



JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Thursday 27th August 2015 Room 6LM1, Stephenson House, 75 Hampstead Rd

| Prof R MacAllister | NCL JFC Chair | (Chair) |
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| Mr P Gouldstone | NHS Enfield, Head of Medicines Management | |
| Ms N Shah | NHS Camden, Director of Quality & Clinical Effectiveness | |
| Mr C Daff | NHS Barnet, Head of Medicines Management | |
| Mr A Dutt | NHS Islington, Head of Medicines Management | |
| Mr C Daff | NHS Barnet, Head of Medicines Management | |
| Dr A Stuart | NHS Camden, GP Clinical Lead Medicines Management | |
| Mr T James | MEH, Chief Pharmacist | |
| Mr B Sandhu | NEL CSU, Assistant Director Acute Services | |
| Mr J Paszkiewicz | NEL CSU, Senior Prescribing Advisor | |
| Dr R Fox | RNOH, DTC Chair | |
| Dr V Thiagarasah | NHS Enfield, Medicines Management GP | |
| Mr I Man | WH, Interim Deputy Chief Pharmacist | |
| Ms S Sanghvi | UCLH Formulary Pharmacist | |
| Mr J Minshull Ms I Samuel | NCL JFC, Support Pharmacist | |
| | RFH, Formulary Pharmacist | |
| Mr P Bodalia | UCLH, Principal Pharmacist (Medicines Management & | |
| | Clinical Trials) | |
| Mr A Barron | NCL JFC, Support Pharmacist | |
| Mr E Hindle | MEH, Formulary Pharmacist | |
| Dr M Griffiths | UCL, Clinical Teaching Fellow | |
| Dr B White | UCLH, Consultant Paediatrician | |
| Dr E Kostopoulou | UCLH, Clinical Fellow Paediatric Endocrinology | |
| Dr D Gale | RFH, Consultant Nephrologist | |
| Dr Y Jayran-Nejad | RFH, Consultant in Pain Medicine | |
| Dr A Drebes | RFH, Consultant Haematologist | |
| Prof L Smeeth | NCL JFC Vice-Chair | |
| Ms W Spicer Dr R Breckenridge Dr R Sofat Mr A Shah Ms P Taylor | RFH, Chief Pharmacist | |
| | UCLH, DTC Chair | |
| | UCLH, Consultant Clinical Pharmacologist | |
| | RNOH, Chief Pharmacist | |
| | NHS Haringey, Head of Medicines Management | |
| Ms S Drayan | NMUH, Chief Pharmacist | |
| | Prof R MacAllister Mr P Gouldstone Ms N Shah Mr C Daff Mr A Dutt Mr C Daff Dr A Stuart Mr T James Mr B Sandhu Mr J Paszkiewicz Dr R Fox Dr V Thiagarasah Mr I Man Ms S Sanghvi Mr J Minshull Ms I Samuel Mr P Bodalia Mr A Barron Mr E Hindle Dr M Griffiths Dr B White Dr E Kostopoulou Dr D Gale Dr Y Jayran-Nejad Dr A Drebes Prof L Smeeth Ms W Spicer Dr R Breckenridge Dr R Sofat Mr A Shah Ms P Taylor Ms S Drayan | Prof R MacAllisterNCL JFC ChairMr P GouldstoneNHS Enfield, Head of Medicines ManagementMs N ShahNHS Camden, Director of Quality & Clinical EffectivenessMr C DaffNHS Barnet, Head of Medicines ManagementMr A StuartNHS Camden, GP Clinical Lead Medicines ManagementMr J PaszkiewiczNEL CSU, Assistant Director Acute ServicesMr J PaszkiewiczNEL CSU, Senior Prescribing AdvisorDr V ThiagarasahNHS Enfield, Medicines Management GPMr I ManWH, Interim Deputy Chief PharmacistMs S SanghviUCLH Formulary PharmacistMr P BodaliaUCLH, Principal Pharmacist (Medicines Management & Clinical Trials)Mr A BarronNCL JFC, Support Pharmacist (Medicines Management & Clinical Trials)Mr A BarronNCL JFC, Support PharmacistMr E HindleMEH, Formulary PharmacistDr M GriffithsUCL, Clinical Teaching FellowDr B WhiteUCLH, Consultant PaediatricianDr F KostopoulouUCLH, Clinical Fellow Paediatric EndocrinologyDr J Sayan-NejadRFH, Consultant NephrologistDr Y Jayran-NejadRFH, Consultant NephrologistDr S SofatUCLH, Consultant Clinical PharmacologistMr A ShahRNOH, Chief PharmacistMr A ShahRNOH, Chief PharmacistMr S ShahRNOH, Chief Pharmacist |

