North Central London
Medicines Optimisation Network

Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 18th August 2022

		Present	Apologies
Prof A Hingorani	NCL JFC Chair	✓	
Dr B Subel	NCL JFC Vice Chair	✓	
Ms W Spicer	RFL, Chief Pharmacist		✓
Ms G Smith	RFL, DTC Chair		✓
Dr A Scourfield	UCLH, DTC Chair		✓
Mr J Harchowal	UCLH, Chief Pharmacist	✓	
Dr R Urquhart	UCLH, Divisional Clinical Director	✓	
Dr K Tasopoulos	NMUH, DTC Chair	✓	
Ms S Stern	NMUH, Chief Pharmacist		✓
Dr M Kelsey	WH, DTC Chair	✓	
Mr S Richardson	WH, Chief Pharmacist		✓
Dr S Ishaq	WH, Consultant Anaesthetist		✓
Dr A Worth	GOSH, DTC Chair		✓
Mr S Semple	NCL ICS, Interim Chief Pharmacist; GOSH, Interim Chief Pharmacist	✓	
Mr A Sell	RNOH, DTC Chair	✓	
Mr A Shah	RNOH, Chief Pharmacist	✓	
Prof A Tufail	MEH, DTC Chair		✓
Ms N Phul	MEH, Chief Pharmacist		✓
Ms J Bloom	MEH, Associate Chief Pharmacist	✓	
Ms K Delargy	BEH, Chief Pharmacist	✓	
Ms L Reeves	C&I, Chief Pharmacist		✓
Dr L Waters	CNWL, Consultant Physician in HIV		✓
Ms R Clark	NCL ICB, Head of Medicines Management (Camden)		✓
Mr P Gouldstone	NCL ICB, Head of Medicines Management (Enfield)	✓	
Ms E Mortty	NCL ICB, Interim Head of Medicines Management (Haringey)	✓	
Ms M Singh	NCL ICB, Head of Medicines Management (Barnet)	✓	
Mr A Dutt	NCL ICB, Head of Medicines Management (Islington)	✓	
Dr D Roberts	NCL ICB, Clinical Director (Islington)	✓	
Ms S Sanghvi	IPMO Programme Team, JFC Principal Pharmacist	✓	
Mr G Grewal	IPMO Programme Team, JFC Support Pharmacist	✓	
Mr K Simpson	IPMO Programme Team, Senior Data analyst	✓	
Ms I Samuel	RFL, Formulary Pharmacist	✓	
Mr H Shahbakhti	RFL, Formulary Pharmacist	✓	
Ms M Thacker	RFL, Clinical Lead Pharmacist	✓	
Mr A Barron	UCLH, Principal Pharmacist	✓	
Mr S O'Callaghan	UCLH, Formulary Pharmacist	✓	
Ms A Sehmi	NMUH, Formulary Pharmacist	✓	
Mr J Flor	WH, Lead Pharmacist	✓	
Ms H Thoong	GOSH, Formulary Pharmacist	✓	
Ms M Kassam	MEH, Senior Pharmacist	✓	
Ms H Weaver	NHSE, Specialised Commissioning Pharmacist	✓	

Ms A Fakoya	NCL ICB, Contracts & Commissioning Pharmacist	✓	
Dr A Hosin	UCLH, Clinical Pharmacology Registrar	✓	
Dr D Patch	RFL, Consultant Hepatologist	✓	
Ms N Kanani Alviri	RFL, Specialist Hepatology Pharmacist	✓	
Dr D Ludwig	Consultant, Rheumatology	✓	
Ms J Toft	Pharmacist, Gastroenterology	✓	
Dr M Hussein	Registrar, Gastroenterology	✓	
Dr R Popat	Consultant, Haematology	✓	

2. Meeting observers

Prof Hingorani welcomed observers to the meeting.

3. Members' declaration of interests

Declarations of interests register included for information. No interests relevant to the agenda were declared. Ms Sanghvi asked members and regular observers to send through any outstanding forms.

4. Minutes of the last meeting

The minutes and abbreviated minutes were accepted as an accurate reflection of the July 2022 meeting.

