

North East London Formulary & Pathways Group (FPG) Wednesday 25th January 2023 at 12.30pm via MS Teams

Minutes

Attended by:	
Dr Sarah Hall (SH)	Chair, GP, Medicines Optimisation Lead for Tower Hamlets
Gurvinder Rull (GR)	Co-Chair, Consultant Clinical Pharmacology, Barts Health NHS Trust
Belinda Krishek (BK)	Director of Medicines Optimisation, NHS North East London (NEL)
Iffah Salim (IS)	CAMHS Directorate Lead/ MI Pharmacist, East London Foundation Trust (ELFT)
Maruf Ahmed (MA)	Formulary Pharmacy Technician, Barts Health NHS Trust
Jaymi Teli (JT)	Lead Formulary & Pathways Pharmacist, Barts Health NHS Trust
Nilou Nourishad (NN)	Commissioning & Contracting Pharmacist, NHS NEL
Rahil Patel (RP)	Senior Prescribing Advisor, NHS NEL
Nicola Fox (NF)	Commissioning & Contracting Senior Pharmacy Technician, NHS NEL
John Booth (JB)	Consultant Nephrologist, Barts Health NHS Trust
Annett Blochberger (AB)	Deputy Head of Regional Specialised Commissioning – Pharmacy NHSE
Denise Baker (DB)	Medicines Optimisation Business Manager, NHS NEL (minute taker)
Anh Vu (AV)	Joint Formulary Pharmacist, NHS NEL
Louise Abrams (LA)	Clinical Pharmacologist, DTC Chair, Homerton Healthcare NHS Foundation Trust (HHFT)
Dinesh Gupta (DG)	Assistant Chief Pharmacist, Clinical Service, Barking, Havering & Redbridge University Trust (BHRUT)
Mohamed Kanji (MK)	Prescribing Advisor, NHS NEL
Apologies:	
Sibel Ihsan (SI)	Lead Directorate Pharmacist for Waltham Forest, North East London Foundation Trust (NELFT)
Kiran Dahele (KD)	Formulary Pharmacist, NELFT
Iola Williams (IW)	Chief Pharmacist, HHFT
Natalie Whitworth (NW)	Commissioning & Contracting Pharmacist, NHS NEL
Tase Oputu (TS)	Lead Pharmacist, Medicines Commissioning & Pathways, Barts Health NHS Trust
In Attendance:	

Lead Respiratory Pharmacist, Barts Health NHS Trust Christabelle Chen (CC) Sanjay Patel (SP) Deputy Director of Medicines Optimisation, NHS NEL Paul Pfeffer (PP) Respiratory Consultant, Barts Health NHS Trust Anika Dewshi (AD) Respiratory Pharmacist, Barts Health NHS Trust Severe Asthma and Allergy Specialist Pharmacist, Barts Health NHS Trust Laia Castro (LC) Medicine Optimisation Pharmacist, NHS NEL Yvonne Lim (YL) Yogendra Parmar (YP) Chief Executive Officer, City & Hackney and Camden & Islington Local Pharmaceutical Committee (LPC) Shilpa Shah (SS) Chief Executive Officer, NEL LPC Dalveer Johal (DJ) Pharmacy Services Manager at NEL LPC Dr Sandra Watson (SW) Consultant Obstetrician & Gynaecologist, Clinical Lead for Gynaecology, HHFT Navdeep Sahota (NS) Practice Prescribing Support Officer, NHS NEL Imran Khan (IK) QIPP Pharmacist, NHS NEL Wai-Lun Chu (WC) Senior Prescribing Advisor, NHS NEL Bola Sotubo (BS) Senior Transformation Manager, NHS NEL

No.	Agenda item and minute	Action
1.	Quoracy check	
	It was confirmed that the meeting was quorate.	
2.	Welcome / Introduction and Apologies	
	The Chair welcomed all to the meeting and apologies were noted as above.	
3.	Declarations of interest from member and presenters	
	The Chair reminded members and presenters of their obligation to declare any interests relating to agenda items.	
4.	Minutes from previous meeting	
	The minutes of the previous meeting (December 2022) were agreed as an accurate record.	
5.	Matters Arising	
	Review of Action Log	
	The following updates were provided:	
	 Escalated doses of Adalimumab in patients with psoriasis – the group were advised that the NEL Psoriasis pathway 	
	had been produced but was awaiting formulary submissions by the respective consultants to support dose escalations	
	and the use of drugs for high impact (body) sites. The pathway would be submitted to the FPG in two stages with the	
	first in February 2023 and the second stage submission in June 2023.	

