North Central London
Medicines Optimisation Network

JOINT FORMULARY COMMITTEE (JFC) – MINUTES
Minutes from the meeting held on 21st October 2021

Present:	Prof R Sofat	NCL JFC Chair	(Chair)
	Dr B Subel	NCL JFC Vice Chair	(Vice Chair)
	Dr M Kelsey	WH, DTC Chair	
	Dr K Tasopoulos	NMUH, DTC Chair	
	Ms G Smith	RFL, DTC Chair	
	Mr S Semple	MEH, Chief Pharmacist	
	Ms K Delargy	BEH, Chief Pharmacist	
	Mr J Harchowal	UCLH, Chief Pharmacist	
	Mr P Gouldstone	NCL CCG, Head of Medicines Management (Enfield)	
	Ms M Singh	NCL CCG, Head of Medicines Management (Barnet)	
	Ms E Mortty	NCL CCG, Deputy Head of Medicines Management (Haringey)	
	Mr A Dutt	NCL CCG, Head of Medicines Management (Islington)	
	Ms R Clark	NCL CCG, Head of Medicines Management (Camden)	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Ms W Spicer	RFL, Chief Pharmacist	
	Dr A Scourfield	UCLH, Interim DTC Vice Chair	
	Mr S Richardson	WH, Chief Pharmacist	
	Dr A Sell	RNOH, DTC Chair	
	Mr A Shah	RNOH, Chief Pharmacist	
	Mr T Dean	Patient Partner	
In attendance:	Ms S Sanghvi	North London Partners, Principal Pharmacist	
	Mr A Barron	UCLH, Principal Pharmacist	
	Mr G Grewal	North London Partners, JFC Support Pharmacist	
	Mr R Rajan	North London Partners, JFC Support Pharmacist	
	Ms I Samuel	RFL, Formulary Pharmacist	
	Ms S Amin	UCLH, Formulary Pharmacist	
	Ms M Kassam	MEH, Senior Pharmacist	
	Ms S Y Tan	NEL CSU, Contracting and Commissioning Pharmacist	
	Ms A Fakoya	NEL CSU, Commissioner Support Pharmacist	
	Ms A Sehmi	NMUH, Formulary Pharmacist	
	Ms H Thoong	GOSH, Formulary Pharmacist	
	Dr A Hosin	UCLH, Clinical Pharmacology Registrar	
	Dr B Powell	UCLH, Clinical Pharmacology Registrar	
	Dr J Kimpton	UCLH, Clinical Pharmacology Registrar	
	Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	
	Ms C Dalton	GOSH, Senior Pharmacist	
	Mr K Malhotra	RNOH, Consultant Orthopaedic Foot & Ankle Surgeon	
	Dr P Harrow	UCLH, Consultant Gastroenterologist	
	Ms J Toft	UCLH, Specialist Pharmacist	
	Ms A Mott	UCLH, Specialist Pharmacist	
	Dr M Leandro	UCLH, Consultant Rheumatologist	
	Dr E Armeni	UCLH, Registrar in Endocrinology and Diabetes	
	Ms N Sanghera	SWL, APC Pharmacy Programme Lead	
Apologies:	Ms L Reeves	C&I, Chief Pharmacist	
	Mr A Tufail	MEH, DTC Chair	

Mr S Tomlin	GOSH, Chief Pharmacist
Ms S Stern	NMUH, Chief Pharmacist
Dr D Burrage	WH, Consultant in Emergency Medicine

2. Meeting observers

Ms Weaver (NHSE, Specialised Commissioning Pharmacist), Ms E Armeni (UCLH, Registrar in Endocrinology and Diabetes), and Ms N Sanghera (SWL, APC Pharmacy Programme Lead) were welcomed as observers of the meeting.

Prof. Sofat informed the Committee that she would be standing down as JFC Chair from February 2022. The process to recruit a new Chair will commence shortly. The Committee thanked Prof. Sofat for her enormous contributions to the JFC, and wished her well in the future endeavours.

3. Minutes of the last meeting

The minutes and abbreviated minutes of the 16 September 2021 meeting were accepted as an accurate reflection of the meeting.

