

North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Minutes of the meeting held on Tuesday 5th July 2022

Present

Nicola Allen	Acting Operations Director & Clinical Lead for	GHFT
	Community Services & OPMH Services	
Ian Campbell	Assistant Director, Pharmacy and Medicines	NUTH
	Optimisation	
Alasdair Green	Formulary Pharmacist	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Paul Fieldhouse	Clinical Director of Pharmacy	NCICFT
Alastair Green	Formulary pharmacist	NHCT
Matt Grove	Consultant Rheumatologist	NHCT
Chris Jewitt	GP prescribing lead	NENC ICB
		13T
Jane Lothian	Medical secretary Northumberland LMC	N LMC
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers (acting	Clinical Director of Primary Care	NENC ICB
chair)	·	00L
Mark Thomas	Chief Pharmacist	GHFT
Susan Turner	Pharmacist	NECS

Apologies

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David Campbell	Chief Pharmacist/Clinical Director for Medicines	NHCT
	Optimisation	
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Alan McCubbin	Chair, Newcastle and North Tyneside LMC	NNT LMC
Jane Welsh	Clinical Lead for Community Services	GHFT

Member organisations

Member organisations	
GHFT	Gateshead Health NHS Foundation Trust
NENC ICB 13T	Newcastle Gateshead
NENC ICB 99C	North Tyneside
NENC ICB 01H	North Cumbria
NCICFT	North Cumbria Integrated Care Foundation Trust
NENC ICB 00L	Northumberland
NoT LPC	North of Tyne Local Pharmaceutical Committee
NNT LMC	Newcastle and North Tynesdie LMC
N LMC	Northumberland LMC
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
CNTWT	Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre
ST&G LPC	South Tyneside and Gateshead LPC

2022/32	Declarations of interest
	None
2022/33	Appeals against previous decisions
	None
2022/34	Minutes and decision summary from previous meeting.
	The following documents were accepted as a true record:
	 Decision summary from 5/4/22.
	Minutes from 5/4/22.
2022/35	Matters arising not on the agenda or Action Log.
	2022/29: Clarification to block contract arrangements. Funding allocations
	across the ICB have been set and access to NICE approved TA medications
	are expected from within that those allocations.
2022/36	Action Log
	The action log was reviewed and will be updated to reflect the following:
	 2021/39 Opthalmology products review. Action outstanding
	 2021/56 Inclisiran. Action complete. Remove from action log
	 2021/57 SGLT2 top tips diabetes network guidance. Approved through
	NTAG. Remove from action log and signpost to NTAG from APC
	website.
	 2022/07 National procurement for DOACs. NTAG guidance on agenda
	for endorsement. Remove from action log.
	2022/24 Hydroxychloroquine shared care guidance. Agenda item.
	Remove from action log.

2022/37

Report from the Formulary Sub-committee

The formulary website is available at North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary.

Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 19/5/22:

The above minutes and recommendations were received by the committee.

The summary of recommendations made in relation to new product requests is listed in the decision summary.

The following specific points were highlighted for further consideration:

Eloine® (20 mcg ethinylestradiol and 3 mg drospirenone)

This is a combined oral contraceptive (COC) similar to Yasmin® but with a lower ethinylestradiol dose and with a 4-day pill free window. It has been requested on the grounds of evidence for improvement in premenstrual syndrome/premenstrual dysphoric disorder and acne. The FSRH reviewed Eloine® and concluded it is of comparable contraceptive effectiveness to other COCs.

Decision: Deferred

The Formulary Subcommittee have asked for clarification of the positioning of Eloine® compared to Yasmin® and whether there is a need for both agents on the Formulary.

Inhaler choices for children

Further to the recent review of the inhaler section of the formulary it has become apparent that there is a limited choice of inhalers suitable for use in children. The following additions have been recommended by the paediatric specialists, in consultation with the respiratory review group, and are now approved:

ICS

- Clenil® MDI will remain 1st line choice
- fluticasone MDI (Flixotide Evohaler®) will be added to the Formulary.