- <u>NEL Atopic Dermatitis pathway for primary and secondary care</u> the group were advised that this pathway was on hold until the NEL emollient formulary had been completed; formulary estimated for completion by February 2023.
- <u>Rituximab in Connective Tissue Disease</u> Interstitial Lung Disease (ILD) number of patients has been reviewed and 10 patients per year. Rituximab in Hypersensitivity Pneumonitis – number of patients has been reviewed and 1-2 patients per year. A list of specialist ILD services was no longer required as the above was not part of NHS England specialised commissioning.
- Omnitrope Biosimilar the group were advised that Somatropin and Omnitrope were now excluded from tariff and therefore further clarification was required within NEL ICB regarding its approach to the commissioning of excluded drugs for 2023/24; an update would be provided in June 2023.

TA828 Ozanimod for treating moderately to severely active ulcerative colitis

An update to the following item which had been included in the December FPG agenda was provided and the group advised that there were eight patients within Barts Health NHS Trust; HHFT had stated they would be using but were unable to estimate patient numbers as awaiting IBD pathway to be finalised. No patient numbers had been provided from BHRUT.

NEL Blood Glucose Test Strips Guideline (Final)

This document had been updated to include the required amendments and the final version circulated for approval.

Outcome: Approved

NEL Respiratory Inhaler Formulary

The group were advised that following FPG approval, formatting corrections had since been made to this document and an updated version was to be circulated.

For Discussion - Items submitted for Approval

6. Drug application – Mannitol challenge to diagnose bronchial hyper-responsiveness

Barts Health NHS Trust representative was welcomed to the meeting and explained that Mannitol was to be considered as an alternative to histamine nebuliser solution in aiding the diagnosis of asthma/ bronchial hyper-responsiveness when other diagnostics had been inconclusive; this would be an indirect challenge test. The group were advised that issues were being experienced in securing sufficient supplies of the histamine nebuliser solution and the addition of mannitol to the formulary would enable a 3rd line alternative option to be available for use (as per the British Thoracic Society). It was clarified that the use of mannitol for this indication (diagnostic) would be within tariff. It was confirmed that both BHRUT and HHFT clinicians had advised that they did not have any interest in using Mannitol.

It was agreed that mannitol would be added to the formulary with a 'hospital only' status (red) for adult patients.

	Outcome: Approved	
	Formulary status: Hospital only	
7.	Drug application – Methacholine challenge to diagnose bronchial hyper-responsiveness	
	It was explained to the group that methacholine was to be considered as the new 1 st line option replacing histamine nebuliser solution in aiding the diagnosis of asthma/ bronchial hyper-responsiveness in adults when other diagnostics had been inconclusive; this would be for direct challenge testing. Histamine was to remain as an alternative second line option. It was confirmed that there were no known methacholine interactions with oral medications according to the Summaries of Product Characteristic (SPC).	
	A concern was raised regarding the number of serial dilutions required for this medication to be administered and the availability of a protocol to ensure sufficient safety measures were in place to support the ten-step process. The group were advised that the dilution was completed by a machine for this purpose, a specialist physiologist had already written a Standard Operation Procedure (SOP) and identified the training requirements to be completed by clinical staff administering methacholine. It was clarified that there are no interactions between methacholine and orally administered drugs.	
	It was agreed that methacholine would be added to the formulary with a 'hospital only' status (red) unless used within a community diagnostic hub where an appropriate Patient Specific Direction (PSD) and competency document must be in place. A note to this effect would be included in the London formulary which was yet to be finalised.	
	Outcome: Approved Formulary status: Hospital only, unless prescribed within a community diagnostic hub under a PSD	
8.	Drug application – Tezepelumab Free of Charge (FOC) in severe asthma	
	Barts Health NHS Trust representative was welcomed to the meeting and explained the request for tezepelumab to be included as a treatment option for patients with severe asthma who were currently ineligible or unsuitable for the existing biologic therapies. It was also to be considered as an additional treatment option for patients who were not responding to the currently approved biologics. It was confirmed that an approved licensed biologic would continue to be the first line choice for patients. However, there were some patients who frequently attended hospital due to exacerbations and the addition of tezepelumab as an option would support the current unmet clinical need of patients with no other choice of treatment available. AstraZeneca (AZ) had offered a free access scheme which would include a review of treatment within 6-12 months for those patients responding to treatment. Assurances had also been provided by AZ that patient treatment would continue to be funded until NICE approval was received or should approval not be received for tezepelumab, then AZ would continue to fund for patients. Patients had already been identified within NEL who would benefit from this treatment.	