4. Matters arising

4.1 Crizanlizumab and voxelotor in patients with sickle-cell disease

At the September 2021 meeting, the Committee reviewed and clinically approved a free of charge scheme for voxelotor for the treatment of haemolytic anaemia in patients with sickle-cell disease, subject to local Trust financial approval and patient consent. Subsequently, a positive NICE FAD for crizanlizumab for preventing sickle cell crises was published. The Committee reviewed and approved an algorithm outlining the different eligibility criteria, mechanisms and place in therapy for voxelotor and crizanlizumab. The Committee noted NHS England feedback that the two drugs may be used concurrently under the managed access scheme for crizanlizumab. The Committee discussed the NCL FOC scheme policy consent form, and considered the benefits of a London-wide approach to FOC scheme policy, including legal and ethical review of a patient consent form. JFC Support will escalate via the London Formulary Group.

5. JFC Outstanding Items & Work Plan

These items were included for information only. Any questions should be directed to Mr Grewal.

6. Members declarations of conflicts of interest

Nil

7. Local DTC recommendations / minutes

7.1 Approved

DTC site	Month	Drug	Indication	JFC outcome
UCLH	Sept 2021	IV Ketamine	Management of post-operative pain following complex spinal surgery	Decision: UCLH only Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
UCLH	Sept 2021	Cabozantinib†	FoC: Third-line use in patients aged 12 years or older with metastatic osteosarcoma or Ewing sarcoma	Decision: UCLH only Prescribing: Secondary care Tariff status: N/A – free of charge Funding: N/A – free of charge Fact sheet or shared care required: No
UCLH	Sept 2021	Nivolumab†	FoC: Second- or third-line advanced or metastatic anal squamous cell carcinoma	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: N/A – free of charge Funding: N/A – free of charge Fact sheet or shared care required: No

UCLH	Sept 2021	Medications used in critical care (off-label review)		Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: Trust Fact sheet or shared care required: No
		Adrenaline IV infusion	Cardiogenic shock	
		Acetylcysteine IV	Non-paracetamol related hepatic failure (only on the advice of hepatology)	
		Terlipressin bolus	Hepatorenal syndrome (only on the advice of hepatology)	
		Sodium benzoate IV and PO	Refractory hepatic encephalopathy not associated with urea cyclic disorders (only on the advice of hepatology as last line)	
		Actrapid	Hyperkalaemia	
		Artesunate	Malaria	
		Ceftolazone/ tazobactam 3g dose	Off-label dose (on advice of microbiology)	
		Clonazepam IV	Myoclonic Jerks	
		Erythromycin IV and PO	Gastro-intestinal stasis	
		Metoclopramide PO	Gastro-intestinal stasis (short term use only)	
		Glucagon	beta-blocker poisoning	
		Intralipid	anaesthetic-induced cardiovascular toxicity	
		Levosimendan	Left ventricular failure/ cardiogenic shock	
		Meropenem extended infusion (500mg over 3 hours)	Off-label dose (on advice of microbiology)	
		Isoprenaline sulphate	Bradycardia	
		Metoprolol continuous infusion	Tachycardia	
		Nitrous Oxide	Adults with ARDS/ pulmonary hypertension	
		Salbutamol nebules	Hyperkalaemia	
		Pantoprazole continuous infusion	Gastrointestinal bleed	
		Potassium 40mmol in 100ml sodium chloride	Use of unlicensed mini bags	
		Tazocin bolus	For patients who are fluid restricted or for the first dose of initial management of sepsis	
		Terlipressin IV bolus and infusion	Septic shock	
		Clonidine IV infusion	Sedation	

RFL	Oct 2019	Pegylated Interferon alfa (Pegasys)	Myeloproliferative neoplasms (essential thrombocythaemia, polycythaemia and myelofibrosis)	Decision: Added to the NCL Joint Formulary Prescribing: Secondary care Tariff status: In tariff Funding: NHSE (London region) Fact sheet or shared care required: No
NCL CCG: NPR	Sept 2021	Medications used in the treatment of acne (as per recommendation in NICE NG198)		Decision: Added to the NCL Joint Formulary Prescribing: Primary and Secondary care Tariff status: In tariff Funding: Trust and CCG Fact sheet or shared care required: No
		adapalene 0.1% or 0.3% & benzyl peroxide 2.5% (Epiduo)	All acne severity	
		1% clindamycin & 0.025 % tretinoin (Treclin)	All acne severity	
		benzoyl peroxide 3% or 5% & clindamycin 1% (Duac)	Mild to moderate acne	
		Azelaic acid 15%/20%	Moderate to severe acne	
		oral lymecycline/ doxycycline co-administered where indicated	Moderate to severe acne; oral preparation for acne	
		Salicylic acid/lactic acid (16.7%/16.7%)	Preparations for warts and calluses	

† The relevant commissioner should be notified in line with NCL Free of Charge scheme guidance. Approval is conditional on the provision of a free of charge scheme agreement and funding statement.

