North Central London
Joint Formulary Committee

JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Monday 16 October 2017
G12 Council Room, South Wing, UCL, Gower Street, London WC1E 6BT

Present:	Dr R MacAllister	NCL JFC Chair	**(Chair)**
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
	Ms W Spicer	RFL, Chief Pharmacist	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Ms A Fakoya	NEL CSU, Senior Prescribing Advisor	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Mr T Dean	Patient Partner	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Dr M Kelsey	WH, Chair DTC	
	Dr R Woolfson	RFL, DTC Chair	
	Dr F Gishen	RFL, Palliative Medicine Consultant	
	Dr D Hughes	RFL, Consultant Haematologist	
	Ms EY Cheung	Camden CCG, Deputy Head of Medicines Management	
In attendance:	Mr A Barron	NCL JFC, Support Pharmacist	
	Mr J Minshull	NCL JFC, Support Pharmacist	
	Mr P Bodalia	UCLH, Principal Pharmacist	
	Ms R Chennells	WH, Care of Older People Specialist Pharmacist	
	Ms M Bhogal	NMUH, Formulary Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Ms P McCormick	WH, Lead Pharmacist - Medicines	
	Ms M Kassam	MEH, Formulary Pharmacist	
Apologies:	Ms R Clark	Camden CCG, Head of Medicines Management	
	Mr C Daff	Barnet CCG, Head of Medicines Management	
	Dr R Sofat	UCLH, DTC Chair	
	Prof L Smeeth	NCL JFC Vice-Chair	
	Mr G Kotey	NMUH, Chief Pharmacist	
	Dr P Hyatt	NMUH, DTC Chair	
	Prof A Tufail	MEH, DTC Chair	
	Dr V Thiagarasah	Enfield CCG, GP Clinical Lead Medicines Management	
	Dr R Fox	RNOH, DTC Chair	
	Mr A Shah	RNOH, Chief Pharmacist	
	Dr R Kapoor	UCLH, Consultant Neurologist	
	Ms L Reeves	C&I, Chief Pharmacist	
	Mr T James	MEH, Chief Pharmacist	
	Mr B Sandhu	NEL CSU, Assistant Director Acute Services	
	Dr A Bansal	Barnet CCG, GP Clinical Lead Medicines Management	
	Mr S Richardson	WH, Chief Pharmacist	

2. Meeting observers

The Chair informed the Committee that Dr V Thiagarasah (Enfield CCG, GP Clinical Lead Medicines Management) has stepped down from the JFC. *In absentia*, the Chair thanked Dr Thiagarasah for his contribution to the Committee.

3. Minutes of the last meeting

Ms Cheung asked that the minutes be amended to reflect that immediate-release fentanyl preparations are not included in the Camden Palliative Care Guidelines.

The minutes and abbreviated minutes were otherwise accepted as an accurate reflection of the September meeting.

4. Matters arising

4.1 Idebenone for Duchenne Muscular Dystrophy (Early Access to Medicines Scheme; EAMS)

In July and September 2017 the Committee considered an application for idebenone to slow respiratory decline in adults with Duchenne Muscular Dystrophy (DMD). The Committee considered the treatment effect for idebenone observed in the DELOS study to be small (FVC estimated treatment difference of +5.96% predicted [95% CI: 0.16 to 11.76] at 52 weeks) even for patients whose respiratory decline was expected to progress at a high rate (DELOS inclusion criteria 10 to 18 years; mean age 13.5 years). There was no statistically significant improvement in other respiratory measures (FVC% predicted, the measure preferred in clinical practice) or in other pre-specified secondary endpoints. The Committee concluded that the benefits of idebenone for adults with DMD to be highly uncertain and likely to be marginal at best.

Working under the assumption that idebenone would obtain a license for DMD and be nationally commissioned (via NHS England) the Committee conditionally approved the EAMS at the September meeting and asked JFC Support to raise the Committee's concerns at a national level (with NHSE and the NICE HST team). The Paediatric North Star network, a UK clinical network specialising in the care of young patients with DMD, was expected to issue advice imminently on the appropriateness of the EAMS.

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending a rejection of the application to add DMD as a licensed indication for idebenone. The CHMP was of the opinion that the study results were insufficient to determine the benefit of idebenone; although a difference in peak expiratory flow (PEF) in favour of idebenone was observed, there was no clear improvement in other indicators of breathing function or in muscle strength, motor function or quality of life. The CHMP also had some concerns about the way the study was conducted and analysed. The manufacturer, Santhera, intend to appeal the decision.