5. Matters arising

Nil.

6. Review of action tracker

Action tracker included for information.

7. JFC Outstanding Items & Work Plan

These items were included for information only. Any questions should be directed to Ms Sanghvi.

8. Local DTC recommendations / minutes

DTC site	Month	Drug	Indication	JFC outcome
RFL	June 2022	FOC scheme – Lenalidomide†*	Relapsed or refractory B-cell lymphoma	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care **Tariff status:** N/A – Free of charge **Funding:** N/A – Free of charge **Factsheet or shared care required:** No
RFL	June 2022	Nadolol*	Long QT syndrome	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care initiation, primary care continuation **Tariff status:** In tariff **Funding:** Trust/ICB **Factsheet or shared care required:** No
RFL	June 2022	Doxycycline injection*	Sclerotherapy	**Decision:** RFL only **Prescribing:** Secondary care only **Tariff status:** In tariff **Funding:** Trust **Factsheet or shared care required:** No **Additional information:** Subject to application for a new interventional procedure
RFL	June 2022	FOC scheme – Imlifidase†*	Anti-GBM disease	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care **Tariff status:** N/A – Free of charge **Funding:** N/A – Free of charge **Factsheet or shared care required:** No

† 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. * Subject to funding consideration.

8.1 Brivaracetam for epilepsy in paediatrics

The Committee considered the formulary status of brivaracetam for the treatment of paediatric patients with epilepsy. The Committee previously approved brivaracetam for use in adults in accordance with NICE NG217 ('*Epilepsies in children, young people and adults'*) as a 2nd line add on option for generalised epilepsy, myoclonic epilepsy and focal epilepsy, in line with NICE guidance, for use in patients who could not tolerate levetiracetam or, exceptionally, in patients eligible for levetiracetam but deemed by the specialist epilepsy team to be at high risk of behavioural side effects. The Committee acknowledged that the recommendations from NICE also apply to paediatric cohorts and having separate recommendations would lead to inequitable treatment. The Committee agreed to add brivaracetam to the NCL Joint Formulary for the same indications approved in the adult cohort.

Decision: Approved as a 2nd line add on option in children, young people and adults for generalised epilepsy, myoclonic epilepsy, and focal epilepsy, in line with NICE guidance, for use in patients who could not tolerate levetiracetam or, exceptionally, in patients eligible for levetiracetam but deemed by the specialist epilepsy team to be at high risk of behavioural side effects
Prescribing: Secondary care initiation, primary care continuation
Tariff status: In tariff
Funding: Trust/ICB
Fact sheet or shared care required: Specialists to seek acceptance of primary care continuation prior to initiation; deferred to shared care group to consider production of an interface document

9. New Medicine Reviews

9.1 Minutes from the rapid review subcommittee meeting on 11 August 2022

A rapid review subcommittee met to discuss an agreed process to review medicines which have been requested for use in one NCL organisation but have historically been on formulary in a different NCL organisation, but where there are no available minutes or evaluation/local guideline to provide sufficient reassurance of all clinical, safety and budget impact aspects. The subcommittee reviewed the rapid review template and made several suggested changes. The final template was presented to the JFC and was approved. The JFC ratified the minutes from the subcommittee meeting and approved all its recommendations.

Month	Drug	Indication	JFC outcome
August 2022	Sodium benzoate	Urea cycle disorders	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** Tariff excluded **Funding:** NHSE **Fact sheet or shared care required:** N/A
August 2022	Sodium Phenylbutyrate	Urea cycle disorders	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** Tariff excluded **Funding:** NHSE **Fact sheet or shared care required:** N/A
August 2022	Arginine	Urea cycle disorders	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** Tariff excluded **Funding:** NHSE **Fact sheet or shared care required:** N/A
August 2022	Levocarnitine	Urea cycle disorders	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** Tariff excluded **Funding:** NHSE **Fact sheet or shared care required:** N/A
August 2022	L-ornithine	Guanidinoacetate methyltransferase (GAMT) deficiency	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** Tariff excluded **Funding:** NHSE **Fact sheet or shared care required:** N/A