7.2 Not approved

DTC site	Month	Drug	Indication	JFC outcome
UCLH	Sept 2021	Medications used in critical care (off-label review)		Decision: Not approved (for case-by-case consideration)
		MethylBlue IV	septic shock (as a last line agent)	
		Ubiquinone (co-enzyme Q10)	Statin-induced myopathy and rhabdomyolysis	

8. New Medicine Reviews

8.1 Subcutaneous infliximab for patients with inflammatory bowel disease (Applicant: Dr P Harrow, UCLH)

The Committee considered an application for subcutaneous (SC) infliximab, a TNF inhibitor, for patients with ulcerative colitis (UC) or Crohn's disease (CD) following induction with intravenous (IV) infliximab, for whom patient-centred factors pose a barrier to hospital attendance. JFC had previously approved SC infliximab for use in Rheumatoid Arthritis (RA) during the COVID-19 pandemic; this was subsequently paused, and the Committee agreed to re-review once an application was submitted.

Schreiber et al was a Phase I, randomised, open-label study to compare the efficacy and safety of SC infliximab and IV infliximab for maintenance therapy in patients with moderate to severe UC or CD following IV induction therapy (n=131). Patients were given IV infliximab 5mg/kg at weeks 0 and 2; at week 6, they were randomised to receive either SC infliximab (120mg if weighing <80kg, or 240mg if weighing ≥80kg) or IV infliximab 5mg/kg. The primary endpoint, non-inferiority in pharmacokinetics assessed in C_{trough} levels at week 22, was established between SC and IV infliximab. The proportion of patients achieving clinical response at week 22 between those patients receiving SC versus IV infliximab was not statistically different in either the UC cohort (63.2% vs 43.6% [p=0.1113]) or the CD cohort (78.6% vs 42.9% [p=0.1564]). Similarly, the proportion of patients achieving remission at week 22 between those patients

receiving SC versus IV infliximab was not statistically different in either the UC cohort (44.7% vs 25.6% [p=0.0977]) or the CD cohort (35.7% vs 14.3% [p=0.6126]). Key limitations of the study include the open-label design, the small sample size, the escalated off-label dose used in patients ≥80kg and that the study was not powered for outcomes related to efficacy. However, it does indicate that through this alternative route, the drug is behaving in a similar manner.

The EMA approved SC infliximab through an agreed plan, based on phase 3 data in the Rheumatoid Arthritis (RA) cohort to demonstrate non-inferior efficacy, and phase 1 data in the IBD cohort to demonstrate pharmacokinetic non-inferiority. As such, the EMA designate SC infliximab as a 'biosimilar' product, which is now licensed in all indications that IV infliximab is licensed in. The only phase 3 trials underway were placebo-controlled studies to fulfil licensure requirements in countries that designate SC infliximab as an 'originator' product; therefore, new information from robust trials comparing SC to IV infliximab would be unlikely in the near future.

In terms of safety, discontinuation rates between SC and IV infliximab were similar (11 vs. 15). There were 25 localised injection site reactions reported with SC infliximab, compared with 2 infusion-related reactions with IV infliximab. In terms of risk mitigation, training for self-administration would be available via homecare providers. Trusts have sufficient experience in managing biosimilar-to-biosimilar switches, as well as IV to SC switches. The use of the SC infliximab is associated with a 'low' risk in preparation and administration, compared to the 'high' risk associated with the IV preparation.

In terms of budget impact, an estimated 35% of patients currently receiving IV infliximab switching to SC infliximab is expected to cost an additional £500,000 per annum in drug acquisition costs by the end of year 2. However, there would be significant cost savings associated with the reduction in activity costs, due to a reduction of IV administration in hospital. When considered together, switching 35% of patients currently receiving IV infliximab to SC infliximab is expected to save between £94,000 to £141,000 per annum by the end of year 2 (which includes a nominal fee to maintain capacity within homecare at UCLH, though this is not consistent across NCL Acute Trusts). There is also expected to be substantial reduction in hospital staff time and increase in infusion clinic capacity (reducing the wait time for new patients to start treatment). There would also be improvements in patient-centred factors (e.g. reduction in 7 hospital attendances per annum, reduced patient travel time, reduced time out of work or education, and the potential environmental benefit from reduced footfall).