The Committee took the view that it could not endorse the use of a medicine which has been rejected by the scientific advisory group to the EMA. Further, the proposed cohort at NHNN (respiratory decline of any age, specifically adults) represented a population outside of the evidence base. Conclusions based on a putative clinical benefit in these patients were even more uncertain than those considered by the CHMP as part of the application for the license extension. The Committee were uncertain how the MHRA could continue to support an EAMS, which is specifically designed to make innovative medicines available to patients pre-licensing approval, if the licensing body does not consider the medicine to deliver any convincing benefit and therefore by definition does not consider the medicine to be innovative. In summary, the Committee agreed to retract their previous conditional approval and defer their decision until the outcome of the EMA appeal is communicated and confirmation of where this leaves the EAMS.

Action: Request minutes from the Paediatric North Star Network where idebenone for use in paediatrics was considered. Clarify with MHRA what they plan to do with the EAMS now there is negative CHMP.

Post meeting note: The Paediatric North Star Network recommended the idebenone EAMS, provided that the company is willing to supply the medicine for free and that specialists explain clearly to each family, with consent, the current uncertainty of the benefit and side effect profile, while the drug licence authorisation is pending and further research study results are awaited.

Post meeting note: The MHRA advise "The European Union Marketing Authorisation Application process has not concluded, given that the Company intends to seek a re-examination of the CHMP opinion. In this case, a final regulatory opinion will be reached by CHMP prior to the decision by the European Commission, after completion of the re-examination procedure. The EAMS scientific opinion will be revisited if necessary at that time. In the meantime, the EAMS scientific opinion remains in place with the same reporting requirements as before"

5. Declarations of relevant conflicts of interest

There were no declarations of interest

6. Local DTC recommendations / minutes

6.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
RFL	Aug-17	Mexiletine (unlicensed)	Erythromelalgia after failure of analgesia and vasodilators	Decision: Approved Prescribing: Secondary care only Tariff status: In tariff Funding: Secondary care Fact sheet or shared care required: No
RFL	Aug-17	Cangrelor	Primary percutaneous coronary intervention (PPCI) who are intubated and cannot tolerate oral antiplatelets	Decision: Approved Prescribing: Secondary care only Tariff status: In tariff Funding: Secondary care Fact sheet or shared care required: No

6.2 Approved under evaluation

DTC site	Month	Drug	Indication	JFC outcome
RFL	Aug-17	Artiss fibrin sealant	Simple mastectomies – as part of the '23 hour mastectomy' pathway	Decision: Under evaluation at RFL only[†] Prescribing: Secondary care only Tariff status: In tariff Funding: Secondary care Fact sheet or shared care required: No

[†] WH are known to perform 23-hour mastectomies without fibrin sealants. The application to use Artiss at RFL was considered cost-neutral as the drug acquisition cost was covered by the uplift in tariff reimbursement associated with same-day discharges (normal admission for mastectomy = £2663; day case mastectomy = £2959). In order to achieve cost-neutrality, the majority of patients eligible for Artiss would need to be discharged on the same day *and* would otherwise have been admitted overnight if they had not received Artiss. The RFL evaluation will require a comparison with historical data or data from other sites (e.g. WH) to provide meaningful outcomes. The Committee recommended that other indications for fibrin sealants are reviewed at JFC if they are applicable to multiple Trusts.

7. New Medicine Reviews

7.1 Adalimumab and ustekinumab for fistulising Crohn's disease

The Committee considered an application to use adalimumab and ustekinumab for fistulising Crohn's Disease (CD) as an alternative to infliximab where patients express a preference for SC therapy and/or where patients have failed therapy with infliximab. Infliximab is the only biologic to have been investigated for fistulising CD in placebo controlled RCTs (Present et al. 1999, Sands et al. 2004) and is the only biologic to be recommended by NICE for this indication. There are no controlled trials measuring the effect of adalimumab or ustekinumab on fistulising CD as the primary end-point.. International guidelines (ECCO and 'World Gastroenterology Organisation') are outdated and do not include ustekinumab.