It was clarified that the decision to discontinue the treatment would only be made if Barts Health NHS Trust clinicians decided that patients were not responding well to tezepelumab or if the Trust was unable to offer the annual reviews expected; this was similar criteria set by NICE for the discontinuation of all biologics for severe asthma. The group were advised that whilst NICE was due to release their guidance regarding tezepelumab during Q2 of 2023, it was felt that with the added implementation time for treatment this was too long for patients to wait. It was confirmed that standard biologics would be used first and tezepelumab only used for patients who were refractory to the agreed first line treatments. It was highlighted that tezepelumab was unlikely to receive approval by NICE on its first appraisal. This was not an unusual occurrence as other submissions for severe asthma biologics had also been refused and the request for more data made. The group felt that the evidence base was sound with a pathway in place to support the use of tezepelumab, although the group were advised of NHS England's opposition to the introduction of a free of charge access scheme as such schemes undermine the pricing structure within the NHS with no commissioning policy and advised that any financial risk would be with the respective Trust. Outcome: Approved Formulary status: Hospital only Introduction to QIPP plan and following agenda items (9,10,11) NHS NEL representative advised that agenda items 9,10 and 11 had formed part of QIPP cost saving plan which had been submitted and endorsed by the IMOC and supported the NEL ICB deficit. The significant savings that could be achieved with the change to recommended brands was explained to the group and that rebate schemes were not in place for any medications referred to in items 9,10 and 11. It was confirmed that the three agenda items were the only switch programmes to be considered for 2022/23. Resources such as ScriptSwitch/OptimiseRx messages would be utilised to support implementation of the switch programmes. The ICB was looking at a 20-30% switch via this approach. All switch protocols included patient exclusion criteria and it was emphasised that patients who experienced any issues such as adverse effect would be transferred back to their initial prescribed product. Barts Health NHS Trust representative advised that at the present time it would not be cost effective for the Trust to consider the switches outlined and therefore they would remain as primary care initiatives, with Trust maintaining generic prescribing on discharge summaries. The group were advised that BHRUT would align prescribing with primary care where appropriate. Recommended brands update for Buprenorphine patches, Oxycodone capsules and modified-release (MR) tablets 9.

NHS NEL representative explained that the following recommendations were being requested for approval:

Buprenorphine patches	1 st recommending brand	2 nd recommending brand
5, 10, 15 and 20microgram/hour	*Rebrikel	Sevodyne
35, 52.5 and 70microgram/hour	Bupeaze	Carlosafine
*Rebrikel is only available in 5, 10 and 20microgram/hour.		

Oxycodone capsules	1st recommending brand	2 nd recommending brand
ALL STRENGTHS (5mg, 10mg	Shortec	Lynlor
and 20mg)		·
Oxycodone MR tablets	1 st recommending brand	2 nd recommending brand
5mg, 10mg, 15mg, 20mg, 30mg,	Oxypro	Oxeltra
40mg, 60mg and 80mg		

It was clarified that brand selection was based on cost effectiveness and stock availability and availability of the product in different strengths. It was confirmed that stock levels had been discussed with suppliers and all brands were widely available with no issues identified; price guarantees had also been received. Discussions with local community pharmacies had also been undertaken with regard to supporting the implementation of this work. ScriptSwitch and OptimiseRx messages would be added to the clinical systems within primary care along with the availability of resources to support the implementation of the switch programme.

The group were advised of the potential savings for the NEL ICB if a target of 33.3% of prescribing was switched to the recommended brands.