August 2022	Midodrine	Familial dysautonomia (Riley-Day syndrome) in paediatrics	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care initiation, primary care continuation **Tariff status:** In tariff **Funding:** Trust/ICB **Fact sheet or shared care required:** No (low patient numbers) – individualised management plan to support transfer of prescribing required
August 2022	Flunarizine	Migraine prevention - where established therapies (e.g., betablockers, tricyclic antidepressants, angiotensin-II receptor antagonists and antiepileptics) are ineffective, not tolerated or contraindicated.	**Decision:** Added to the NCL Joint Formulary **Prescribing:** Secondary care only **Tariff status:** In tariff **Funding:** Trust **Fact sheet or shared care required:** N/A **Additional information:** Flunarazine should not be used before CGRP mAbs in adults unless required to fulfil commissioning criteria (≥3 prior preventative treatments) to access CGRPs and no other established preventative therapy is suitable

10. Rapid reviews for DMARDs used for neurology indications

The Committee considered rapid reviews for several DMARDs (azathioprine, mycophenolate and methotrexate) for off-label use for multiple neurological indications and to consider addition into current NCL interface documents to aid transfer of prescribing and monitoring to primary care.

10.1 DMARDs for Neuromyelitis Optica

Summary	
Drug	Methotrexate, Mycophenolate, Azathioprine
Indication	Neuromyelitis Optica
Formulation/Route	Oral tablets
Dose	Methotrexate: 5mg-25mg once weekly Azathioprine: 1mg/kg/day (total daily dose) increasing at 2-6 weekly intervals to maximum up to 2-3mg/kg/day Mycophenolate: 500 mg once a day up to 1.5g twice a day
Legal status and procurement	Legal status: POM Storage & handling requirements: Cytotoxic
Patient cohort	Adults
Requesting site	UCLH (NHNN)
Efficacy	**GREEN**
Safety	**AMBER**
Funding route and cost	• In tariff • Annual cost per patient £7.50 to £250 (depending on drug and dose)
Estimated impact	• <50 adult patients (but estimate~5% NCL) • Budget impact for NCL <£1000 (drug cost only) with long term monitoring and prescribing proposed to move to primary care following specialist initiation and dose stabilisation in line with existing methotrexate shared care document and DMARD factsheet.

10.2 DMARDs for Inflammatory Myopathies

Summary	
Drug	Azathioprine, mycophenolate
Indication	Inflammatory myopathy (rheumatology)
Formulation/Route	Oral tablets
Dose	Azathioprine: 1mg/kg/day (total daily dose) increased at 4 weeks to 2mg/kg/day to maximum up to 3mg/kg/day Mycophenolate: 500 mg once a day up to 1.5g twice a day
Legal status and procurement	Legal status: POM Storage & handling requirements: Cytotoxic
Patient cohort	Adults
Requesting site	UCLH (NHNN)
Efficacy	**GREEN**
Safety	**AMBER**
Funding route and cost	• In tariff • Annual cost per patient up to £250 (depending on drug and dose)
Estimated impact	• 100-200 adult patients (but estimate ~10% NCL and overlap with other specialties for this indication) • Budget impact for NCL <£1000 (drug cost only) with long term monitoring and prescribing proposed to move to primary care following specialist initiation and dose stabilisation in line with existing DMARD factsheet.

10.3 DMARDs for Inflammatory Neuropathies

Summary	
Drug	Azathioprine, mycophenolate
Indication	Inflammatory neuropathy
Formulation/Route	Oral tablets
Dose	Azathioprine: 1mg/kg/day (total daily dose) increasing at 2-6 weekly intervals to maximum up to 2-3mg/kg/day Mycophenolate: 500 mg once a day up to 1.5g twice a day
Legal status and procurement	Legal status: POM Storage & handling requirements: Cytotoxic
Patient cohort	Adults
Requesting site	UCLH (NHNN)
Efficacy	**AMBER**
Safety	**AMBER**
Funding route and cost	• In tariff • Annual cost per patient up to £250 (depending on drug and dose)
Estimated impact	• 100-200 adult patients (but estimate ~10% NCL and overlap with other specialties for this indication) • Budget impact for NCL <£1000 (drug cost only) with long term monitoring and prescribing proposed to move to primary care following specialist initiation and dose stabilisation in line with existing DMARD factsheet