The Committee heard from Dr Harrow that several other large London Trusts have already implemented SC infliximab in practice due to the advantages to the patients' quality of life. Patients are sometimes admitted to hospital for infusions, and therefore the use of SC infliximab would also reduce hospital admissions. Switching route of administration would not be mandatory, and clinicians would offer the choice of switching to SC infliximab to all eligible patients.

In camera, the Committee recognised the direct and indirect benefits to patients and hospital services; importantly that increasing infusion clinic capacity will reduce the delay to initiating treatment and provide choice for patients to receive care closer to home. The Committee acknowledged that switching to SC infliximab would result in a cost pressure for pharmacy budgets; Trusts were encouraged to utilise homecare provision of SC infliximab in order to realise cost-savings related to a reduction in hospital activity. The Committee were supportive of adding SC infliximab to the Joint Formulary. The CSU will follow up with NCL Finance and Contracts Working Group (FCWG) for approval and consideration of the impact of current block contract agreements.

In summary, the Committee agreed to add SC infliximab to the NCL Joint Formulary for use in patients with ulcerative colitis or Crohn's disease.

Decision: Approved (pending finance approval)
Prescribing: Secondary care only
Tariff status: Tariff excluded
Funding: CCG
Fact sheet or shared care required: No

8.2 Rivaroxaban for prevention of VTE in patients undergoing midfoot or hindfoot surgery requiring plaster immobilisation (Applicant: Mr K Malhotra, RNOH)

The Committee considered an application for rivaroxaban, a Factor Xa inhibitor, for the prevention of VTE in patients undergoing midfoot or hindfoot surgery requiring plaster immobilisation. The current practice in NCL is to use low molecular weight heparin (LMWH). The Committee were informed that both LMWH and the proposed use of rivaroxaban are off-label for this indication.

The PRONOMOS trial was a randomised, double-blind, non-inferiority study, which compared rivaroxaban with enoxaparin in patients undergoing non-major orthopaedic surgery in the lower limbs, who required at least 2 weeks of thromboprophylaxis (n=3604). Patients were randomised to rivaroxaban 10mg daily or subcutaneous enoxaparin 40mg daily. The primary endpoint (composite of distal or proximal VTE, or VTE–related death during treatment period) was significantly better with rivaroxaban than enoxaparin (0.2% vs 1.1%; [p<0.001]). Key limitations of the study include premature discontinuation of enrolment which resulted in a smaller than expected sample size, 8.4% of patients had incomplete or no assessment of the primary outcome (which necessitated imputations), no true placebo arm, the relatively young cohort of patients (median age of 41), and the small number of events which meant that the trial had limited power to evaluate subgroup effects.

In terms of safety, rivaroxaban did not show a significant difference in risk of major bleeding compared to enoxaparin (1.1% vs 1.0%; [p=0.89]).

In terms of budget impact, the use of rivaroxaban would be expected to save up to £74 per patient per 42-day course.

The Committee heard from Mr Malhotra that there is little evidence base available for surgeries of foot and ankle fractures (as compared to hip or knee surgery), therefore the presented evidence was relatively substantial to make a clinical decision on the use of a medication in lower limb surgery. Candidate patients will be screened prior to initiation to assess contraindications and suitability for treatment (e.g. mechanical valve, renal dysfunction, drug interactions) and RNOH are proactively auditing patients discharged with LMWH at regular intervals post-discharge for patient tolerability and adverse events. Staff will be trained to screen and counsel patients appropriately prior to treatment initiation, utilising existing NCL documents where available.

In camera, the Committee considered the advantage of using rivaroxaban as a less invasive method of administration for patients and that would also reduce requirements for community nurse administration. The Committee heard that there are ongoing supply issues with LMWH, therefore rivaroxaban also provides a reliable alternative. The full treatment course would be supplied from Trusts. The Committee recommended that implementation in other Trusts must include appropriate pre-initiation screening to ensure safe and appropriate use and avoid extrapolation to unapproved indications.

In summary, the Committee agreed to add rivaroxaban to the NCL Joint Formulary for the prevention of VTE in patients undergoing midfoot or hindfoot surgery requiring plaster immobilisation.

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

9. Review of JFC interim approval: Delayed use of biosimilar rituximab (and JAK inhibitors) for rheumatoid arthritis during COVID-19 pandemic (Applicant: Dr M Leandro, UCLH)

The Committee reviewed the decision from the December 2020 meeting to pause or delay rituximab treatment for rheumatoid arthritis (RA) during the COVID-19 pandemic, which was initially approved for 6 months. The Committee considered newly published data from two observational studies and noted that there were no relevant RCTs.

