North of Tyne, Gateshead and North Cumbria
Area Prescribing Committee

Minutes of the meeting held on Tuesday 19th October 2021

Present:

Pat Bottrill	Lay Representative	
David Campbell (Chair)	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Ian Campbell	Assistant Director, Pharmacy and Medicines Optimisation	NUTH
Sarah Chandler	Lead Clinical Pharmacist – Business Services, Procurement and Informatics	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson	Chief Pharmacist/Controlled Drugs Accountable Officer	CNTW
Paul Fieldhouse	Clinical Director of Pharmacy	NCICFT
Neil Gammack	Chief Pharmacist	GHFT
Alastair Green	Formulary Pharmacist	NHCT
Matt Grove	Consultant Rheumatologist	NHCT
Naeem Iqbal	GP Prescribing Lead	NT CCG
Steve Llewellyn	Medicines Optimisation Pharmacist	NGCCG
Jane Lothian	Medical secretary Northumberland LMC	N LMC
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Alan McCubbin	Chair, Newcastle and North Tyneside LMC	NNT LMC
Geraint Morris	Chief Officer North of Tyne LPC	NoT LPC
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Clinical Director of Primary Care	N CCG
Susan Turner	Pharmacist	NECS

Apologies

Jane Welsh	Clinical Lead for Community Services	GHFT

Member organisations

GHFT	Gateshead Health NHS Foundation Trust
NG CCG	Newcastle Gateshead CCG
NT CCG	North Tyneside CCG
NC CCG	North Cumbria CCG
NCICFT	North Cumbria Integrated Care Foundation Trust
NCCG	Northumberland CCG
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

2021/49	DC welcomed representatives of the local LMCs to the committee. He also informed the committee that Simon Thomas has notified him of his intention to retire on 31st March 2022, so won't be involved in the APC or formulary committee after that date. DC wished to note formally what a huge contribution Simon has made to the safe and cost-effective use of medicines across our area (and beyond) over the years and thanked him, in his absence, for the expertise and leadership he has brought to our local decision-making processes. The committee wish him a long and happy retirement.
2021/50	**Declarations of interest** A McC declared his role as chair of Newcastle and North Tyneside local medical committee and his role as a GP in North Tyneside.
2021/51	**Appeals against previous decisions** None
2021/52	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 6/7/21. • Minutes from 6/7/21.
2021/53	**Matters arising not on the agenda or Action Log.** None
2021/54	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2019/53 Progesterone 25mg SC/IM Injection (Lubion®). The APC agreed in 2019 that Lubion® would be added to the formulary for luteal support in patients who've had a previous failed biochemical pregnancy in a FET cycle. This approval was subject to reporting back of outcomes to the formulary subcommittee after 40 patients. The requisite numbers of patients have now been treated and the FSC have received a report from the applicant. The use has been approved on an ongoing basis. Remove from action log. • 2019/53 Follitropin delta (Rekovelle®) injection. The addition of Rekovelle® to the formulary was approved in October 2019 for the purposes of a 100-patient evaluation only. The fertility service had paused seeing patients during COVID and as of June 2021 only 40 patients have been treated so far. Deadline extended. • 2021/39 Opthalmology products review. Deadline extended to March 2022. • 2021/45 Bempedoic acid. NEELI guidance has been updated to include Bempedoic acid and this is referenced in the formulary entry. Remove from action log.
2021/55	**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 9/9/21:** 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: **Plenvu®** Plenvu® is a lower volume (2 litres) alternative to Moviprep® (4 litres) for