2. Meeting observers

Prof MacAllister welcomed the applicants and observers to the meeting.

3. Minutes of the last meeting

Item 6.4 had a typo in the title. The title should be amended to read: "Ropivacaine continuous infiltration via Painbuster for nephrectomy or breast surgery".

The minutes were otherwise accepted as an accurate record of the meeting.

4. Matters arising

Item 6.1 – Funding for Evicel has been confirmed with Barnet CCG. Item 6.2 – Funding for the Rituximab when administered in combination with idelalisib for this indication has been confirmed with NHS England.

4.1 Octreotide LAR for PLD [APPEAL] (Applicant: Dr D Gale)

The Committee reviewed an appeal for the use of octreotide LAR in PLD citing a new publication since the Committee review in June 2015. The Committee recalled their previous discussion, reaching a decision of non-approval on the basis that liver volume did not appear to significantly reduce with treatment, the price of octreotide LAR was high, and the uncertainty of duration of therapy. This was compounded by the only data being available in the form of open-label studies which are open to bias when interpreting subjective outcome data such as patient satisfaction scores.

The Committee heard from Dr Gale the rationale for his appeal was to clarify the main aim of treatment and to discuss the new data available to appease the Committee's previous concerns.

Dr Gale informed the Committee that although the observed reduction in liver volume was relatively small (approximately 300 mL against a baseline of 5 L) as specified in the previous submission, the clinical impact for the patient is important, specifically on quality of life parameters such as breathing, walking and eating. Dr Gale reported that the new data (four year open-label extension study of the origin Hogan study) showed that a treatment break resulted in liver growth (3.4%, approximately 200ml), and that restarting octreotide LAR demonstrated sustained benefit of halting enlargement of the liver and therefore preventing liver surgery (reduction of 500ml, approximately 13%).

The Committee questioned whether the subjective outcome of improved symptoms and the objective outcome of reduced liver size were always experienced together; however it was not possible to elicit an answer on this. Dr Gale explained that the need for a liver transplant defines the stopping criteria. It would not be appropriate to stop treatment based on failure to achieve liver volume reduction as halting growth would be beneficial.

The Committee asked whether avoiding renal dialysis was an important outcome. Dr Gale explained that ADPKD has recently been recognised as a rare renal disease and as such a registry of patients will be established to monitor this. The RFH has the only renal-liver clinic in the country.

Although there was discussion about the use of short-acting octreotide, Dr Gale reported that he was unaware of any evidence of it being effective in this condition.

The Committee agreed that the primary aim of treatment is to obviate the need for liver surgery, which is associated with 12% mortality, quality of life burden and significant costs to the NHS. Although a treatment break should be encouraged after a minimum of 2 years continuous treatment, it was suggested that stopping criteria would likely be listing for liver surgery for functional decline.

The Committee agreed to approve octreotide short-acting and long acting under the category of evaluation for the RFH site only for the treatment of polycystic liver disease, to be started only when patients are being considered for addition to the transplant list. Patients will stop treatment if there is no response or when they receive a transplant. As part of the evaluation, it was proposed that serial MRI scans should be performed every 6 months, and pain / quality of life scores should be monitored at three-monthly intervals. As this is a rare condition, this approval is subject to individual funding being approved by NHS England.

