Network
Fact sheet or shared care required: To be confirmed by NCL Medicines Optimisation Network
Audit required: No

10. **JFC Work Plan**
Mr Bodalia informed the Committee that there was an interest in improving transparency about the work JFC Support is undertaking. The JFC Work Plan will be uploaded every 1-2 weeks to the secure part of the JFC website for all members to access and comment.
Mr Minshull informed the Committee that work on the DOAC guideline has stalled due to the bundling of two separate problems; firstly the anticoagulation commissioning pathway and secondly the choice of therapy. The Committee agreed that the commissioning pathway does not need to be brought back to the JFC. The CCG leads requested that the JFC Support Pharmacists prioritise the review on choice of anticoagulation agents (the place for warfarin and DOACs, and which DOAC should be prescribed) to progress this. The CCG leads also requested that a draft version of the guideline is submitted to them for comment in advance of being brought back to JFC.

As part of the OAD/GLP-1RA work stream, it was requested that GLP-1RA in combination with insulin was specifically reviewed at JFC.

11. **Next meeting**
    Thursday 28th January 2016, Room 6LM1, Stephenson House, 75 Hampstead Rd.

12. **Any Other Business**
    Nil