ICS/LABA

• Combisal® MDI, which is available in the same three strengths and indications as Seretide Evohaler® pMDI, provides significant potential cost savings for the NHS and will be added to the formulary.

HRT

The FSC had received several additional request for HRT products, all of which were endorsed. This was partly to expand patient choice but also to widen clinician choice, particularly during this current period of supply constraints.

2022/38

Report from the Medicines Guidelines and Use Group

Draft minutes from meeting held on 6/6/22 were received and noted.

- Guidelines approved:
 - Vit B12 approved by chair's action. It was acknowledged that differing labs have different reference ranges and these have all been included.

- Menopause guidelines approved.
- O Hydroxychloroquine SCG approved subject to addition of contact details and reference to the local prioritisation for retinal screening whilst capacity is expanded. MG emphasised that specialists are responsible for referral for retinal screening but that primary care can refer back in to the disease specialist teams anyone they come across who appears to have been lost to follow up. The section on drug interactions has also been updated.
- Lithium SCG update approved. JL pointed out that patients often do not remain under specialist care when on lithium and the guideline is therefore not applicable to many patients.
- IMDs document request to extend to the end of Sept 22 agreed as we await RMOC shared care guidance
- Guideline not approved:
 - Northumbria HF guidance. The committee noted the variance from NICE and the lack of consensus across all cardiology teams in the APC area.
- Guideline deferred by MGUG:
 - Prescribing intervals deferred whilst further work is done to balance the competing challenges of improving the use of repeat dispensing with a request to consider wider acknowledgement of the potential time savings for GPs and patients in extending the duration of prescription.

2022/39 Regional palliative care guidelines

The committee endorsed the use of these regional guidelines across our area and will signpost to them from the APC website.

2022/40 Report from opiate/pain management sub-group

GS gave a summary of how the local group has been successful in engaging with colleagues across our NHS organisations as well as managing to get representation from Northumberland local authority and engagement with MSK services. The local group's focus has expanded from opioid/gabapentinoid use to the management of long term pain. Work is also being picked up by the AHSN, under the national patient safety collaborative, and GS and HS are linking in with colleagues across the ICS footprint to explore what can be achieved at scale to support local work.

2022/41 NENC ICS

The committee received:

- APC briefing for comment and response to ICS interim lead pharmacist.
- NENC MO Subcommittee (NTAG) Interim TOR May 2022 draft v2
- Formulary merging proposal

APC s have been asked to endorse:

- NTAG changing its terms of reference to become the ICS medicines committee and
- Working with colleagues from the other 2 APCs in the ICS to merge the 3 existing APC formularies into one ICS wide formulary.

The committee was generally supportive of the proposed direction of travel, and were supportive of a larger role for clinical networks, but did have some concerns, as outlined below:

 The suggestion that APCs remain to consider products not considered by NTAG. That does not create the efficiencies and consistency being sought by the ICS. APCs in their current form should become redundant

- in time but it is possible we would benefit from retaining 3 "implementation" subgroups (on historical APC footprint) for the purposes of assuring local implementation, engagement and audit.
- Members agreed we, and our subgroups and subcommittees, would continue to meet in our current format until such time as it becomes apparent this is not necessary. In the interim, clarity is needed on the governance structure around existing APCs. CCGs no longer exist and therefore cannot approve their recommendations and guidelines. The committee feel that APC minutes, guidelines and decisions should be submitted to NTAG, as the ICB MO committee, for approval.
- Membership and quoracy of NTAG should be defined more clearly to ensure there is wider clinical leadership, recognised by a more diverse professional membership, as well as finance, commissioning, local authority and public health representation.
- Further clarity is needed around the delegated authority that the committee has in terms of the financial impact of its decisions, particularly in terms of how that will sit with "sub ICB localities" if prescribing budgets are further devolved to them.
- There is a real concern that we will lose local clinical engagement and subsequent impact on ownership of decisions. The inclusion or otherwise of medicines in the formulary, and in particular their RAG status, impacts significantly on local pathways/guidelines and therefore consensus may be challenging.
- It will take a considerable amount of time/resource to merge formularies.
 Where is that resource (in particular manpower) coming from in the short term?
- Timeliness of future decision making.