The Committee considered the prospective data supporting the use of adalimumab for this indication. Subgroup analyses of secondary endpoints from two short-term induction studies (4 weeks; GAIN and CLASSIC-1) showed no benefit for fistula response or remission. The longer term CHARM study (56 weeks), was a randomised, double-blind, placebo controlled maintenance study to assess the benefit of adalimumab in adults with moderately to severely active CD. All patients received open-label adalimumab induction for 4 weeks before being randomised to adalimumab or placebo. The secondary endpoints included fistula remission. In total 854 patients started the study, 76 withdrew and were not randomised, 499 were randomised responders and 279 were randomised non-responders. At randomisation (week 4), 15% (n=[64+53]/[499+279]) had a fistula at baseline; of those who withdrew at week 4, 17.1% (n=13/76) had a fistula at baseline. Results from the fistula subgroup analysis found that, of those randomised to

treatment (i.e. ± week 4 response), a significantly greater proportion of patients randomised to adalimumab experienced fistula closure compared to placebo (30% vs. 13%, p=0.043). It was noted that patients dropped out during the adalimumab open-label phase, in part due to intolerance and lack of efficacy; therefore it was expected that the results be biased in favour of adalimumab (i.e. enrichment). Subgroup analyses from multiple single arm, open-label studies show adalimumab administration was associated with fistula remission in approximately 20-40% of patients in whom infliximab was not tolerated/ineffective (primary or secondary failures).

The supportive evidence for ustekinumab was very limited; a small subgroup analysis of a secondary endpoint (n=26) from the ustekinumab maintenance study (IM-UNITI) reported 80.0% of patients with fistulising CD achieved a fistula response, and this difference was numerically (not statistically) better than placebo. A conference abstract of ustekinumab induction studies (merger of UNITI-1, UNITI-2 and CERTIFI data) showed a numerically higher initial response rate with ustekinumab compared with placebo (26.0% vs. 16.9%; p=0.14). Two multicentre retrospective analyses of patients treated with ustekinumab included subgroup analyses for patients with perianal CD (a wider term which included fistulising CD); both studies found approximately two-thirds of patients experienced clinical improvement with ustekinumab.

With regards to safety, there is an absence of data indicating any meaningful differences between infliximab, adalimumab and ustekinumab for this condition. Ustekinumab may be preferred for patients in whom anti-TNF are contraindicated e.g. NYHA III-IV. The budget impact for the two patient groups was considered separately. For patients using adalimumab or ustekinumab as a SC alternative to biosimilar infliximab, adalimumab is expected to be similar priced in the medium term (biosimilar anticipated in October 2018) however ustekinumab will be more expensive. For patients using adalimumab or ustekinumab after failure of biosimilar infliximab, this will be a budget pressure of £7,500 to £9,500 per patient per annum. UCLH and RFL anticipate <10 patients per annum (who are not also eligible for treatment due to concurrent moderate-to-severely active CD) therefore a budget impact of <£100,000 can be expected.

The Committee considered the evidence base for adalimumab (anti-TNF) and ustekinumab (anti IL-12 and 23) to be weak. The case for adalimumab was supported by known efficacy of infliximab, an alternative anti-TNF, however infliximab is known to be more effective than adalimumab in other conditions (e.g. psoriasis) a likely consequence of intravenous compared with subcutaneous delivery. Thalidomide, which also works via TNF inhibition, has also shown effectiveness in retrospective analyses. Tacrolimus was suggested as an alternative treatment option however whilst the evidence base was high quality, the reported results were disappointing. Ustekinumab was thought to be the best available treatment for patients in whom anti-TNF therapy has failed. The Committee were reluctant to allow adalimumab to be offered for patients who 'show a preference to SC therapy' as adalimumab is not known to be as effective as IV infliximab. Practice must be to retain first-line infliximab. Adalimumab was to be reserved for patients were the convenience advantage of adalimumab was sufficient to compensate for its inferiority as a treatment, and patients would be expected to be counselled about this choice. There are no data indicating any advantage of ustekinumab versus adalimumab, therefore ustekinumab was rejected as a first-line option for this cohort. Adalimumab and ustekinumab were then considered for patients who fail to respond to IV infliximab; the different mechanism of action for ustekinumab was thought to be advantageous therefore both drugs were approved for this indication.