Outcome: Approved

10. Updated protocol on switching prescribing of Mesalazine MR tablets / Asacol MR tablets to cost-effective brand Octasa

NHS NEL representative was welcomed to the meeting and advised the group that this item's recommendation had previously been approved by the Area Prescribing Committee for Barking & Dagenham, Havering and Redbridge CCG in July 2019 and approved by the Joint Prescribing Group for City & Hackney CCG in 2018. Therefore, the following recommendation was to be considered for implementation across the NEL ICB to maximise potential savings:

• Cost effective switch from generic mesalazine 400mg and 800mg MR Tablets, and branded Asacol 400mg and 800mg MR Tablets to the cost-effective brand Octasa

ScriptSwitch and OptimiseRx messages would be added to the clinical systems within primary care and resources made available to support the implementation of the switch programme. There was also a plan to implement the switch through secondary care teams which the group were requested to support. However, it was noted that gastroenterologists within BHRUT, Homerton Trust and Barts Health Trust were already supporting the use of Octasa as the existing preferred choice.

Financial information was shared with the group which outline the potential maximum saving and a target saving of 20%.

Outcome: Approved

11. Updated protocol on switching Metformin oral solution to powder for oral solution

NHS NEL representative was welcomed to the meeting and explained that a switch from metformin oral solution to metformin 500mg powder for oral Solution would provide a significant potential saving across NEL if the following recommendation was approved:

• Switch patients who were prescribed metformin hydrochloride 500mg/5ml oral solution and do not tolerate metformin oral tablets to the more cost-effective and bioequivalent metformin 500mg powder for oral Solution.

Financial information was shared which outlined the NEL ICB's prescribing spend during 2021/22 together with potential cost savings if all three strengths of metformin oral solution were switched to the powder for oral solution formulation.

It was confirmed that the aim of the programme was to switch 20% of patients, and an SOP had been prepared to support the programme. It was highlighted that the metformin switch would not be recommending a brand, and hence generic formulations would be prescribed.

Outcome: Approved

A North East London Local Pharmaceutical Committee presented a presentation

City & Hackney Local Pharmaceutical Committee (LPC) representative was welcomed to the meeting and outlined the concerns that were highlighted in the NEL and C&H LPC branded generic switching position statement. These included:

- Ongoing medicine shortages (currently over 200) and the sourcing of alternative products increasing workload/work pressure upon primary care.
- Convoluted patient journey/exacerbate patient confusion and frustration potentially increasing workload such as counselling to patients.
- Regulatory burden of CDs and the switching between CDs and maintaining sufficient stock levels within pharmacy.

Additional paperwork had also been submitted to highlight the effect of branded generic switching on waste management and articles reflecting on the undermining of the Nationally agreed Community Pharmacy funding envelope.

NEL LPC representative expressed support for all the highlighted concerns above and reiterated that the current medicine shortages were extremely time consuming with the increase of prescription amendments to alternative medications. Further issues raised were the workload involved in producing an SSP to support any stock shortages and the time lapse experienced in changing wholesaler for a community pharmacy, should this be required. Concern was also raised regarding the consideration of switch programmes that were agreed in 2018/19 and the appropriateness of implementing these workstreams at the present time. The group considered and discussed the above points raised. NHS NEL representative confirmed that assurances had been provided by the wholesalers that the medications that were referred to in the switch programmes would be readily available and it was reiterated that prescribing data would enable supply and demand to be monitored. However, the group concluded that all three workstreams had previously been endorsed by the IMOC for implementation across NEL ICB and would be approved. Noted. 12. Patient Information Leaflet (PIL) to support NEL Blood Glucose Test Strips Guidelines NHS NEL representative was welcomed to the meeting and presented the Patient Information Leaflet (PIL) that had been developed to support the implementation of the NEL Blood Glucose Test Strips Guidelines. It was explained that the aim of the document was to reinforce clinicians' advice and recommendations to patients/carers and provide additional written information that would support the appropriate self-management of blood glucose testing using a blood glucose meter. It was confirmed that whilst the leaflet had been shared with the NEL Diabetes Partnership group and the communications team for their input, the document had not been considered by patients for feedback on content, format and suitability of wording i.e. user-friendly language/ use of clinical terminology, and if there is a need to develop version(s) with content translated into additional language(s), in order to make the document more accessible to patients. It was requested that feedback is sought regarding the areas outlined in the document, and then re-submitted at a future meeting. **Outcome:** Not approved, document requires further update. 13. Joint statement: Access to Continuous Glucose Monitors for adults living with Type 2 Diabetes in London NHS NEL representative presented the above document to the group and requested that the statement be endorsed and adopted for use across NEL ICB which currently had three policies/statements in place. It was confirmed that a NEL Task & Finish Group had been established to feed into the pan London work being produced.

