NCL Joint Formulary Committee (JFC) Meeting

Minutes from the meeting held on Thursday 24th April 2014

In Chadwick 2.18, Gower Street, UCL

1. Present:	Prof R MacAllister	NCL JFC Chair
	Dr R Urquhart	UCLH Chief Pharmacist
	Mr A Shah	RNOH Chief Pharmacist
	Ms P Shah	CSU Pharmacist
	Mr A Dutt	NHS Islington, Head of Medicines Management
	Ms R Clarke	NHS Camden, Deputy Head of Medicines Management
	Prof L Smeeth	NCL JFC Vice-Chair
	Mr T James	MEH Chief Pharmacist
	Ms P Taylor	NHS Haringey Head of Medicines Management
	Ms S Drayan	NMUH Chief Pharmacist
	Mr TF Chan	BCF Chief Pharmacist
	Dr M Kelsey	WH DTC Chair
	Mr P Gouldstone	NHS Enfield, Head of Medicines Management
	Dr R Fox	DTC Chair, RNOH
In attendance:	Dr R Pepper	Specialist Registrar, Rheumatology, UCLH
	Mr E Hindle	MEH Pharmacist
	Dr D Creer	Consultant, BCF
	Mr A Jones	Pre-registration Pharmacist, UCLH
	Dr R Simon	Consultant, NMUH
	Ms I Samuel	Pharmacist, RFH
	Mr K Thakrar	Pharmacist, UCLH
	Dr A Grosso	Pharmacist, UCLP
	Mr B McKenna	Medicines Management, Islington CCG
Apologies:	Mr C Daff	NHS Barnet, Head of Medicines Management
	Dr L Wagman	Barnet CCG, GP
	Mr A Karr	NCL Procurement Chair
	Dr P Ancliff	GOSH DTC Chair
	Dr D Bavin	Camden CCG, GP
	Dr E Boleti	Consultant, RFH
	Dr J Hurst	Consultant, RFH
	Ms W Spicer	Chief Pharmacist, RFH
	Ms J Cope	GOSH Chief Pharmacist
	Dr R Breckenridge	UCLH UMC Chair

2. Minutes of the last meeting

Dr Fox requested clarification on the JFCs position with respect to pregabalin in neuropathic pain. Dr Fox thought the JFC had agreed that pregabalin should be available on Formulary for patients intolerant to gabapentin. Prof MacAllister reminded the Committee that it was agreed that pregabalin should be available for patients experiencing off-target adverse events (such as allergy). However, the JFC considered such events as too rare for pregabalin to hold a formulary position for such niche usage. It was agreed that such requests could be dealt with according to local off-formulary exceptional procedures.

3. Matters arising

3.1 Pentoxifylline for Peyronie's disease

The Committee has yet to receive a response from the BSU. The Committee suggested waiting another month before making a final decision.

3.2 Overactive Bladder Syndrome (OAB) Guideline

Prof MacAllister informed the Committee that a number of UCLH consultants, from varying specialties, had written to himself and Dr Breckenridge regarding the draft OAB guidance. It was agreed that this should be discussed at the UCLH Use of Medicines Committee before being brought to the JFC for further discussion.

3.3 Linaclotide for constipation-associated irritable bowel disease (IBS-C)

Dr Emmanuel (UCLH) has now requested permission for linaclotide to be restricted to prescribing in his tertiary referral patients only. The Committee considered this request however failed to see the merits of this therapy in IBS-C hence it was agreed that this therapy should remain non-formulary.

4. Members declarations of relevant conflicts of interest

None were declared.

5. Medicine Reviews

5.1 Belimumab (GSK) for refractory systemic lupus erythematosus [SLE] (Applicant: Dr A Salama, Presentation: Mr A Jones)

Belimumab, a human monoclonal antibody, acting through inhibition of B-lymphocyte stimulator, is licensed as adjunct therapy for adults with active auto-antibody positive SLE with high disease activity resistant to standard treatment.

The Committee assessed two double-blinded, multi-centre, randomised, placebo-controlled trials. The combined trial population totalled 1,684 and compared patients on standard SLE therapy with belimumab 1mg/kg, 10mg/kg and placebo. Infusions were given on days 0, 14, 28 and then every 28 days until week 48 (BLISS-52) or week 72 (BLISS-76). Exclusion criteria were severe active lupus nephritis, severe active CNS lupus, any previous treatment with rituximab or any treatment with cyclophosphamide in the previous six months.

Although the duration of the trials varied, the primary endpoint for both – SLE responder index – was evaluated at 52 weeks. The pooled analysis reported a significant benefit with the 10mg/kg dose versus placebo (50.6% vs. 38.8%) for the primary endpoint. The secondary endpoints involving reduction in steroid dose from >7.5mg prednisolone daily by at least 25%, median time to first flare and occurrence of severe flares, all showed a significant benefit. However the additional secondary endpoint 'health-related quality of life', assessed using the short-form health survey (SF-36, v2) showed no difference against placebo.