4.2 Tapentadol for severe chronic pain with neuropathic component [APPEAL] (Applicant: Dr Y Jayran-Nejad)

The Committee considered an appeal application for the use of tapentadol modified-release (MR) tablets for the management of severe chronic pain with a neuropathic component in adults. Following review at the March 2013 meeting the Committee were unable to establish a place in therapy for this medication due to marginal improvements in tolerability compared to oxycodone, and lack of comparison with tramadol. The Committee noted an article published in the BMJ which described how patients suffering from chronic pain are not interested in small "mean" reductions in pain, instead expecting at least 50% reductions in pain score, ideally nothing worse than mild pain. The Committee also noted the bias inherent in open-label studies and studies that rely on subjective outcomes, such as pain intensity.

With regards to new data forming the basis of the appeal, the Committee considered evidence from four open-label studies: three uncontrolled studies (Galvez et al 2013; Steigerwald et al 2012; Strick 2014) and one in which patients were randomised to receive tapentadol MR or oxycodone/naloxone MR (Baron et al 2015). The Committee continued to take the view that the obvious comparator drug for tapentadol MR was tramadol. A meta-analysis comparing these two drugs indirectly was also considered (Mercier et al 2012).

The Committee heard that patients in the Galvez et al (2013) study were adults with chronic low back pain (62% with neuropathic element), who had been responding to, but not tolerating, a strong opioid analgesic for \geq 3 months. Only 94 patients were assessed in the per-protocol population, but reasons for drop out were not presented. The primary endpoint (percentage of patients at week 6 with the same or lower pain intensity score compared with week -1) was achieved by 81% of per-protocol patients. A secondary endpoint (percentage of patients with the same or lower pain intensity score and improvement in satisfaction score at week 6) was achieved by 66% of patients; 73% of patients reported pain control to be "good", "very good" or "excellent" at week 6 whilst receiving tapentadol MR. Other secondary endpoints considered were patient global impression of change (PGIC); clinician global impression of change (CGIC); EQ-5D, SF-36 and Hospital Anxiety and Depression Scale. At week 12, 9.7% of patients reported pain to be "very much improved" and 36.6% "much improved". EQ-5D at week 12 had increased by 0.16 compared to baseline (p<0.0001). The scores for individual components of the painDETECT score were all significantly reduced from baseline at weeks 6 and 12, indicating a reduction in neuropathic pain symptoms. The open-label design without a control group introduced the usual uncertainties in interpreting these data, and the Committee took the view that this was low quality evidence that tapentadol had advantages compared to oxycodone.

When tapentadol MR was compared to oxycodone/naloxone MR (Baron et al 2015), an enriched study design had been used where patients were excluded if they did not respond to treatment during the titration phase. Tapentadol MR was considered to be non-inferior to oxycodone/naloxone MR [-1.820, - 0.184; p<0.001 (oxycodone/naloxone results not reported)]. Pain intensity at 12 weeks was reduced more with tapentadol MR than with oxycodone/naloxone MR (difference in difference (DD) all patients - 1, p<0.001; DD neuropathic pain patients -0.8, p=0.007). Neuropathic pain scores reduced more in the tapentadol MR group than in the oxycodone/naloxone MR group at week 12 (difference in difference -2.9 [-4.9 to -1], p=0.002).

The Committee discussed that, although Steigerwald et al (2012) showed pain intensity to reduce from 7.5 points (baseline) to 4.1 points (week 6) for tapentadol MR, this was in an uncontrolled study in patients who had previously only been taking WHO step 1 or 2 analgesics (i.e. not strong opioids) and it didn't address the neuropathic element of pain. The proportion of patients with a decrease in pain activity of at least 1 point on the NRS-3 was 96.9% at 6 weeks.

The Committee considered longer-term use of tapentadol MR. A report of 1,457 patients receiving 3 months of tapentadol MR treatment and 588 patients over 12 months was considered (Strick 2014). Pain intensity was reduced by 2.4 points to 4.4 (11 point NRS) during the 3 months observation period and by 3.2 points to 3.5 in the 12 month period. The Committee noted that only 38.1% (3 month cohort) and 56.5% (12 month cohort) of patients experienced a pain reduction of at least 50%.