	bowel cleansing prior to colonoscopy. The available evidence suggests Plenvu® is non-inferior to Moviprep® in terms of successful bowel cleansing. Plenvu® is intended to be used as a second line option, as it is still slightly more expensive than Moviprep®, which makes a difference given the large quantities of the product that are used. Clinicians locally have reported that efficacy in cleansing seems comparable in use to Moviprep®, not better. Plenvu® will therefore be reserved for patients where large volumes of fluid load are a clinical problem. **Decision:** Plenvu® is approved as a second line option for bowel cleansing prior to colonoscopy. **Insulin aspart (Fiasp®) and Insulin Lispro (Lyumjev®)** Insulin aspart (Fiasp®) is an ultra-fast, short acting insulin that can be injected close to mealtimes which increases flexibility for the patients. It is non-inferior to insulin aspart (NovoRapid®) in terms of change in HbA1 from baseline. It is available in 100units/ml pre-filled pen, cartridge and vials. The application was supported by diabetes specialists across the APC footprint. Insulin Lispro (Lyumjev®) is another ultra-fast, short acting insulin that can be injected close to mealtimes, increasing flexibility for patients. It is non-inferior to insulin lispro (Humalog®) in terms of change in HbA1 from baseline. Specialists at NHCFT and NUTH have questioned the need for both Lyumjev® and Fiasp® on formulary. Insulin Lispro (Lyumjev®) is available in 2 different strengths (100 units/ml and 200 units/ml) with one presentation being named "KwikPen Junior" despite not being licensed for children. The formulary subcommittee have recommended that insulin lispro (Lyumjev®) is not added to formulary on the grounds that the application wasn't supported as widely as the Fiasp® application, there were some minor safety concerns around the risk from the higher strength formulation and there was a potential risk of inadvertent prescribing in children due to the naming of one presentation including the term "junior". **Decision:** Insulin aspart (Fiasp®) was approved for addition to the formulary as a GREEN drug. The application for Insulin Lispro (Lyumjev®) was refused. **Olanzapine Long-Acting Injection (Zypadhera®)** Olanzapine Long-Acting Injection (Zypadhera®) has been requested for the treatment of schizophrenia in adults within secure psychiatric services. In patients with schizophrenia, olanzapine long-acting injection is non-inferior to oral olanzapine in terms of preventing exacerbations. The risk of post injection syndrome requires that patients are monitored for 3 hours after injection. CNTW plan to set a specific clinic for the post injection monitoring. Decision: Olanzapine Long-Acting Injection (Zypadhera®) was approved for use in secure psychiatric services only, as a RED drug.
2021/56	**Incliseran** On 1st September 2021, NICE published a positive final appraisal document (FAD) for Inclisiran, which recommended it as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet in adults, providing certain criteria are met. On 22nd September a letter received from NHSE&I confirmed that a

	commercial deal has been agreed between Novartis and NHS England to provide inclisiran at a discounted price (undisclosed), making it available for administration in primary care. The agreement commits to enable inclisiran access, via a population health management approach identifying eligible patients across England, allowing approximately 300,000 people to receive it over the next three years. NHSE&I have requested a number of actions including an urgent request to convene APC meetings to approve use of inclisiran in line with the NICE FAD, making routine funding of inclisiran available within 30-days of the publication of the FAD, and permitting primary care prescribing. Due to the exceptionally rapid turnaround time, the APC agreed, via email, to allow DC to take chair`s action approving inclisiran as a green drug, and it has therefore already been added to the formulary. The APC has published an additional position statement, available on the website, outlining that it will need to work with clinicians on the patient pathway to include inclisiran alongside: • high intensity statins (HISTs) • ezetimibe for use as an adjunct when statin monotherapy is ineffective, or as monotherapy for those patients that are intolerant to statins (NICE TA385) • PCSK9 inhibitors (alirocumab, evolocumab) for use either alone or in combination with statins or ezetimibe (NICE TA393, 394) • Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia as an adjunct to diet in adults (NICE TA694) Consideration will also need to be given to the service delivery model, including issues such as mechanisms for dispensing, education & training, storage etc. MGUG is tasked with working with local clinicians, following the updated NEELI and AAC documentation, on the above pathway and supporting documentation. There is work needed in primary care to ensure that patients have been worked through the appropriate steps on intensification and intolerance pathways before prescribing is initiated. Clinician education will also be required.

2021/57	**Report from the Medicines Guidelines and Use Group**
	Draft minutes from meeting held on 6/9/21 were received and noted.
	The committee also received and noted a document outlining how MGUG would ensure that the RMOC shared care processes would integrate with local guidance.
	
	• Guidelines approved:
	  o Methylphenidate SCG – secondary to brain injury
	  o Continence product formulary
	  o Catheter formulary
	
	The APC has also been asked to host on their website an SGLT-2 in diabetes top tips document that had been prepared and approved regionally by the diabetes clinical network. The committee agreed but will ask MGUG to hold a review date, of March 2023, for this. If an update, or assurance that the document is still valid, is not received by then we will remove it from the website.
	