Despite limited published data, the Committee agreed to support the application due to the major impact on QoL for individuals with fistulising Crohn's disease. A review of patient numbers treated over two years was requested; NEL CSU would conduct this review. In summary, the Committee approved adalimumab and ustekinumab for fistulising CD subject to the following conditions: (1) Infliximab biosimilar is the preferred agent; (2) if patients are not able to receive infliximab (due tolerability or practicality concerns), adalimumab may be considered; (3) ustekinumab may be used where anti-TNFs are contraindicated or have previously failed.

Decision: Approved
Prescribing: Secondary care only
Tariff status: Excluded from tariff
Funding: CCG funding to be agreed as part of the IBD Gastro High Cost Drug pathway.
Fact sheet or shared care required: No

7.2 Pembrolizimab for urothelial cancer (Pre-NICE FOC scheme, Applicant: Dr Vilarino-Varela, RFL)

The Committee considered an application to use pembrolizumab to treat locally advanced or metastatic urothelial cancer. The drug is currently being offered free of charge whilst NICE is evaluating the cost-

effectiveness of the intervention; NICE is expected to publish its technology appraisal guidance in January 2018. The Committee noted that the standard first-line treatment is platinum-based chemotherapy; the company is offering pembrolizumab free of charge where a patient has advanced whilst on platinum-containing chemotherapy, and to patients who are ineligible for chemotherapy. Pembrolizumab is a humanised monoclonal antibody against programmed cell death.

The Committee considered the evidence from the KEYNOTE-45 study (n=542), a pivotal, open-label, randomised phase III trial of pembrolizumab versus investigator's choice of chemotherapy. The committee heard that the median follow-up was 14.1 months (range 9.9 to 22.1 months), with a median duration of treatment of 3.5 months for pembrolizumab (range <0.1 months to 20 months) and 1.5 months for chemotherapy (range <0.1 months to 14.2 months). Overall survival (OS) and progression free survival (PFS) were used as co-primary end-points, with the power calculation presented for both outcomes.

The study demonstrated significantly longer overall survival with pembrolizumab compared to chemotherapy (hazard ratio for death 0.73; 95% CI 0.59 to 0.91, p=0.002); median overall survival was 10.3 months (95% CI 8 to 11.8 months) for pembrolizumab compared to 7.4 months (95% CI 6.1 to 8.3 months) for chemotherapy. A subgroup analysis was discussed that suggests that OS and PFS trend towards improvement in the cohort of patients who are "strongly positive" for PD-L1, compared to those who are "positive", though it was noted that the 95% CI for hazard ratio cross one for PFS in both subgroups. Additionally, it was noted that the objective response rate was higher in the pembrolizumab group than the chemotherapy group (21.1% vs. 11.4%; p=0.001).

The Committee noted that NICE has issued a negative Appraisal Consultation Document for pembrolizumab, however it was recognised that this position may change if the company reduces the price of the medicine to improve its cost-effectiveness. It was noted that the company is only offering two years of free treatment, which may become a problem if NICE does not issue a positive technology appraisal; patients will need to be clearly counselled and consented on this point.

Pembrolizumab is associated with a range of very common side effects (fatigue, pruritus, rash, diarrhoea, nausea). Immune-related adverse reactions, including severe reactions, have also been reported. Pneumonitis has been reported in 3.5% of exposed individuals, therefore patients should be monitored for signs and symptoms of pneumonitis, with appropriate investigation and treatment given.

The Committee questioned whether PD-L1 testing would be conducted before pembrolizumab would be prescribed, as capacity to test for this in NCL is limited. The Committee agreed that PD-L1 testing would only be necessary if this was an entry criterion for the KEYNOTE-45 trial; it was noted that the free of charge scheme did not require PD-L1 testing to be performed before treating with pembrolizumab.

The Committee felt that the scheme should only be approved for patients with characteristics matching the trial participants. Following the meeting, Mr Minshull confirmed that participants were only included in the trial if they had received prior platinum-based chemotherapy, therefore it would not be appropriate to approve the free of charge scheme for patients ineligible for platinum based chemotherapy.

In summary, the Committee was satisfied that pembrolizumab is likely to be beneficial in patients with advanced or metastatic urothelial cancer that has progressed whilst on cisplatin-based chemotherapy. The Committee therefore approved pembrolizumab in this indication, for use according to the free of charge scheme. The Committee did not approve use of pembrolizumab in patients who have not received prior platinum-based chemotherapy due to ineligibility; the Committee would need to review the evidence based for this cohort of patients.