Comparative efficacy of tapentadol MR compared to tramadol in chronic, non-malignant pain was provided by Mercier et al (2014) in the form of a meta-analysis following a systematic review. Treatment

duration in the included studies was 12 weeks in OA and back pain and 9 weeks in neuropathic pain. The authors reported that assuming a baseline pain intensity of 6.9, tramadol 300 mg daily reduces pain by 46% (95% CI 41-51%) and tapentadol 100 mg to 250 mg twice daily by 36% (95% CI 35-37%). Tramadol 300 mg daily was shown to reduce the 12 week pain intensity score by 0.69 points more than tapentadol (statistically significant, but not clinically relevant). Constipation and vomiting were significantly higher in the tramadol group; dizziness was slightly higher in the tapentadol group.

When considering safety, the Committee heard that in one study (Strick 2014) 313 patients (21.5%) experienced 737 ADRs, of which 95.9% were not serious. A further study reported that 85 of 125 patients reported 245 adverse events potentially caused by tapentadol (Galvez et al 2013), with 20 patients stopping therapy due to side effects. The most common causes were gastrointestinal disorder (n=46, 39%) including nausea (n=19, 15.2%) and constipation (n=15, 12%). Dizziness occurred in 16 patients (13%). A review of UK primary care patients (Morgan et al 2014) identified that tapentadol MR had a lower rate of adverse events than oxycodone MR (HR=0.486; range: 0.302-0.782) and morphine MR (HR=0.489; range: 0.326-0.732). There was no significant difference between discontinuation rates in tapentadol MR, oxycodone MR (HR=0.826; range: 0.605-1.128) or morphine MR (HR=0.914; range: 0.694-1.204). Tapentadol MR was associated with less healthcare resource use than oxycodone MR and morphine MR, though statistical significance was not quoted and associated costs avoided were not presented.

The Committee heard how tapentadol is understood to have no effect on QT interval or ECG (heart rate, PR interval, QRS duration, T-wave or U-wave morphology). Tapentadol and its metabolites are almost exclusively renally cleared (99%), none of the metabolites has analgesic activity. Dose adjustments are not needed in patients with mild or moderate renal impairment, and are not recommended in severe renal impairment. Tapentadol is not recommended in patients with severe hepatic impairment. Tapentadol should not be used during breastfeeding and should only be used in pregnancy if the potential benefit outweighs the risk.

The Committee discussed the potential for abuse and diversion of tapentadol, noting that evidence is limited to patient surveys and reviews of internet noticeboards, which find that tapentadol may be less likely than other opioid analgesics to be obtained illicitly, though the committee discussed that this is possibly due to less awareness of tapentadol and that it is a newer analgesic.

Dr Jeyran-Nejad explained that tapentadol MR is being requested as an alternative analgesic option for patients who have failed treatment with other opioids. Failure rates are high (often above 50%) and have been reported to be 90% for tapentadol and 100% for oxycodone. After considering simple analgesics (paracetamol with or without NSAIDs), amitriptyline would be considered, followed by gabapentin, then adding in a weak opioid (e.g. tramadol), followed by a strong opioid (e.g. morphine). Tapentadol MR would be considered after this. Dr Jeyran-Nejad explained that, in his experience, many patients cannot tolerate treatment with tramadol. The Committee noted that tramadol was now considered to be a strong opiate.

Based on the marginal improvements in tolerability with no clear efficacy advantages over oxycodone or tramadol, the Committee remained unconvinced as to the place in therapy for tapentadol. On this basis, the Committee stood by their previous decision and agreed that tapentadol should not be added to the NCL Joint Formulary.

5. Declarations of relevant conflicts of interest

Mr Gouldstone declared that has participated in an Advisory Board for Novo Nordisk (manufacturer of insulin degludec).

6. New Medicine Reviews

6.1 Carvedilol for primary/secondary prophylaxis oesophageal variceal bleeding (Applicant: Dr D Suri (not present), WH; Presentation: Ms S Sanghvi)

The Committee reviewed an application for carvedilol as a second line option for primary and secondary prophylaxis of variceal bleeding. Both carvedilol and propranolol are non-cardioselective beta blockers, but carvedilol has additional α 1 receptor blockade actions. The Committee heard that the application is in line with recommendations from the British Society of Gastroenterology (BSG) UK guidelines on management of variceal haemorrhage in cirrhotic patients.