It was agreed that DC and GS would formally respond to Ewan Maule, in his role as interim ICS lead pharmacist and chair of NTAG, outlining the above.

2022/42 RMOC

There were no new RMOC recommendations received whilst the restructure continues but the committee were informed that the RMOC national shared care guidelines are with the national publications approval team and are expected to be issued imminently.

2022/43 Northern (NHS) Treatment Advisory Group (N-TAG)

The following updates from the NTAG meeting of were received and noted. Approvals will be reflected in the formulary.

- June 2022 NTAG Workplan
- NTAG Annual Report 2021/22
- NTAG Biosimilars Statement new
- Budesonide orodispersible for maintenance treatment of eosinophilic oesophagitis – new
- iPORT advance updated to also include a limited cohort of type 2 diabetes patients
- Flash Glucose Monitoring updated to reflect latest NICE guidance on glucose monitoring. The document has been sent to the NENC Value Based Commissioning Group to consider updating the regional VBC policy and overall CGM policy
- NICE type 2 diabetes guidance NTAG supported regional adoption

subject to financial sign off from ICS. Ewan Maule has taken a paper to the ICS finance team.

- Dapagliflozin in CKD Top Tips new
- SGLT2 in Heart failure Top Tips new
- SGLT2 in Type 2 Diabetes updated version approved. Replaces versions previously approved individually by APCs
- DOAC for AF decision aid endorsed by the Cardiac Network

It was agreed that links to NTAG guidance will be added to the APC website for guidance that the APC would previously have produced. Once the ICS MO structures are fully formed this will be reconsidered.

2022/44 NICE Technology Appraisals

The formulary will be amended to reflect the following NICE recommendations:

HST18 Atidarsagene autotemcel for treating metachromatic leukodystrophy	R
HST19 Elosulfase alfa for treating mucopolysaccharidosis type 4A	Ē
HST20 Selumetinib for treating symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 and over	5
TA780 Nivolumab with ipilimumab for untreated advanced renal cell carcinoma	Ē
TA781 Sotorasib for previously treated KRAS G12C mutation- positive advanced non-small-cell lung cancer	Ē
TA782 Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm	n/
TA783 <u>Daratumumab monotherapy for treating relapsed and refractory multiple myeloma</u>	Ē
TA784 Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer	Ē
TA785 Nivolumab with cabozantinib for untreated advanced renal cell carcinoma	n/
TA786 Tucatinib with trastuzumab and capecitabine for treating HER2-positive advanced breast cancer after 2 or more anti-HER2 therapies	Ē
TA787 Venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable	Ē
TA788 Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy	F
TA789 Tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations	Ē
TA790 TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices	n/
TA791 Romosozumab for treating severe osteoporosis	Ī.
TA792 Filgotinib for treating moderately to severely active ulcerative colitis	F

TA793 Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus	n/a
TA794 <u>Diroximel fumarate for treating relapsing</u> —remitting multiple sclerosis	R
TA795 Ibrutinib for treating Waldenstrom's macroglobulinaemia	n/a
TA796 Venetoclax for treating chronic lymphocytic leukaemia	R
TA798 <u>Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation</u>	R
TA799 Faricimab for treating diabetic macular oedema	R
TA800 <u>Faricimab for treating wet age-related macular</u> <u>degeneration</u>	R
TA801 Pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer	R
TA802 Cemiplimab for treating advanced cutaneous squamous cell carcinoma	R
TA804 Teduglutide for treating short bowel syndrome	R

2022/45 NHS England

The following NHS England communications were noted and will be reflected in the formulary:

SSC2352 NICE Technology Appraisal Final Appraisal Determination: daratumumab monotherapy for treating relapsed and refractory multiple myeloma

SSC2355 National procurement for antiretrovirals for HIV treatment and prevention (pre-exposure prevention (PrEP) and post-exposure prevention (PEP))

SSC2356 NICE Technology Appraisal Final Appraisal Determination: venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable

SSC2358 NICE Technology Appraisal: cabotegravir with rilpivirine for treating HIV-1.