	Due to the pending RMOC guidelines MGUG have decided to extend the review date of the IMD guidelines to March 22.

2021/57	**Letter from NENC LMCs to APC chairs** DC shared with the committee a letter he had received from the NENC LMCs in relation to concerns they had about recently approved gender dysphoria guidance. The view from the APC was that the complaints need to be directed to NHSE, as the commissioner of the service, rather than the APCs and that the guidelines themselves are actually very helpful in providing additional information for GPs who are currently expected to take on part of the patients' care. It is acknowledged that the guidelines do not address concerns relating to commissioning of the service. Ewan Maule, the ICS interim lead pharmacist, has asked Jonathan Slade for confirmation that he has responded to the LMCs on behalf of NHSE, as the commissioners of gender dysphoria services. The new ICS medical director Neil Halford is also aware of this letter. A McC and JL outlined that the LMC desire would be for formal shared care guidance to be put in place by NHSE. They also highlighted that there are other services where GPs have similar concerns around the responsibilities they are being given for delivery of elements of care in circumstances where they feel it is more appropriate to be specialist led. As the largest ICS in the country they feel there is potential for the NENC to take some positive action in terms of commissioning arrangements.
2021/58	**Report from opiate/pain management sub-group** GS informed the committee that the pain management subgroup had looked at some additional data relating to the way we measure primary care opioid prescribing data. A lot of the national measures of opioid prescribing are based on the BNF sub-chapter 'Opioid analgesics' and the report used at this APC pain management group mirrors that. Rather counter-intuitively, this chapter doesn't include combination opioids like co-codamol, co-dydramol, co-proxamol etc. as they appear in a different BNF sub-chapter ('Non-opioid combination products'). Including them only adds a relatively moderate amount to each of our CCG/practice prescribing rates as we have had a long-standing policy to prescribe separate paracetamol and codeine rather than combination products. Nationally most CCGs use much more co-codamol, and much less single ingredient codeine, than us. Including combination products therefore increases the national figure to a greater extent and narrows the gap between our local CCGs vs the national figure. Despite this, we still have a significantly higher than average rate of prescribing for chronic pain. The APC policy of not prescribing combination products is still supported but the subgroup has asked that codeine 15mg is given first line formulary status. Currently there is low use of 15mg codeine phosphate tablets suggesting that the default prescribing position in the region is for 30mg codeine phosphate tablets. The APC agreed that the proposal to switch to codeine 15mg as first line should be approved. Whilst the APC subgroup will continue to focus on the prescribing aspects of high consumption it is important to remember the population health aspects of this. GS and EM have a meeting scheduled with key members of the evolving ICS to escalate the concerns around the non-medical influences on chronic pain in our region.
2021/59	**RMOC** Following publication of the "RMOC Shared Care for Medicines Guidance – a Standard Approach", the fourth and fifth sets of draft shared care protocols developed by the RMOC Shared Care Working Group have been published. Members have been encouraged to respond. The medicines included in these

	consultations were: • Azathioprine (non-transplant) • Hydroxychloroquine • Mycophenolate mofetil (non-transplant) • Oral ciclosporin (non-transplant) • Oral and subcutaneous methotrexate (excluding cancer) • Sulfasalazine The documents are intended to represent the minimum information required to support safe, effective sharing of prescribing of the specified drugs, and have been drafted in line with the agreed RMOC process using key sources such as the BNF, relevant Summaries of Product Characteristics, MHRA safety warnings, national guidance and specialist input. The committee was asked by RMOC North to consider draft guidance on managing requests from private providers for shared care. This was received positively but members were asked to respond to the consultation by 21/10/21 if they felt there was any further amendment needed.
2021/60	**DHSC publication: Good for you, good for us, good for everybody.** DC outlined that this national publication has the potential to define the direction of travel for medicines optimisation for the next 10 years. Local input and strong leadership are needed to deliver the aims and recommendations in the report.
2021/61	**Northern (NHS) Treatment Advisory Group (N-TAG)** http://ntag.nhs.uk/ The following recommendations were updated/approved by NTAG at their meeting on the 7th September 2021 and will be available on their website: • Lurasidone (Latuda®) for the treatment of schizophrenia in adults and adolescents aged 13 years and over – updated recommendation recommending use as an option as per criteria specified in recommendation, and also including use in adolescents. The APC agreed that lurasidone will have green plus formulary status. • Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer – updated recommendation that once daily oral 5mg tadalafil may be considered as an option for the management of erectile dysfunction following treatment for prostate cancer. Oral 2.5mg tadalafil is not recommended by NTAG for this indication on the basis of cost. • Buprenorphine prolonged release injection for opioid dependence – new recommendation that these products offer an alternative option for the management of opioid dependence after oral methadone and/or oral buprenorphine. The formulary subcommittee will approve the specific product to be used locally following discussion with appropriate clinicians. The formulary will reflect these recommendations.
2021/62	**NICE Technology Appraisals** The formulary will be amended to reflect the following: • HST15 Onasemnogene abeparvovec for treating spinal muscular atrophy • TA712 Enzalutamide for treating hormone-sensitive metastatic prostate cancer • TA713 Nivolumab for advanced non-squamous non-small-cell lung cancer after chemotherapy