10.4 DMARDs for neurological sarcoidosis

Summary	
Drug	Methotrexate (most commonly used), Mycophenolate, Azathioprine
Indication	Sarcoidosis (neurology)
Formulation/Route	Oral tablets
Dose	Methotrexate: 5mg-25mg once weekly Azathioprine: 1mg/kg/day (total daily dose) increasing at 2-6 weekly intervals to maximum up to 2-3mg/kg/day Mycophenolate: 500 mg once a day up to 1.5g twice a day
Legal status and procurement	Legal status: POM Storage & handling requirements: Cytotoxic
Patient cohort	Adults
Requesting site	UCLH (NHNN)
Efficacy	**GREEN**
Safety	**AMBER**
Funding route and cost	• In tariff • Annual cost per patient £7.50 to £250 (depending on drug and dose)
Estimated impact	• <50 adult patients (but estimate~5% NCL and overlap with other specialties for this indication) • Budget impact for NCL <£1000 (drug cost only) with long term monitoring and prescribing proposed to move to primary care following specialist initiation and dose stabilisation in line with existing methotrexate shared care document and DMARD factsheet.

10.5 DMARDs for neurological vasculitis

Summary	
Drug	Methotrexate, Mycophenolate, Azathioprine
Indication	Vasculitis (neurology)
Formulation/Route	Oral tablets
Dose	Methotrexate: 5mg-25mg once weekly Azathioprine: 1mg/kg/day (total daily dose) increasing at 2-6 weekly intervals to maximum up to 2-3mg/kg/day Mycophenolate: 500 mg once a day up to 1.5g twice a day
Legal status and procurement	Legal status: POM Storage & handling requirements: Cytotoxic
Patient cohort	Adults
Requesting site	UCLH (NHNN)
Efficacy	**GREEN**
Safety	**AMBER**
Funding route and cost	• In tariff • Annual cost per patient £7.50 to £250 (depending on drug and dose)
Estimated impact	• <50 adult patients (but estimate~5% NCL and overlap with other specialties for this indication) • Budget impact for NCL <£1000 (drug cost only) with long term monitoring and prescribing proposed to move to primary care following specialist initiation and dose stabilisation in line with existing methotrexate shared care document and DMARD factsheet.

10.6 Committee discussion

The Committee acknowledged the experience of the DMARDs in neurological indications at NHNN and were reassured that they were no substantial differences in initiation and monitoring between neurology indications compared to those which are already contained in the current NCL interface documents (i.e., for indications in gastroenterology, rheumatology and dermatology). It was also recognised that approval would reduce inequity

in access to DMARDs for patients suffering with neurological disorders. The Committee also recognised that NHNN review patients from across the UK, and other regions may have a different formulary position (e.g., non-formulary or requiring a shared care). The Committee agreed that clinicians who refer patients into an NCL service should adhere to NCL governance processes, including the continuation of recommended treatments using NCL interface documents.

In summary, the Committee agreed to add methotrexate, mycophenolate and azathioprine to the NCL Joint Formulary for several neurological indications (Neuromyelitis Optica, inflammatory myopathies, inflammatory neuropathies, neurological sarcoidosis and neurological vasculitis).

Decision: Approved
Prescribing: Secondary care initiation, primary care continuation
Tariff status: In tariff
Funding: Trust/ICB
Fact sheet or shared care required: Yes – deferred to the NCL Shared Care Group for updates to the DMARDs quick reference guide and methotrexate shared care.

11. Sodium benzoate for overt hepatic encephalopathy

The Committee considered an application for sodium benzoate, an unlicensed D-amino acid oxidase [DAO] inhibitor, up to a maximum dose of 5g BD for the treatment of overt hepatic encephalopathy following inadequate response, intolerance, or contraindication to rifaximin, lactulose and phosphate enemas.