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	Outcome: Ratified for use in NEL	
14.	SGLT2i prescribing checklist	
14.	NHS NEL representative was welcomed to the meeting and presented the above checklist that had been produced to support	
	and supplement the NEL Management of Type 2 Diabetes Guidelines. A declaration of interest was shared with the group.	
	The checklist provided quick reference information for clinicians and outlined a number of areas for advice and guidance such as sick day rules, symptoms of ketoacidosis and Fournier gangrene. It was confirmed that a patient information leaflet had also been produced and was currently with the communications team for their consideration. The importance of gaining patient feedback was highlighted. It was acknowledged that whilst prompt messages were useful, not all clinical areas had an appropriate prescribing support tools (ScriptSwitch/OptimiseRx/Ardens) and therefore the checklist was produced for clinicians as an overall reference guide for sharing.	
	The group had a discussion around the counselling of non-diabetic patients who are taking an SGLT2i. It was suggested that there was no harm in counselling all patients (including non-diabetics) for ketoacidosis, Fournier gangrene and on sick day rules.	
	Outcome: Approved	
	A / NHSE Circulars for Ratification / Implementation	
15.	NICE TA Ratification and Horizon Scanning	
	A summary sheet was presented to the group which had been added to MS Teams to gather patient numbers, establish individual Trust costs and overall total cost within NEL for the following NICE TAs:	
	Relugolix-estradiol-norethisterone acetate (TA832) - Barts Health have 174 patients and 50 patients within Homerton.	
	Cost pressure of £209,000	
	Fostamatinib (TA835) – live from 13.01.23 with 5 patients receiving a dose of 100mg and 5 patients receiving a dose of	
	150mg within Barts Health. ICB commissioned	
	Toomy within barts riedith. Tob commissioned	
	Outcome: Ratified for use in NEL	
16.	NICE TAs for Discussion	
	TA832 Relugolix-estradiol-norethisterone acetate (Ryeqo)	

Homerton Healthcare NHS Foundation Trust representative was welcomed to the meeting to discuss the above NICE TA which was an oral tablet being introduced to treat symptomatic fibroids; this medication was to replace ulipristal which had been withdrawn from the market due to safety concerns. The group were advised that clarity was still to be sought regarding the duration of use of the medication, requirements for a DEXA scan and the return of normal ovarian function for patients. Patient numbers were expected to be approximately 50 at Homerton. It was clarified that Ryeqo would not be considered as an alternative to LHRH agonist injections as a pre-surgical treatment.

The group agreed to approve use of this drug in line with the NICE TA and added to formulary with an Amber status. It was agreed that initiation would be undertaken in secondary care and then continued within primary care. A pathway/robust protocol was requested to include reference to when prescribing would be transferred to primary care, adverse effects/ stopping medication and the requirement for bone scan and frequency. It was also requested that a review in one year should take place to evaluate use and patient numbers.

Post meeting Chairs discussion:

It was agreed that in the interim, Ryeqo would be approved as a 'hospital only' medication. The formulary status would be updated to Amber (transfer of care) once the relevant treatment pathway and transfer of care information have been agreed across NEL.

Outcome: Approved

Formulary status: Hospital only - status to be reviewed to Amber (Transfer of care) once transfer of care information agreed with specialist teams.