	• TA714 Dasatinib for treating Philadelphia-chromosome-positive acute lymphoblastic leukaemia: terminated appraisal • TA715 Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed • TA716 Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency • TA717 Duvelisib for treating relapsed follicular lymphoma after 2 or more systemic therapies: terminated appraisal • TA718 Ixekizumab for treating axial spondyloarthritis • TA719 Secukinumab for treating non-radiographic axial spondyloarthritis • TA720 Chlormethine gel for treating mycosis fungoides-type cutaneous T-cell lymphoma • TA721 Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer • TA722 Pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement • TA723 Bimekizumab for treating moderate to severe plaque psoriasis • TA724 Nivolumab with ipilimumab and chemotherapy for untreated metastatic non-small-cell lung cancer Negative appraisal • TA725 Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy • TA726 Daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) • TA727 Isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) • TA728 Midostaurin for treating advanced systemic mastocytosis • TA729 Sapropterin for treating hyperphenylalaninaemia in phenylketonuria • TA730 Avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours (terminated appraisal) • TA731 Vericiguat for treating chronic heart failure with reduced ejection fraction (terminated appraisal) • TA732 Baloxavir marboxil for treating acute uncomplicated influenza (terminated appraisal) • TA733 Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia • TA734 Secukinumab for treating moderate to severe plaque psoriasis in children and young people
2021/63	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC2269: Rituximab for Immunobullous Disease (Ocular Amendment) • SSC2270: Abatacept for treatment of severe treatment-resistant morphoea (localised scleroderma) (adults and children 2 years and over) • SSC2272: Early Access to Medicines Scheme – tepotinib as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial

	transition (MET) exon 14 skipping alterations. • SSC2273: Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people aged 2 years and over. • SSC2274: Baricitinib for use in monogenic interferonopathies (adults and children 2 years and over • SSC2278: pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement • SSC2279 - Specialised Commissioning Update August 2021 to October 2021 • SSC2280 - NICE Technology Appraisal Final Appraisal Determination: abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy • SSC2282 - NICE Technology Appraisal Final Appraisal Determination - Midostaurin for treating advanced systemic mastocytosis • SSC2284 - Early Access to Medicines Scheme – nivolumab as monotherapy for the treatment of advanced or recurrent gastric or gastro-oesophageal junction cancer. • SSC2287 - NICE Technology Appraisal Final Appraisal Determination: apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer • SSC2288 - NICE Technology Appraisal Final Appraisal Determination: apalutamide with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer. • SSC2289 - NICE Technology Appraisal Final Appraisal Determination: nivolumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy. • SSC2290 - NICE Technology Appraisal Final Appraisal Determination: pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer. • SSC2291- NICE Technology Appraisal Consultation Document: Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies
2021/64	**Chair's action** • Approval of abnormal LFT guidance – chair's approval taken in 2020 but omitted from minutes. Included here for completeness. • Approval of RAG status change of fidaxomicin from RED to GREEN PLUS to allow use in line with new NICE recommendations. • Incliseran approval as Green
2021/65	**Any other business** None
	Date and time of next meeting(s) Tuesday 11/1/22 12.30-2.30 Microsoft teams Click here to join the meeting

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 19 th October 2021.**

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 from previous meetings				
Product	**Approved**	**Refused**	**Deferred**	**Notes**
None				
2) New Requests				
Product	**Approved**	**Refused**	**Deferred**	**Notes**
Cefazolin 1g & 2g Vials for injection	✓ R			Cefazolin has been requested as an alternative to flucloxacillin in patients with non-immediate penicillin allergy or in those who can't tolerate flucloxacillin or the alternatives. It is a first-generation cephalosporin with good activity against staphylococcus. Low quality evidence from fairly large cohort studies suggest cefazolin is of similar efficacy to flucloxacillin with no safety concerns. **Decision:** cefazolin will be added to the formulary as a RED drug. To be used on the advice of microbiology and ID physicians only.