The COVID-19 Global Rheumatology Alliance (C19-GRA) study was an observational cohort study analysing physician registry data for people with RA on biologic or targeted therapies who were diagnosed with COVID-19 (March 2020 to April 2021; n=2869). Multivariable adjusted analysis showed higher odds of hospitalisation (OR 4.53), and death (OR 4.57) with rituximab compared to TNF inhibitor therapy. There was also a signal for an association between JAK inhibitor (JAKi) therapy and higher odds of hospitalisation

(OR 2.40) and death (OR 2.04) compared to TNF inhibitor therapy. There were no significant associations between abatacept or IL-6 inhibitors and worse COVID-19 outcomes.

The OpenSAFELY Cohort study (preprint) was an observational cohort study analysing data for patients with immune mediated inflammatory diseases from linked English healthcare datasets (March to September 2020; n=1,163,438). Across all indications, 1,998 patients were prescribed rituximab and 871 patients were prescribed JAK inhibitors. After adjusting for confounders, the results showed an association between rituximab therapy and increased risk of COVID-19 related death (HR 1.68) and hospitalisation (HR 1.59) compared to standard systemic therapy. JAK inhibitors were associated with increased risk of hospitalisation (HR 1.81) but not COVID-19 related death.

Key limitations were the observational design of both studies with potential unmeasured confounders, and that neither study analysed timing of medication in relation to COVID-19 disease course. The C19-GRA disease specific registry was subject to selection bias and variation in international approaches to RA and COVID-19 management. Despite these limitations, it was noted that both studies had appropriate methodology and had reached similar conclusions. The results were noted to be relevant to an early stage of the pandemic, with uncertainty remaining as to the impact of COVID-19 vaccination and availability of new COVID-19 monoclonal antibody drugs on these risks.

The Committee heard that NICE have updated their NG167 rapid guideline to recommend that clinicians assess whether patients with stable disease can stop maintenance rituximab or be switched to an alternative immunosuppressant.

In terms of budget impact, the delay of biosimilar rituximab to third line choice is not associated with a cost-pressure overall. However, the delay of both JAKi and biosimilar rituximab would result in a significant budget impact due to the earlier use of more expensive therapies e.g. abatacept and IL-6 inhibitors.

The Committee agreed that observational data from two large studies indicate a risk of more severe COVID-19 outcomes for patients on rituximab therapy, including COVID-19 related death. The pandemic remains a 'caution for use' for rituximab and it is appropriate for patients to be offered other treatment options in the second line setting. This is supported by updated NICE guidance (NG167). It was agreed that where a patient chooses to pause/delay rituximab, they should remain on their new treatment until failure, and that biosimilar rituximab should be used as third line agent (unless contraindicated).

The Committee also noted the new signal for increased risk of hospitalisation with JAKi therapy. Dr Leandro (UCLH) told the Committee that this new signal warranted individual discussions with patients regarding benefits and risks to reach informed treatment decisions. Patients would still have the option to continue on rituximab or JAKi therapy if this was in their best interest, provided they were aware of the data regarding COVID-19 risk. Dr Leandro also outlined new MHRA safety alerts for JAKi in relation to cardiovascular and malignancy risk. The Committee agreed that while the evidence was less certain than for rituximab, it still warranted individual patient discussions of JAKi safety and risks in relation to COVID-19 and other factors to assess the most appropriate treatment choice during the pandemic, acknowledging that these risk assessments were complex and changing. The Committee noted a potentially significant budget impact if JAKi (as recommended 2nd line alternative to rituximab during pandemic) were also delayed and recommended further analysis of the potential budget impact by NEL CSU via the RA working group.

In summary, the Committee agreed to extend the decision for rituximab to be paused or delayed during the current pandemic, with alternative agents made available for second line use. The Committee agreed that the early signal for increased risk of COVID-19 hospitalisation with JAKi warranted individual patient discussion to establish whether JAKi form an appropriate alternative 2nd line option for the individual. This decision should be reviewed once further evidence relating to impact of COVID-19 vaccination is published.

Decision: Approved (for review after 12 months)
Prescribing: Secondary care
Tariff status: Excluded from tariff
Funding: Trusts are receiving block payment from CCGs therefore the short-term cost-pressure will be borne by the Trust (not the commissioner) and will require individual Trust funding approval. NELCSU to confirm budget impact estimates for JAKi delay.
Fact sheet or shared care required: No

10. Review: Increased risk of death with pregabalin

This item was deferred to the next meeting.