Of the trial population, 52% (585/1125) met the criteria for which a MA was granted, while 35% (396/1125) met the criteria for the target population (SELENA-SLEDAI score ≥ 10).

The Committed noted that NICE. has not approved this drug due to its perceived cost-effectiveness. The current approximated ICER ranges between £64,400 and £71,000 per QALY gained, compared with standard care. A recalculated figure involving a patient-access scheme remained above the threshold. Additionally, there are as yet no data to show relative effectiveness against rituximab or effectiveness in rituximab non-responders. The Committee considered this important as the proposed usage would involve patients previously treated with rituximab – a key exclusion criteria in the trials. There is also no evidence of effectiveness in patients recently treated with cyclophosphamide.

The Committee also reviewed pooled data from three placebo-controlled studies involving 674 patients – of which 472 were exposed to treatment for at least 52 weeks. Of the most frequent side effects, only diarrhoea and nausea occurred slightly more in the belimumab group. Serious adverse effects were experienced by 17% in the belimumab group and 16% in the control group.

Excluding administration costs, the estimated annual cost of belimumab is £11,000 +VAT, whereas rituximab is about £7,000 +VAT.

In summary, the Committee agreed that belimumab had activity in SLE. The JFC saw a place for belimumab in patients whom had responded to rituximab but were suffering from intolerable adverse events. The proposed patient group was for patients approaching dialysis requirements hence it was agreed to restrict belimumab usage to the Royal Free Hospital only. The Committee noted that the RFH would need to approve the costs associated with using this therapy.

5.2 Relvar® (GSK) for asthma and chronic obstructive pulmonary disease [COPD] (Applicant: Dr D Creer; Presentation: Dr H Amer)

The Committee reviewed an application for Relvar which is a new combination inhaler containing a new long-acting $beta_2$ agonist (vilanterol) and a new inhaled corticosteroid (fluticasone furoate). Relvar demonstrated non-inferiority in both asthma and COPD compared to existing combination inhalers, although the studies were originally designed to demonstrate superiority. Relvar is a once daily preparation which was suggested may improve adherence although this has not been demonstrated in studies to date. It was also proposed that introducing this agent would result in cost-savings, but the Committee were mindful of generic combination inhalers entering the market in the next few years. The Committee also noted concerns regarding the blue 'reliever-style' packaging, 'reliever-sounding' name, lack of lower dose formulations and risk of potential confusion with fluticasone propionate products which have differing potency and dosing. In summary, the Committee agreed that Relvar should not be made available.

5.3 Ranolazine (A Menarini) for stable angina (Applicant: Dr R Simon; Presentation: Mr K Thakrar)

The Committee reviewed an application for ranolazine as a potential add-on treatment in patients with chronic stable angina who are inadequately controlled or intolerant to first line therapies (such as beta blockers and calcium channel blockers) and are not suitable for revascularisation. This drug has been available for some time, but there had been little interest in using it at most of the hospitals in NCL. Its mechanism of action is uncertain, but is different from other available anti-anginal drugs. The Committee reviewed two trials showing that ranolazine improves exercise tolerance and reduces the number of angina attack by about one every two weeks when comparison to placebo. However the Committee could find no direct or indirect comparisons to other anti-anginal medicines such as long-acting nitrates and ivabradine. The Committee agreed that ranolazine's relatively neutral effect on blood pressure and heart rate may be an advantage in hypotensive and/or bradycardic patients. It was therefore agreed that that ranolazine should be made available to consultant cardiologists at Barnet & Chase Farm only. It was also agreed that NCL should try and agree a joint algorithm with NEL.

6. Treatment Pathways

6.1 Acute coronary syndrome

This item was deferred to the next meeting.

6.3 Neuropathic pain

This item was deferred to the next meeting.

6.4 Ulcerative colitis (mesalazines)

This item was deferred to the next meeting.

7. Local DTC recommendations

UCLH: Alicaforsen (appeal) approved for antibiotic-refractory inflammatory bowel disease for 5 patients at UCLH. This was ratified by the Committee.

NMUH: Sorbaderm film & cream approved for patients requiring a barrier preparation. This was ratified by the Committee.

NMUH: Riamet® (artemether/lumefantrine) approved for malaria according to local protocols. This was ratified by the Committee.

RNOH: Dexmedetomidine was not approved for sedation of adults in the ICU setting. The Committee suggested that the evidence for this indication and use in conscious sedation be discussed at the next JFC as other centres are also proposing its use.

8. Date of next meeting: 29th May 2014

9. Any other business

There was no other business.