SSC2360 NICE Technology Appraisal Final Appraisal Determination: Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy

SSC2361 NICE Technology Appraisal Final Appraisal Determination: tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations.

SSC2362 Early Access to Medicines Scheme – Lutetium (177Lu) vipivotide tetraxetan for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC).

SSC2364 Early Access to Medicines Scheme – Risankizumab for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease

	SSC2371 NICE Technology Appraisal Final Appraisal Determination: ibrutinib for treating Waldenstrom's macroglobulinaemia (CDF review
	TA491).
	SSC2372 NICE Technology Appraisal Final Appraisal Determination:
	venetoclax for treating chronic lymphocytic leukaemia.
	SSC2373 is regarding National Orbis Drug Access Arrangements –
	mobocertinib for treating EGFR Exon 20 insertion-positive advanced non-
	small-cell lung cancer after platinum-based chemotherapy.
	SSC2375 NICE Technology Appraisal Final Appraisal Determination:
	durvalumab for maintenance treatment of unresectable non-small-cell lung
	cancer after platinum-based chemoradiation.
	SSC2379 NICE Technology Appraisal Final Appraisal Determination:
	cemiplimab for treating advanced cutaneous squamous cell carcinoma
	SSC2380 NICE Technology Appraisal Final Appraisal Determination:
	pembrolizumab plus chemotherapy for untreated, triple-negative, locally
	recurrent unresectable or metastatic breast cancer.
2022/46	Chair's action
	Approval of Vit B 12 guidance
2022/47	Any other business
	The committee agreed that minutes and decision summary should be
	submitted to EM for approval through the ICB MO committee.
	Date and time of next meeting(s)
	Tuesday 11 th October 2022 v TEAMS



North of Tyne, Gateshead and North Cumbria **Area Prescribing Committee**

Summary of decisions made regarding new product requests considered at a meeting of the Committee on Tuesday 5th July 2022.

Classification of products:

R = 'RED' drugs for hospital use only

A = 'AMBER' drugs suitable for use under Shared Care arrangements
G+ = 'GREEN PLUS – Drugs normally recommended or initiated by hospital specialist, but where the provision of an information leaflet may be appropriate to facilitate continuing treatment by GPs. Many of these information sheets are in the process of development.

G = 'GREEN' – Drugs where initiation by GPs is appropriate.

1) Requests deferred Product	Approved	Refused	Deferred	Notes		
None	Approved	Refuseu	Deletted	Hotes		
2) New Requests						
Product	Approved	Refused	Deferred	Notes		
Clofazimine 50 mg and 100 mg capsules	R			Clofazimine has been requested for the treatment of non-tuberculous mycobacterial (NTM) infections, on the advice of microbiology and Infectious Diseases (ID) physicians. It was noted that the evidence base for clofazimine in NTM infections is weak but was also recognised that NTM infections are very challenging to treat, and that clofazimine is relatively inexpensive. Decision: Approved Clofazimine will be added to the formulary, as a red drug, for use on the		
Eloine® (20 mcg ethinylestradiol and 3 mg drospirenone)			G	advice of microbiology or ID physicians. This is a combined oral contraceptive (COC) similar to Yasmin® but with a lower ethinylestradiol dose and with a 4-day pill free window. It has been requested on the grounds of evidence for improvement in premenstrual syndrome/premenstrual dysphoric disorder and acne. The FSRH reviewed Eloine® and concluded it is of comparable contraceptive effectiveness to other COCs. Decision: Deferred The Formulary Subcommittee have asked for clarification of the positioning of Eloine® compared to Yasmin® and whether there is a need for both agents on the Formulary.		