11. Preferred choice of CGRP inhibitor in NCL

In April 2021, the Committee agreed patients initiating their first CGRP inhibitor should be initiated on the lowest cost option. The FDA have since amended the Prescribing Information for erenumab – patients should now be monitored for new-onset hypertension, or worsening of pre-existing hypertension, with consideration given to treatment discontinuation in the event that an alternative cause is not identified.

Clinical teams at RFL and UCLH were in agreement that in light of this update, all patients initiating a CGRP inhibitor should be advised of a small risk of hypertension and for patients to agree to monitor their blood pressure at baseline, Day 1, 2, 7, 28 and 84. The decision to recommend monitoring for all patients (not just those prescribed erenumab) was because a class effect could not be excluded given available data. It was also agreed that, if contracts are such that erenumab is the lowest cost CGRP, a choice between erenumab and the second cheapest product with a NICE TA should be considered for patients who have controlled or poorly controlled hypertension. Patients who are severely hypertensive should not receive CGRP inhibitors (erenumab, galcanezumab or fremanezumab).

The Committee agreed with the proposals and recommended Trusts work with their pharmacy and finance teams to implement these recommendations, and update any locally available PILs.

12. Inclisiran and AAC Rapid Uptake Products

The Committee discussed a letter from NHS England's Accelerated Access Collaborative (AAC) outlining rapid implementation and funding arrangements for inclisiran, a novel cholesterol-lowering treatment. The Committee noted that UCLP AHSN will be establishing a working group to support further implementation discussions for inclisiran in NCL following publication of NICE TA733, including clarification of lipid pathway, anticipated uptake and service delivery model.

More broadly, the Committee discussed uncertainties regarding the implications of this new AAC rapid implementation mechanism for formulary processes, noting that NCL JFC and DTCs have established processes to support implementation of NICE-approved medications into clinical pathways. The Committee are supportive of a high quality, effective and transparent 'do it once' national approach to evaluation of drugs through NICE and to implementation support e.g. national pathways. However, the Committee sought clarity on the whether the AAC letter signalled a new category of 'rapid uptake products', and the implications of this on established processes. The Committee agreed to escalate the following questions via the NHS England regional pharmacy team:

- Is there a new category of 'rapid uptake products' where AAC are supporting early rapid implementation of NICE decisions?
- What is the process and criteria for selecting medicines such as inclisiran for rapid uptake and AAC focus?
- Who is involved in these selection and implementation decisions?
- How are declarations/conflicts of interests managed?
- How can Area Prescribing Committees support with consultation on selection of rapid uptake medicines?
- Can Area Prescribing Committees receive early notification of medicines where there is an expectation for implementation within 30 days of NICE FAD/TA publication?
- Why did AAC recommendations focus on rapid implementation of a single drug, inclisiran, rather than a pathway approach (which was a helpful aid to implementation for other lipid lowering drugs)?
- Will AAC lipid pathways be updated to include inclisiran, and what is the likely timeframe for this?
- Why does implementation of inclisiran focus on prescribing targets (300,000 patients on inclisiran by year 3) rather than an outcomes-based measure?
- Is the payment mechanism of 'nominal price' expected to extend to other medicines in the future?
- Has the financial risk related to potential increase in (nominal) cost of inclisiran after the 3 year contract been assessed, and who is expected to bear this risk?

13. Free of charge scheme: Baricitinib

The Committee were informed of a scheme for baricitinib, offering a 3-month discount for patients initiated on treatment for NICE approved indications; RA and atopic dermatitis. In RA, the NELCSU RA working group recommend using the most cost-effective JAK inhibitor, which is currently filgotinib, even after applying the discount for baricitinib. For atopic dermatitis, clinical feedback suggests dupilumab as the preferred treatment choice based on indirect comparisons of efficacy data. The Committee noted that the baricitinib discount scheme has limited benefit and may undermine efforts to use filgotinib as the preferred cost-effective choice of JAK inhibitor for RA.

14. Fluoroquinolones position statement

The updated fluoroquinolones position statement was presented for approval. The Committee were provided feedback that the restrictions applied to fluoroquinolones may result in an increase in parenteral antimicrobial therapy and exposure to carbapenems (previously considered last resort). The Committee acknowledged these comments, though the updated guidance was recognised to be in accordance with national recommendations. The Committee approved the updated position statement.

15. Next meeting

Thursday 18th November 2021