Decision: Approved for advanced or metastatic urothelial cancer that has progressed whilst on cisplatin-based chemotherapy only
Prescribing: Secondary care only
Tariff status: Excluded from tariff
Funding: Free-of-charge
Fact sheet or shared care required: No

Post-meeting notes: Dr Vilarino-Varela advised the PD-L1 testing would not be carried out before starting treatment with pembrolizumab as this was not a requirement of the KEYNOTE-45 trial, and extent of PD-L1 expression is not a conclusive factor of pembrolizumab efficacy in urothelial cancer. It was confirmed that the 2 year cut off for treatment with pembrolizumab under the free of charge scheme is in line with how the company is likely to position the drug; two years of treatment was included as one of the trial's exit criteria.

7.3 Denosumab for osteoporosis in men (Applicant: Dr Rosaire Gray, WH)

An application to use denosumab (a fully human monoclonal antibody) in the treatment of osteoporosis in men was considered by the Committee. It was proposed the denosumab would be reserved for use as a third line agent for patients unable to take oral bisphosphonates (either due to intolerance or unable to comply with administration instructions) and unable to receive IV zoledronic acid due to renal dysfunction. The Committee was informed that, unlike in postmenopausal women, there is no NICE technology appraisal to guide this treatment decision, though the National Osteoporosis Guideline Group (NOGG) considers it to be an alternative option to 1st line oral bisphosphonates.

The Committee considered the findings of one pivotal RCT (Orwoll *et al,* 2012) which had formed the basis of the EMEA marketing authorisation extension to include treatment of men with osteoporosis, as well as an open-label extension study, and one meta-analysis that pooled all available data for treatment of osteoporosis in men.

Orwoll *et al* (2012) was an RCT conducted in male adults with a T-score ≤ -2 and ≥ -3.5 (at lumbar spine or femoral neck), randomising people to receive either denosumab 60 mg or placebo every 6 months for 12 months via subcutaneous injection. Patients were excluded if they had a vertebral fracture diagnosed within 6 months before screening, any severe or more than one moderate vertebral fracture on spinal x-ray at screening, a disease known to affect bone metabolism, or low vitamin D levels. Patients were also excluded if they had received bisphosphonate in the last 3 months, if they had received any bisphosphonate for ≥ 3 months in the last 2 years, or ≥ 1 month in the last year. The primary efficacy outcome was percentage change in lumbar spine BMD at 12 months. Denosumab was associated with a BMD increase at lumbar spine of 5.7% at month 12, compared with placebo which was associated with an increase of 0.9%; the difference is mean lumbar spine BMD was 4.8% (95% CI 4% to 5.6%, p<0.0001), which was slightly less than the minimum difference the study was powered to detect. BMD was reported to be statistically significantly higher at all skeletal sites (including TH, FN, TR, and 1/3R) in the denosumab group compared to the placebo group.

An open-label extension to the Orwoll study (Langdahl et al [2015]) reported changes to BMD following 12 months of open-label treatment with denosumab. As this was an open label study, the outcomes were reported as exploratory. This study demonstrated that the benefits seen from treatment with denosumab continued during the open-label phase. No anti-denosumab binding antibody was detected at any point during the 24 months of the study.

Finally, the Committee considered the findings of Nayak and Greenspan (2017) who undertook a meta-analysis of 22 RCTs of osteoporosis treatments that were either conducted only in men, or reported the findings for men separately. The relative risk of vertebral fracture was found to be 0.256 (95% CI 0.029 to 2.238) for denosumab when compared to placebo. In comparison, the equivalent relative risk for alendronate vs. placebo was 0.328 (95% CI 0.155 to 0.692), demonstrating that denosumab does not statistically significantly improve risk of vertebral fractures whereas alendronate (the most commonly prescribed bisphosphonate) does. Data for risedronate were similar to those for alendronate (RR 0.428 [95% CI 0.245 to 0.746]), whereas zoledronic acid had no data available for vertebral fracture, and did not demonstrate a statistically significant improvement in relative risk of clinical fracture. The Committee discussed the importance of this study, noting that use of fracture rate as an outcome may be meaningful to patients, but was of limited value because the trials are usually powered to detect a difference in BMD because the fracture rate is very low. Therefore the Committee gave less weighting to this study.