In terms of efficacy the Committee heard that achieving a hepatic venous pressure gradient (or HVPG) >12mmHg significantly reduces the risk of developing oesophageal varices. The Committee considered a single-blind, randomised controlled study by Banares et al (2002; n=51) which compared the effects of carvedilol and propranolol for primary prophylaxis in patients with cirrhosis. Overall the number of responders was 35% higher in the carvedilol group compared to propranolol; however the mean difference in absolute reduction of HVPG between the two groups was 1.1 mmHg. The study suggested superiority of carvedilol to propranolol; however the Committee noted several limitations in methodology of the trial. In a similar randomised, double-blind study by Hobolth et al (2012; n=38) there were no significant differences in HVPG response between the carvedilol and propranolol treatment groups.

Reiberger et al (2013; n=104) evaluated the haemodynamic response rates to carvedilol in propranolol non-responders for primary prophylaxis of variceal bleeds. The results showed a greater reduction in HVPG with carvedilol compared to propranolol. In patients with non-response to propranolol a further reduction in HVPG of 13% (19.3 vs 16.6 mm Hg; p<0.01) was achieved with carvedilol treatment. There were no significant differences in the reduction of heart rate and blood pressure between the two beta blockers.

The Committee noted that there is a lack of data demonstrating the efficacy of carvedilol in secondary prophylaxis but the data is extrapolated from primary prophylaxis studies to suggest benefit.

Ms Sanghvi informed the Committee that HVPG in not routinely monitored in clinical practice as it is an invasive test. Carvedilol would primarily be used in patients who do not tolerate propranolol. The general adverse effect profiles and contraindications are similar for both beta-blockers, but carvedilol would not be recommended in patients with ascites or severe renal impairment. The Committee agreed that the use of carvedilol second line due to tolerability seemed reasonable as a similar reduction in HVPG can be achieved with lower comparative doses of carvedilol.

Carvedilol is administered as a once daily dose, which is initiated at 6.25mg once daily for one week then increased to maintenance dose of 12.5mg if tolerated and HR >55bpm.The relative costs are £1.26 per month for carvedilol and £3.22 per month for propranolol. Carvedilol therefore offers a cost-effective treatment option, although it is used off label for this indication whereas propranolol is licensed. Carvedilol would be initiated in hospital but GPs could then manage ongoing prescriptions with monitoring of pulse and blood pressure.

Overall the Committee agreed that carvedilol should be added to the NCL Joint Formulary as a second line option for primary and secondary prophylaxis of variceal bleeding for patients who do not respond to or cannot tolerate propranolol.

6.2 Insulin degludec for paediatric type I diabetes (Applicant: Dr B White, UCLH; Presentation: Mr Barron)

The Committee reviewed an application for insulin degludec (Tresiba) for the management of paediatrics and adolescents who are failing to achieve adequate glycaemic control on insulin detemir (Levemir) or insulin glargine (Lantus).

The Committee were informed that that The National Institute for Health and Care Excellence recommends basal-bolus regimens as first-line treatments for paediatrics with type 1 diabetes. The basal insulin is typically twice-daily detemir or once-daily glargine which should be administered at the same times each day to prevent periods of insulin insufficiency. However compliance to fixed-timed doses can be poor in children and adolescents who have a highly variable daily schedules which may result in high HbA1c and episodes of diabetic ketoacidosis.