Plenvu®	✓ R			Plenvu® is a lower volume (2 litres) alternative to Moviprep® (4 litres) for bowel cleansing prior to colonoscopy. The available evidence suggests Plenvu® is non-inferior to Moviprep® in terms of successful bowel cleansing. Plenvu® is intended to be used as a second line option as it is still slightly more expensive than Moviprep®, which makes a difference given the large quantities of the product that are used. Clinicians locally have reported that efficacy in cleansing seems comparable in use to Moviprep®, not better. Plenvu® will therefore be reserved for patients where large volumes of fluid load are a clinical problem. **Decision:** Plenvu® is approved as a second line option for bowel cleansing prior to colonoscopy.
Acarizax® oral lyophilisate	✓ R			Acarizax has been requested as a treatment for dust mite allergy. It is a licensed alternative to Oralvac. The group noted that the evidence, particularly in relation to total combined rhinitis score, wasn't particularly persuasive but it was more persuasive in terms of reducing the risk of moderate to severe asthma exacerbation. It was recognised that a licensed product should be used in preference to an unlicensed preparation. **Decision:** Acarizax® oral lyophilizate will be added to the formulary, as a RED drug, for use by immunology only.
Insulin aspart (Fiasp®)	✓ G			Insulin aspart (Fiasp®**)** is an ultra-fast, short acting insulin that can be injected close to mealtimes which increases flexibility for the patients. It is non-inferior to insulin aspart (NovoRapid®) in terms of change in HbA1 from baseline. It is available in 100units/ml pre-filled pen, cartridge and vials. The application was supported by diabetes specialists across the APC footprint. **Decision:** Insulin aspart (Fiasp®)will be added to the formulary as a GREEN drug.

Insulin Lispro (Lyumjev®)		✓		**Insulin Lispro** (Lyumjev®) is an ultra-fast, short acting insulin that can be injected close to mealtimes which increases flexibility for the patients. It is non-inferior to insulin lispro (Humalog®) in terms of change in HbA1 from baseline. Specialists at NHCFT and NUTH questioned the need for both Lyumjev® and Fiasp® on formulary. Lyumjev® is available in 2 different strengths (100 units/ml and 200 units/ml). One presentation is called "KwikPen Junior" despite not being licensed for children. **Decision:** The application for Insulin lispro (Lyumjev®) was refused on the grounds that the application wasn't supported as widely as the Fiasp® application, there were some slight concerns around the risk from the high strength formulation and the committee felt that there was a small risk of inadvertent prescribing in children.
Incliseran	✓ G			Approved for use in line with the NICE TA

3) New formulations & extensions to use

Product	Approved	Refused	Deferred	Notes
Olanzapine pamoate monohydrate 210mg, 300mg and 405mg injection (Zypadhera®)	✓ R			**Olanzapine Long-Acting Injection (Zypadhera®)** has been requested for the treatment of schizophrenia in adults within secure psychiatric services. In patients with schizophrenia olanzapine long-acting injection is non-inferior compared to oral olanzapine in terms of preventing exacerbations. The risk of post injection syndrome requires that patients are monitored for 3 hours after injection. CNTW plan to set a specific clinic for the post injection monitoring if approved. **Decision: O**lanzapine LA injection (Zypadhera®) was approved, for use in secure psychiatric services only, as a RED drug.

Quetiapine liquid	✓ R			Quetiapine has been requested as an antipsychotic for the treatment of moderate to severe manic episodes in bipolar disorder. It is requested for short term use only to allow stabilisation in acutely unwell bipolar patients with florid symptoms. This is with regular review and transfer to oral/depot medication as appropriate. **Decision:** Quetiapine liquid was approved for use in CNTW only, as a RED drug.
Fidaxomicin	✓ G+			Updated NICE guidance for the treatment of *C.difficile* has changed the role of fidaxomicin. The committee approved a status change to GREEN plus to allow GPs to prescribe (on the recommendation of a microbiologist).