17. NHSE Circulars

The following NHSE circulars were noted:

- 1. SSC2425 NICE TA –Teduglutide for treating short bowel syndrome (TA804).
- 2. SSC2441 NHSE Clinical Commissioning Policy: Fostemsavir for Multi-Drug Resistant HIV-1 infection (Adults).
- 3. SSC2460 NHSE Clinical Commissioning Policy: Glucarpidase for the urgent treatment of Methotrexate-induced Renal Dysfunction (Update).
- 4. SSC2461 Providers selected: Cystinosis diagnosis and management service (all ages).
- 5. SSC2463 Clinical Commissioning Policy: Catheter ablation for paroxysmal and persistent atrial fibrillation (adults).
- 6. SSC2464 NICE TA Guidance Avacopan for treating severe active granulomatosis with polyangiitis or microscopic polyangiitis (TA825).

- 7. SSC2467 Palivizumab passive immunisation against Respiratory Syncytial Virus (RSV) in at-risk infants (2022/23 Season) December 2022 update.
- 8. Guideline for reimbursement costs for patients on home dialysis summary
- 9. Letter re utilities reimbursement framework Nov 2022
- 10. Interim Clinical Commissioning Policy: Baricitinib for patients hospitalised due to Covid-19 (adults and children aged 2 years and over).
- 11. Interim Clinical Commissioning Policy: IL-6 inhibitors (tocilizumab or sarilumab) for hospitalised patients with Covid-19 (adults).
- 12. Interim Clinical Commissioning Policy: Remdesivir for patients hospitalised due to Covid-19.
- 13. SSC2459 National Orbis Drug Access Arrangements Darolutamide for the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with Docetaxel.
- 14. SSC2458 NICE TA FAD: Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma.
- 15. SSC2465 NICE TA FDG: Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic breast cancer after 1 or more anti-HER2 treatments.
- 16. SSC2466 NICE TA FDG: Regorafenib for previously treated metastatic colorectal cancer.

Outcome: Ratified for use in NEL

Standing Items

18. Commissioning update

The following update was provided:

- On 23 December 2022 NHS England published a suite of guidance documents for consultation relating to the 2023/24 planning cycle, this included 2023/24 Priorities and Operational Planning guidance, Draft NHS Standard Contract 2023/24 and consultation and the draft NHS Payment Scheme Consultation 2023/25 (Parts A, B and C) alongside a number of annexes and other supporting documents
- A 2-year period for the payment system had been proposed to provide more certainty and would support local planning and reduce the administrative burden. However, prices of the drugs would still be reviewed and updated annually. Drugs that were excluded from tariff, high cost drugs were listed in Annex DpA the NHS Payment Scheme prices workbook, 2023-24. The list of HCDs indicated whether funding for the drug would be included in the Aligned Payment and Incentive (API) fixed element or by the variable element with local prices agreed by the commissioner and provider on a cost and volume basis which was a change from the block value used during COVID-19

	 ICB commissioned drugs - only 3 drugs that were part of the fixed element (eltrombopag, romiplostim and tolvaptan). All other drugs would be via cost and volume. New drugs list - 69 new HCDs of which about 30, including 7 HCDs for the treatment of Covid 19, would be the commissioning responsibility of the ICB Comments on the guidance – deadline Friday 27 January 2023. Feedback would be provided and included comments relating to drugs for ITP and growth hormone. Final guidance would be provided before contracts signed 	
	Noted.	
19.	London Formulary Medicines Group (LFMG) meeting update	
10.	LFMG project proposal 2022/23 – Background was provided to the previous workplan which was now coming to an end and the areas that had been covered during the last 18 months were outlined. It was highlighted that an additional pharmacist role to support the production of the formulary had been sought but unfortunately was not going to be recruited to. Various areas were listed and the group were advised that a scoring system had enabled the following priorities to be rated: 1. Formulary 2. Inhaler Formulary including Cystic Fibrosis 3. Ophthalmology/Red List and also Specific pathways The following documents were shared for information: • LFMG meeting notes and slides (Dec 2022)	-
	Pan-London interface prescribing policy and compliance aid update	
	Noted.	
20.	Work plan review – no update provided	
21.	Equality: Monitoring of usage and outcomes – nil at present Items for Ratification	
22.	FPG working documents for approval:	
	Cover sheet	
	Drug application form (from April 2023)	
	Approved subject to amendment.	
Information Items (Items 23 – 28)		
29.	AOB - None	
	Next meeting:	

Wadnesday 22 nd February at 12 30 via MS Teams - calendar invite circulated	
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