The Committee reviewed the evidence for insulin degludec in children which was limited to one Phase III trial in addition to proof of concept study for flexible-dosing of degludec in adults. The paediatrics study was a 26 week, phase III, randomised, controlled, open-label, treat-to-target, non-inferiority trial with a 26 week extension compared the efficacy and safety of once-daily degludec with that of once or twice-daily insulin detemir. Children and adolescents with T1DM and an HbA1c \leq 11% were eligible for inclusion. Subjects were randomised 1:1 to receive degludec or detemir both in combination with mealtime rapid-acting insulin aspart. A treat-to-target approach was used to optimise glycaemic control. Baseline

characteristics were well matched at baseline, with a mean HbA1c of 8.2% and 8.0% for degludec and detemir respectively. The primary end point of non-inferiority of change in HbA1c from baseline to week 26 between degludec and detemir was confirmed; estimated treatment difference was 0.15% (95% CI: 0.03-0.32) which was less than the pre-specified 0.4% margin. At 52 weeks, rates of confirmed hypoglycaemia were similar between groups (57.4 vs 54.1 events per patient year of exposure [PYE], RR=1.11 [95% CI: 0.89-1.38]).

The proof of concept flexible dosing study was a 26 week phase III, randomised, controlled, open-label, treat-to-target non-inferiority trial to compare flexible once-daily degludec to once-daily degludec and once-daily glargine. Adults with T1DM with an HbA1c $\leq 10.0\%$ and BMI ≤ 35 kg/m² were included. Subjects were randomised 1:1:1 to forced-flex degludec (alternating morning and evening dosing), once-daily degludec or once-daily glargine (both at the same time each day) all in combination with mealtime rapid-acting insulin aspart. A treat-to-target approach was used to optimise glycaemic control. Mean decreases in HbA1c from baseline at 26 weeks were -0.4%, -0.41% and -0.58% for forced-flex degludec, degludec and glargine respectively. The primary endpoint of non-inferiority of change in HbA1c from baseline to week 26 between forced-flex degludec and glargine was confirmed; estimated treatment difference was 0.17% (95% CI: 0.04-0.30%) which is less than the pre-specified 0.4% margin. At 26 weeks, rates of confirmed hypoglycaemia were similar between groups (82.4, 88.3 and 79.7 events per PYE for forced-flex degludec, degludec, degludec and glargine respectively; RR_{ForcedFlex-IDeg}=0.92 [95% CI: 0.76-1.12] and RR_{ForcedFlex-IDeg}=1.03 [95% CI: 0.85-1.26]).

The Committee heard that the adverse event profiles were similar for degludec and detemir however noted that the FDA had not approved degludec due to concerns about cardiovascular safety.

With regards to cost, the list price for insulin degludec is £72.00 for 5 x 300 units pre-filled pens which is approximately 70% more the pack price for detemir. The budget impact for insulin degludec in 28 patients was £1,546 – £4,753 per annum however this budget impact would increase year on year unless patients were withdrawn from therapy. The Committee heard that insulin degludec was significantly cheaper than insulin pumps which cost approximately £1,443 per annum.

The Committee questioned the value of non-inferiority studies which use large pre-specified noninferiority margins that gloss over important differences between treatments. The Committee noted that results from the degludec flexible dosing study showed that degludec (forced-flex and once-daily) appeared to be numerically less effective than glargine at reducing HbA1c from baseline. The Committee concluded that there was no evidence that degludec offered any HbA1c advantage over glargine.

Dr White explained that the difficulty in treating this population was encouraging compliance to basal insulin. Dr White acknowledged the limitations of the trial data. He hypothesised that protracted duration of action for degludec would improve compliance in this population. The Committee noted that patients who do not comply with basal-bolus regimens are typically fitted with life-long insulin pumps in accordance with current NICE guidance (TA 151). Dr White explained that the primary aim of insulin degludec is to achieve HbA1c control in this population without the need to escalate to an insulin pump.

The Committee and Dr White agreed that insulin degludec could be made available on an evaluative basis for patients otherwise eligible for an insulin pump. The primary outcome measure would be insulin pump avoidance with reduction in HbA1c from baseline as a secondary outcome. Approximately 20 patients were expected to be included in the audit and results would be presented back to JFC in approximately 1 year. It was clarified that all prescribing would remain in secondary care.

In summary, the Committee agreed that there was insufficient evidence to support the addition of insulin degludec to the NCL Joint Formulary. An evaluation of this insulin in the proposed target population might be worthwhile. Insulin degludec was therefore approved under the Category of Evaluation restricted to the UCLH site for paediatric and adolescent patients who would otherwise require an insulin pump, subject to funding approval at UCLH.