Zacharias et al (2019) conducted a systematic review and meta-analysis to determine the beneficial and harmful effects of pharmacotherapies that specifically target ammonia for the prevention and treatment of hepatic encephalopathy in adults with cirrhosis; 11 studies were included in the analysis (n=943), 3 of which included sodium benzoate as a treatment arm. For the first primary outcome, mortality, there was no advantage in terms of safety or efficacy for sodium benzoate as compared to non-absorbable disaccharides (2 studies, RR = 1.26 [95% CI 0.49 to 3.28]). For the second primary outcome, hepatic encephalopathy, there was also no advantage in terms of safety or efficacy for sodium benzoate as compared to non-absorbable disaccharides (1 study, RR = 1.22 [95% CI 0.51 to 2.93]). For the secondary outcome, blood ammonia levels, this was significantly lower with sodium benzoate compared to placebo (1 study, mean difference = -32 [95% CI -46.85 to -17.15]); however, there was no beneficial or harmful effects with sodium benzoate as compared to non-absorbable disaccharides (2 studies, mean difference = 9 [95% CI -1.1 to 19.11]). Taken together, these findings indicate a treatment effect of sodium benzoate approximately equivalent to that of non-absorbable disaccharides.

In terms of safety, the meta-analysis found no significant difference between sodium benzoate and non-absorbable disaccharides in both serious (1 study, RR = 1.08 [95% CI 0.44 to 2.68]) or non-serious adverse events (2 studies, RR = 1.13 [95% CI 0.96 to 1.32]).

In terms of budget impact, sodium benzoate is expected to cost between £2,100 to £9,000 per annum (depending on dose and place of prescribing).

The Committee heard from Dr Patch that all patients being considered for sodium benzoate would have attempted all previous lines of pharmacotherapy, radiological procedures for porta-systemic encephalopathy would have been discussed and excluded, and transplantation would also have been explored as a treatment option before sodium benzoate was considered. There is a wealth of experience in using sodium benzoate for urea cycle disorders and the aim of treatment in reducing blood ammonia in hepatic encephalopathy is similar. Dr Patch acknowledged sodium benzoate has a high sodium content, and the decision to initiate treatment is usually based on the benefit of treatment versus risk of worsening ascites. Compliance with sodium benzoate may sometimes be an issue due to the high pill burden, and therefore the lowest effective dose is used. Patients would be retained by the hepatology service for routine follow-up, and although there is a desire for primary care continuation for patient convenience, the service would be able to manage medication supply.

In camera, the Committee considered the relatively small evidence base, limitations in the included studies and acknowledged there is no evidence for additive use of sodium benzoate alongside other therapies. However, the Committee were reassured that treatment would be carefully initiated in a cohort of patients with severe hepatic encephalopathy and no other treatment options. There was some concern with continuing sodium benzoate in primary care, particularly since it is an unlicensed medication being used to treat a

relatively specialist condition; however, the Committee were supportive of adding sodium benzoate for overt hepatic encephalopathy to the joint formulary managed by the specialist service.

In summary, the Committee agreed to add sodium benzoate to the NCL Joint Formulary for overt hepatic encephalopathy following inadequate response, intolerance, or contraindication to rifaximin, lactulose and phosphate enemas.

Decision: Approved
Prescribing: Secondary care only
Tariff status: Not routinely commissioned
Funding: Trust
Fact sheet or shared care required: No

12. Intranasal dexmedetomidine for sedation in paediatrics as premedication to general anaesthesia

In July 2022, the Committee approved the use of intranasal dexmedetomidine (IND), an alpha-2 adrenoceptor agonist, prior to painless procedures or scans, conditional on the production of an aligned guideline to ensure equitable treatment and risk management; JFC Support were subsequently informed of an additional request from WH to ratify the off-label use of IND as premedication to general anaesthesia in paediatrics at up to 200micrograms as a single administration, which is currently in use at GOSH (supported by a local Trust guideline).