	4	I	1	T
Cangrelor 50mg vials	✓			Cangrelor has been requested for
(Kengrexal®)				bridging therapy in patients who have
	R			recently had a coronary stent but require
				urgent elective surgery. To avoid major
				bleeding oral antiplatelet agents need to
				be stopped 5-7 days before surgery,
				increasing the risk of stent thrombosis.
				Cangrelor is a short acting antiplatelet
				agent, administered by IV infusion,
				started once the oral antiplatelet agent is
				stopped and continued until a short
				period before the procedure. The
				American College of Cardiology (ACC) suggest that cangrelor is used as the
				first-line agent for perioperative bridging
				while the evidence base for bridging is
				still developing.
				Still developing.
				Decision: Approved
				Cangrelor will be added to the formulary,
				as a Red drug
Otigo® ear drops	✓			Otigo® ear drops (Phenazone 40mg/g
(Phenazone 40mg/g				with lidocaine 10mg/g) will be added to
with lidocaine 10mg/g)	G			the formulary, in line with NICE, to
				support antimicrobial stewardship.
3) New formulations	& extension	s to use		
Product	Approved	Refused	Deferred	Notes
Estradiol 1.53mg/spray	_			Suggested as an alternative to patches
transdermal spray	·			and gels for patients who have issues
transdermal spray (Lenzetto®)	e e			with absorption, find patch adhesive
	G			with absorption, find patch adhesive irritating or the gel messy. Offers
	G			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low
	G			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena®
	G			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low
	G			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved
(Lenzetto®) Estradiol 0.75mg/1.25g	G			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which
(Lenzetto [®])				with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved
(Lenzetto®) Estradiol 0.75mg/1.25g	✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®)				with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram	✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram	✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet.
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets (Vagirux®)	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable Decision: Approved
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets (Vagirux®)	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable Decision: Approved Natural progesterone requested both for
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets (Vagirux®) Micronised progesterone 100 mg	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable Decision: Approved Natural progesterone requested both for its licenced indication and off label use in
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets (Vagirux®)	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable Decision: Approved Natural progesterone requested both for its licenced indication and off label use in conditions such as perimenopause,
(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets (Vagirux®) Micronised progesterone 100 mg	✓G✓			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable Decision: Approved Natural progesterone requested both for its licenced indication and off label use in conditions such as perimenopause, premature ovarian insufficiency, and
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(Lenzetto®) Estradiol 0.75mg/1.25g gel (Oestrogel®) Estradiol 10 microgram vaginal tablets (Vagirux®) Micronised progesterone 100 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \			with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® Decision: Approved Cheaper alternative to Sandrena® which is currently on the formulary Decision: Approved An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable Decision: Approved Natural progesterone requested both for its licenced indication and off label use in conditions such as perimenopause, premature ovarian insufficiency, and adolescents undergoing pubertal induction following chemotherapy. It has less progestogenic and androgenic side
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Testosterone gel (Testogel®/Testim®)	√ G+		The RAG status of testosterone for the treatment of low sexual desire in menopausal women is currently Green Plus but this is problematic in areas without a specialist menopause clinic
			Decision: The committee agreed that the status should remain as Green Plus and that specialist involvement and agreement on appropriateness and monitoring via "Advice and Guidance" was enough to allow GPs to initiate.
Modafinil	G +		Modafinil is psychostimulant for the treatment of narcolepsy. It has now been requested for treatment of idiopathic hypersomnia. Limited evidence suggests benefit in terms of increasing sleep latency and driving performance. The current status of modafinil, for narcolepsy, is Green Plus and there are no specific monitoring requirements Patients will remain under the care of the specialist sleep service but it was agreed that Green Plus was appropriate.
			Decision: Approved for idiopathic hypersomnia, as a Green Plus drug.
Rituximab	R		Requested for autoimmune hepatitis in patients who have failed or who are intolerant of therapies such as azathioprine, mycophenolate mofetil, corticosteroids and tacrolimus. Limited evidence is available to support use but use via IFR in a limited number of patients locally has been successful in terms of normalising LFTs and reducing the use of other immunosuppressants.
			Decision: Approved for the treatment of autoimmune hepatitis, as a Red drug.
Capsaicin 0.025% cream	G		Request submitted to change the current formulary status from Green Plus to Green in line with NICE osteoarthritis guidance.
			Decision: Approved
Dacepton® apomorphine (10mg/ml and 5mg/ml)	A		A similar product to APO-go®, with a longer in-use expiry in the syringe driver/pump therefore leading to savings.
			Decision: Approved
4) NHS England Spec	ialised Servi	ces communication	s noted and endorsed by APC
SSC2352 NICE Technology daratumumab monotherapy multiple myeloma	for treating rela	psed and refractory	position
SSC2355 National procurer and prevention (pre-exposure prevention (PEP))			The formulary will reflect the SSC position