Action: Mr Barron and Dr White to develop an audit protocol, data collection table and secure funding from Novo Nordisk or the UCH Medicine Division. Dr White to present his experience of insulin degludec to the JFC after 1 year.

7. Adrenaline auto-injectors (Emerade[®])

The Committee heard that a new adrenaline auto-injector (Emerade) was available. The price of Emerade was near equivalent to that of EpiPen however Emerade benefited from a longer shelf-life (30 months vs 18 months) and a longer needle. The Committee discussed that cost-savings associated with Emerade would only be realised if community pharmacies dispensed stock with a long expiry however the Committee were satisfied that the longer shelf-life was likely to reduce wastage. The CCGs were not in favour of working with the auto-injector manufacturers to provide training for health care professionals; details of how to use the devices are available on the websites. The Committee agreed to replace EpiPen with Emerade on the NCL Joint Formulary.

8. Chronic urticarial pathway and guideline

Ms Sanghvi presented a treatment pathway for chronic idiopathic urticaria and angioedema developed with the allergy and dermatology consultants at UCLH. Supporting documents included (1) a high dose antihistamine guideline which would support GPs to prescribe higher doses of cetirizine, outside the product licence, (2) omalizumab protocol in response to NICE TA 339 and (3) ciclosporin guidelines outlining the monitoring and stopping criteria requested by the Committee at the January 2015 JFC meeting. The Committee approved these documents pending minor changes.

9. DOAC clinical pathway and prescribing guide for AF and VTE

The Committee discussed the clinical pathway and prescribing guide for Direct Oral Anticoagulants (DOACs), which have been produced on behalf of clinicians within North Central London to replace guidance issued in 2013. This class of agents was previously known as Novel Oral Anticoagulants or NOACs) These documents propose to make DOACs available as a first-line option for all patients with VTE/PE or AF requiring stroke prevention.

The Committee agreed with the detailed information and guidance (e.g. on which DOAC to choose, exclusion/inclusion criteria and pre-prescribing checklist). It took the view that many GPs would be confident to manage DOAC prescribing within primary care, so referring patients to anticoagulation clinics should be an option, and not mandated. There was a request from CCG representatives for the opportunity to share these documents with GPs to obtain further comments. The Committee therefore deferred a final decision on these documents pending review.

The Committee discussed that when the results of a network meta-analysis conducted as part of an NIHR sponsored Health Technology Assessment programme is published, it will be possible to work with local haematology and anticoagulation teams to identify a hierarchy of drug choice.

Action: Mr Minshull to recirculate documents to CCG Heads of Medicines Management and Trust Formulary Pharmacists to obtain comments from stakeholders within their organisations.

10. Meningitis B for Routine Vaccination Schedule

The Committee heard that immunisation against meningococcal B disease will be added to the childhood immunisation programmes as part of the routine schedule in England from 1st September 2015. The Committee agreed to add Meningitis B vaccine (Bexsero[®]) to the NCL Joint Formulary with Acute Trusts only supplying and administering for long-stay patients admitted around the time of a scheduled dose.

11. Drug Safety Update: InductOs

The Committee were informed that the manufacture of InductOs had been suspended due to manufacturing problems associated with the absorbable collagen matrix. The manufacturer has written to providers to inform them that stocks are expected to be depleted as of the end of October 2015. The RNOH has communicated this internally with a contingency plan to manage patients.

12. Local DTC recommendations / minutes

This item was deferred to the September meeting.

12.1 Taurolidine for recurrent catheter-related bloodstream infections in patients on home parenteral nutrition

The Committee heard that the UCLH DTC approved taurolidine (Taurolock[®]) in April 2012 for secondary prophylaxis against recurrent catheterrelated bloodstream infections (CRBI) in patients on home parenteral nutrition (HPN). On the basis of this approval, the Committee agreed to add taurolidine to the NCL Joint Formulary.

13.

Next meeting Thursday 24th September, Room 6LM1, Stephenson House, 75 Hampstead Rd.

Any Other Business 14.

Nil