A meta-analysis discussed in brief in the previous evaluation was explored further. Jun et al (2017) conducted a systematic review and meta-analysis to determine the effect of IND as premedication to general anaesthesia in children undergoing surgical procedures. 13 relevant studies were included in the analysis (n=1,168) which included 4 studies versus oral midazolam and 6 studies versus intranasal midazolam. IND was significantly better at providing satisfactory sedation at parent separation compared with other premedication regimes (RR = 1.45 [95% CI 1.19 to 1.76]), but there was no difference between IND and other premedication regimes for sedation at mask induction (RR = 1.25 [95% CI 0.98 to 1.59]). In a subgroup analysis of satisfactory sedation at parent separation, IND was not statistically better than intranasal midazolam (RR = 1.42 [95% CI 0.96 to 2.11]) but was significantly better than oral midazolam (RR = 1.56 [95% CI 1.15 to 2.11]). In a further subgroup analysis of satisfactory sedation at mask induction, IND was not significantly better than intranasal midazolam (RR = 1.14 [95% CI 0.77 to 1.67]) or oral midazolam (RR = 1.40 [95% CI 0.99 to 1.99]). Limitations of the meta-analysis include heterogeneity amongst studies (in terms of doses of IND used, the types of surgery and patient age ranges) and acknowledgment by the authors that there is a risk of overestimating the effects of IND due to the small clinical trials included.

In terms of safety, the Committee were reminded of safety data analysed in July 2022. Studies found IND lowered systolic blood pressure and/or heart rate, though the majority of patients did not require intervention.

In terms of budget impact, IND is expected to cost an additional £800 more at WH for up to 50 patients per annum. This budget impact was not offset against comparators or accounted for any additional atomiser devices required for administration.

The Committee had previously discussed the additional risks of hypotension and bradycardia with IND and the level of experience in practice at GOSH. The Committee were reassured that IND is an efficacious therapy, but as with the use prior to scans and painless procedures, agreed that an aligned treatment guideline between interested Trusts is required to mitigate potential risks. The Committee were informed that WH have started development of a guideline for premedication in paediatrics which includes several other premedication therapies currently in use at GOSH but not on formulary at WH. These will be considered for addition to the NCL Joint Formulary at a future JFC meeting.

Decision: Approved pending submission of guidelines with risk mitigation details
Prescribing: Secondary Care Only
Tariff status: In tariff
Funding: Trusts
Fact sheet or shared care required: No
Additional information: All treatments included in guidance will be brought back to JFC to ensure they have been reviewed for addition to the NCL Joint Formulary. WH and GOSH clinicians to work together to create a set of core principles to include in their respective Trust policies; WH to bring their guideline back to the JFC for final sign-off

13. Biosimilar ranibizumab for medical retinal vascular conditions

The Committee considered a proposal to use biosimilar ranibizumab (Ongavia®), an anti-vascular endothelial growth factor (anti-VEGF) agent, in place of the originator product (Lucentis®). Ongavia® is supported by a study by Holz et al (n=477) to demonstrate that it is clinically equivalent to Lucentis® in the primary outcome of change from baseline best corrected visual acuity at 8 weeks before administration of the third injection. NHSE have issued commissioning recommendations for medical retinal vascular conditions, which suggest that patients should be initiated on biosimilar ranibizumab instead of other anti-VEGF treatments and consideration should be given to switching patients from other biologics to biosimilar ranibizumab (except in the case of aflibercept where used for diabetic macular oedema, central retinal vein occlusion and branch retinal vein occlusion). The Committee were presented with a two-phase approach to implementation:

- Phase 1:
    - Switching of patients already receiving Lucentis to biosimilar ranibizumab
    - Patients initiated on ranbizumab to be prescribed Ongavia® instead of Lucentis®
- Phase 2:
    - Switching of existing patients on other biologics to biosimilar ranibizumab
    - Changes to the ophthalmology pathway to make biosimilar ranibizumab the preferred first line agent in NCL, and confirmation for which indications

The Committee acknowledged the recommendations from NHSE is based on a national procurement exercise and was informed by nationwide discussions amongst the ophthalmic community. The Committee agreed with the proposal to proceed with the phase 1 of biosimilar ranibizumab implementation. The Committee understood that phase 2 has additional complexities which requires additional work (e.g., update to the NCL ophthalmology pathways; adaptation of national patient information leaflet for NCL Trusts). This will be brought back to the Committee for consideration at a future JFC meeting.