SSC2356 NICE Technology Appraisal Final Appraisal Determination: venetoclax with low dose cytarabine for untreated acute myeloid	The formulary will reflect t position	he SSC
leukaemia when intensive chemotherapy is unsuitable SSC2358 NICE Technology Appraisal: cabotegravir with rilpivirine for treating HIV-1.	The formulary will reflect t	he SSC
SSC2360 NICE Technology Appraisal Final Appraisal Determination: Avelumab for maintenance treatment of locally advanced or	The formulary will reflect t position	he SSC
metastatic urothelial cancer after platinum-based chemotherapy SSC2361 NICE Technology Appraisal Final Appraisal Determination:	The formulary will reflect t	he SSC
tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations.	position	
SSC2362 Early Access to Medicines Scheme – Lutetium (177Lu) vipivotide tetraxetan for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC).	The formulary will reflect t position	he SSC
SSC2364 Early Access to Medicines Scheme – Risankizumab for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease	The formulary will reflect t position	
SSC2371 NICE Technology Appraisal Final Appraisal Determination: ibrutinib for treating Waldenstrom's macroglobulinaemia (CDF review TA491).	The formulary will reflect t position	
SSC2372 NICE Technology Appraisal Final Appraisal Determination: venetoclax for treating chronic lymphocytic leukaemia.	The formulary will reflect t position	
SSC2373 is regarding National Orbis Drug Access Arrangements – mobocertinib for treating EGFR Exon 20 insertion-positive advanced non-small-cell lung cancer after platinum-based chemotherapy.	The formulary will reflect t position	he SSC
SSC2375 NICE Technology Appraisal Final Appraisal Determination: durvalumab for maintenance treatment of unresectable non-small- cell lung cancer after platinum-based chemoradiation. The formulary will reflect the SS position		he SSC
SSC2379 NICE Technology Appraisal Final Appraisal Determination: cemiplimab for treating advanced cutaneous squamous cell carcinoma	The formulary will reflect t position	he SSC
SSC2380 NICE Technology Appraisal Final Appraisal Determination: pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer.	The formulary will reflect t position	he SSC
5) Products considered by NICE		
NICE reference	Formulary position	RAG status
HST18 Atidarsagene autotemcel for treating metachromatic leukodystrophy	The formulary will reflect the NICE position	R
HST19 Elosulfase alfa for treating mucopolysaccharidosis type 4A	The formulary will reflect the NICE position	R
HST20 Selumetinib for treating symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 and over	The formulary will reflect the NICE position	R
TA780 Nivolumab with ipilimumab for untreated advanced renal cell carcinoma	The formulary will reflect the NICE position	R
TA781 Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer	The formulary will reflect the NICE position	R
TA782 Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm	Terminated appraisal	n/a
TA783 <u>Daratumumab monotherapy for treating relapsed and refractory multiple myeloma</u>	The formulary will reflect the NICE position	R
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The formulary will reflect