The Committee was aware that denosumab has been the subject of several MHRA safety alerts, including most recently the need to be aware of the risk of osteonecrosis of the external auditory canal. Patients will need to be checked for osteonecrosis of the jaw risk factors before commencing treatment. Cellulitis leading to hospitalisation is an uncommon side effect of denosumab that will require prompt medical attention.

Ms Chennells explained to the Committee that denosumab would only be used in a very small subset of patients who cannot receive zoledronic acid infusion due to poor renal function. As the risk of hypocalcaemia is increased in this group of patients, it is proposed that prescribing not be transferred to primary care, so the specialist can closely monitor patient response.

In summary, the Committee agreed that denosumab was an option for the treatment of osteoporosis as a third line agent in men unable to take oral bisphosphonates (either due to intolerance or unable to comply with administration instructions) and unable to receive IV zoledronic acid due to renal dysfunction. The Committee agreed with the applicant's rationale for keeping treatment in secondary care, therefore this was approved for secondary care prescribing only.

Decision: Approved
Prescribing: Secondary care only
Tariff status: In tariff
Funding: Trusts
Fact sheet or shared care required: No

8. **High intensity ustekinumab for moderate to severely active Crohn's disease – does the NICE TA include the option to dose escalate?**

Ustekinumab is licensed for dosing every 8 weeks for patients who lose clinical response on dosing every 12 weeks. Commissioners ask JFC Support to confirm whether 8 weekly dosing was included within the NICE Technology Appraisal (TA) as the higher dose is not specified in the TA summary (this contrasts with the adalimumab and infliximab TA which does mention dose escalation). Mr Barron presented a paper showing high intensity ustekinumab (90mg every 8 weeks) was considered in the clinical and economic sections of the NICE Assessment Report and therefore high intensity was included within the TA intentions. NICE have written to JFC to confirm this interpretation. The Committee (including the Commissioners) therefore supported the use of high intensity ustekinumab for the proposed indication.

9. **Guideline for blood glucose & ketone monitoring for adults with diabetes**

Mr Barron presented a 'Guideline for blood glucose & ketone monitoring for adults with diabetes' produced by the NCL Diabetes Test strip working group. The group included representation from commissioners and specialists working in both primary and secondary care. The guideline had undergone multiple rounds of review with stakeholders across NCL.

Mr Gouldstone questioned why very low cost strip meters (<£9 for 50 strips) were excluded from the guideline. The Committee heard the working group did not undertake a formal review of all available meters, but rather collated current practice from across the region into a single document. The next version of the guideline would include a formal meter assessment. Ms Cheung raised concerns that the guideline may encourage medical device companies to promote their meters in GP practices and agreed to consider how best to mitigate this risk with primary care colleagues outside the meeting.

The Committee approved the guideline.

10. **Interim position statement and Patient FAQ for FreeStyle Libre 'flash glucose monitor'**

Mr Barron presented the NCL 'Interim position statement and Patient FAQ for FreeStyle Libre' produced by the NCL Diabetes Test strip working group. The patient FAQ had been reviewed by the JFC Patient Partner and a patient representative from NWL.

The Committee considered Freestyle Libre to be an innovative product however there were major concerns over the potential budget impact, estimated to be up to £2 million to £6 million, and whether the additional spend delivered sufficient health and QoL gains to be considered value for money.

Various clinical networks in London were working together to identify suitable eligibility criteria. LPP were keeping Trusts and CCGs informed as to progress. RMOCs were considering reviewing Freestyle Libre as it was not scheduled for a NICE TA.

The Committee approved the Interim position statement and Patient FAQ.

11. **EMA's restrictions on use of linear gadolinium agents in MRI body scans**

The EMA suspended market authorisation for the following products; linear intravenous Magnevist® (gadopentetic acid), linear intravenous Omniscan® (gadodiamide) and linear intravenous Optimark® (gadoversetamide). Linear intravenous Multihance® (gadobenic acid) should be restricted to liver scans. Trusts were asked to consider the implication of the licensing suspensions within their own organisations.

12. **JFC Work plan**

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

13. **Next meeting**

Monday 20 November 2017, G12 Council Room, South Wing, UCL, Gower St. WC1E 6BT

14. **Any other business**

Nil