14. Minimising the teratogenic risk of valproate to patients of childbearing potential in NCL

The Committee were presented with a new NCL guideline to minimise the teratogenic risk of valproate to patients of childbearing potential in NCL. The guideline outlines the roles and responsibilities of clinicians through each step of the patient pathway to ensure all patients are routinely reviewed and have a valid annual risk acknowledgement form where applicable. The Committee commended the programme of a work as a good example of collaborative working across the sector. The Committee approved the guideline, which will be used initially in a pilot before implementation across the sector.

15. JFC reflections and strategic priorities for 2022/23

The Committee were presented with a SWOT analysis for the 2021/22 NCL MON annual report based on the current ways of working. Suggestions were provided for strategic priorities for 2022/23, including an update to the NCL JFC Terms of Reference following the transition to the NCL Integrated Care System, governance arrangements for commissioning decisions Committee membership and formulary process to improve implementation and harmonisation of formulary decisions across the sector. The Committee were invited to send additional suggestions, comments and insights to the JFC Support team. The SWOT analysis will be brought back to future JFC meetings on a regular basis to monitor progress and for continuous improvement.

16. Rapid review: Pigmanorm for melasma

Summary	
Drug	Pigmanorm cream (hydroquinone 5% w/w, hydrocortisone 1% w/w and tretinoin 0.1% w/w)
Indication	Hyperpigmentation related to melasma
Formulation/Route	Topical cream
Dose	Applied once daily
Legal status and procurement	Legal status: Unlicensed Storage & handling requirements: Nil
Patient cohort	Adults
Requesting site	UCLH
Efficacy	**AMBER**
Safety	**AMBER**
Funding route and cost	• In tariff • Unlicensed and not price not standardised; cost varies from £30 to £193 per 15g tube in primary care; £10.97 plus VAT per 15g tube in secondary care
Estimated impact	• Currently prescribed in primary care • Potential safety concerns with long-term use without routine review • Current annual cost of £12,000 per annum across NCL primary care; currently transferred to primary care with no routine review.
Discussion	• Pigmanorm is listed in the BAD specials list and is usually recommended for a 6-month duration due to possible adverse effects if continued long-term • NCL specialists would prefer to retain on formulary and transfer to primary care • Risks identified with primary care continuation, with current patients continuing treatment beyond 6 months with no specialist monitoring or review • Substantially lower price to procure in secondary care compared to primary care • Primary care guidelines have reviewed previously and have advised against use of skin lightening agents and camouflage creams in primary care • No issues identified with retaining Pigmanorm on formulary if supplies are made from Secondary care
Decision and prescribing Status	• Decision: Approved • Prescribing status: Secondary care prescribing only

17. Newly licensed metolazone 5mg tablets

The Committee were informed that a newly licensed formulation of metolazone 5mg tablets recently became available. Currently, unlicensed metolazone products are in use. A NICE medicines bulletin identified that the licensed product has higher bioavailability compared to other metolazone products. There is a risk that patients may be switched from the unlicensed product to the licensed product without active monitoring. The Committee agreed a series of recommendations to ensure patients continue on their current metolazone product until a formal JFC evaluation has been conducted.

18. Next meeting

Thursday 15th September 2022

19. Any other business

Ms Sanghvi will be taking maternity leave for the next year. The Committee thanked Ms Sanghvi for her contributions to the Committee and wished her luck. Ms Amin has been successfully appointed to cover the role of Principal Pharmacist for the next 12 months. Mr Grewal has been successfully appointed to back-fill Ms Amin's post for 12 months (Lead Pharmacist IPMO Programme team). Two new JFC Support Pharmacists have been appointed and will start over the coming months.