The formulary will reflect

the NICE position

the NICE position

terminated appraisal

R

n/a

R

cell carcinoma

therapies

TA784 Niraparib for maintenance treatment of relapsed, platinum-

TA785 Nivolumab with cabozantinib for untreated advanced renal

HER2-positive advanced breast cancer after 2 or more anti-HER2

TA786 Tucatinib with trastuzumab and capecitabine for treating

sensitive ovarian, fallopian tube and peritoneal cancer

TA787 Venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable	The formulary will reflect the NICE position	R
TA788 Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy	The formulary will reflect the NICE position	R
TA789 <u>Tepotinib for treating advanced non-small-cell lung cancer</u> <u>with MET gene alterations</u>	The formulary will reflect the NICE position	R
TA790 TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices	Terminated appraisal	n/a
TA791 Romosozumab for treating severe osteoporosis	The formulary will reflect the NICE position	R
TA792 Filgotinib for treating moderately to severely active ulcerative colitis	The formulary will reflect the NICE position	R
TA793 Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus	Terminated appraisal	n/a
TA794 <u>Diroximel fumarate for treating relapsing</u> —remitting multiple <u>sclerosis</u>	The formulary will reflect the NICE position	R
TA795 Ibrutinib for treating Waldenstrom's macroglobulinaemia	Negative appraisal	n/a
TA796 Venetoclax for treating chronic lymphocytic leukaemia	The formulary will reflect the NICE position	R
TA798 <u>Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation</u>	The formulary will reflect the NICE position	R
TA799 Faricimab for treating diabetic macular oedema	The formulary will reflect the NICE position	R
TA800 Faricimab for treating wet age-related macular degeneration	The formulary will reflect the NICE position	R
TA801 Pembrolizumab plus chemotherapy for untreated, triplenegative, locally recurrent unresectable or metastatic breast cancer	The formulary will reflect the NICE position	R
TA802 Cemiplimab for treating advanced cutaneous squamous cell carcinoma	The formulary will reflect the NICE position	R
TA804 Teduglutide for treating short bowel syndrome	The formulary will reflect the NICE position	R

6) Northern (NHS) Treatment Advisory Group (N-TAG) <u>NTAG – Northern Treatment Advisory Group</u>

The following recommendations will be adopted across the APC area and the formulary will reflect the N – TAG position:

- NTAG Biosimilars Statement new
- Budesonide orodispersible for maintenance treatment of eosinophilic oesophagitis new
- iPORT advance update
- Flash Glucose Monitoring update
- NICE type 2 diabetes guidance
- Dapagliflozin in CKD Top Tips new
- SGLT2 in Heart failure Top Tips new
- SGLT2 in Type 2 Diabetes update. Replaces version previously approved individually by APC
- DOAC for AF decision aid

7) Regional Medicines Optimisation Committee (RMOC)

No updates

8) Appeals against earlier decisions by the APC

Product	Approved	Refused	Deferred	Notes
None				

9) Guidelines approved. http://www.northoftyneapc.nhs.uk/guidance/

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Vit B12	Approved
Menopause guidelines	Approved

Hydroxychloroquine SCG	Approved
Lithium SCG	Update approved
IMDs	Expiry date extended to ed Sept

10) Miscellaneous decisions by the APC			
Potassium permanganate	There has been a recent NPSA safety alert regarding inadvertent oral ingestion of potassium permanganate. There are several actions, many of which will be getting dealt with via the medication safety officer network. Decision: The Formulary will be updated to include the link to the NPSA safety alert along with the following specific statements: Not to use issue potassium permanganate on repeat prescription. Tablets will not be recommended for use		
Neovaginal atresia following vaginoplasty – vaginal lubricants	Request from a gender dysphoria services to allow inclusion of lubricant preparations to help prevent neovaginal atresia following vaginoplasty. Work will be progressed with the specialist services in order to clarify the protocol for use of these products and that will then be included in the gender dysphoria guidance.		
GPs with Extended Roles (GPwER)	The formulary currently refers to hospital specialists in the context of Green Plus drugs. To support GPwER's recommending these treatments it was agreed to change the statement to just say "specialists".		
Inhaler choices for children	Further to the recent review of the inhaler section of the Formulary it has become apparent that there is a limited choice of inhalers suitable for use in children. The following additions are now approved: ICS		
	 Clenil[®] MDI will remain 1st line choice fluticasone MDI (Flixotide Evohaler[®]) will be added to the Formulary. 		
	 Combisal® MDI, which is available in the same three strengths and indications as Seretide Evohaler® pMDI, provides significant potential cost savings for the NHS and will be added to the formulary. 		
Pregabalin use in pregnancy	The link to the MHRA alert will be added to the formulary entry. It was agreed that links to NPSA/MHRA alerts will be added to the formulary on a case-by-case basis and that a statement will be added to formulary to say that the formulary should not be considered the definitive resource for these alerts.		