4) NHS England Specialised Services communications noted and endorsed by APC

SSC2269: Rituximab for Immunobullous Disease (Ocular Amendment)	The formulary will reflect the SSC position
SSC2270: Abatacept for treatment of severe treatment-resistant morphoea (localised scleroderma) (adults and children 2 years and over)	The formulary will reflect the SSC position
SSC2272: Early Access to Medicines Scheme – tepotinib as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.	The formulary will reflect the SSC position
SSC2273: Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people aged 2 years and over	The formulary will reflect the SSC position
SSC2274: Baricitinib for use in monogenic interferonopathies (adults and children 2 years and over	The formulary will reflect the SSC position
SSC2278: pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement	The formulary will reflect the SSC position
SSC2280 - NICE Technology Appraisal Final Appraisal Determination: abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	The formulary will reflect the SSC position
SSC2282 - NICE Technology Appraisal Final Appraisal Determination - Midostaurin for treating advanced systemic mastocytosis	The formulary will reflect the SSC position
SSC2284 - Early Access to Medicines Scheme – nivolumab as monotherapy for the treatment of advanced or recurrent gastric or gastro-oesophageal junction cancer.	The formulary will reflect the SSC position
SSC2287 - NICE Technology Appraisal Final Appraisal Determination: apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer	The formulary will reflect the SSC position
SSC2288 - NICE Technology Appraisal Final Appraisal Determination: apalutamide with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer.	The formulary will reflect the SSC position
SSC2289 - NICE Technology Appraisal Final Appraisal Determination: nivolumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy.	The formulary will reflect the SSC position
SSC2290 - NICE Technology Appraisal Final Appraisal Determination: pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer.	The formulary will reflect the SSC position

SSC2291- NICE Technology Appraisal Consultation Document: Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies	The formulary will reflect the SSC position

5) Products considered by NICE

NICE reference	Formulary position	RAG status
HST15 Onasemnogene abeparvovec for treating spinal muscular atrophy	The formulary will reflect the NICE position	R
TA712 Enzalutamide for treating hormone-sensitive metastatic prostate cancer	The formulary will reflect the NICE position	R
TA713 Nivolumab for advanced non-squamous non-small-cell lung cancer after chemotherapy	The formulary will reflect the NICE position	R
TA714 Dasatinib for treating Philadelphia-chromosome-positive acute lymphoblastic leukaemia	Terminated appraisal	
TA715 Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed	The formulary will reflect the NICE position	R
TA716 Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency	The formulary will reflect the NICE position	R
TA717 Duvelisib for treating relapsed follicular lymphoma after 2 or more systemic therapies	Terminated appraisal	
TA718 Ixekizumab for treating axial spondyloarthritis	The formulary will reflect the NICE position	R
TA719 Secukinumab for treating non-radiographic axial spondyloarthritis	The formulary will reflect the NICE position	R
TA720 Chlormethine gel for treating mycosis fungoides-type cutaneous T-cell lymphoma	The formulary will reflect the NICE position	R
TA721 Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer	The formulary will reflect the NICE position	R
TA722 Pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement	The formulary will reflect the NICE position	R
TA723 Bimekizumab for treating moderate to severe plaque psoriasis	The formulary will reflect the NICE position	R
TA724 Nivolumab with ipilimumab and chemotherapy for untreated metastatic non-small-cell lung cancer	Negative appraisal	
TA725 Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	The formulary will reflect the NICE position	R
TA726 Daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma	Terminated appraisal	
TA727 Isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma	Terminated appraisal	
TA728 Midostaurin for treating advanced systemic mastocytosis	The formulary will reflect the NICE position	R
TA729 Sapropterin for treating hyperphenylalaninaemia in phenylketonuria	The formulary will reflect the NICE position	R
TA730 Avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours	Terminated appraisal	
TA731 Vericiguat for treating chronic heart failure with reduced ejection fraction	Terminated appraisal	
TA732 Baloxavir marboxil for treating acute uncomplicated influenza	Terminated appraisal	
TA733 Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia	The formulary will reflect the NICE position	G
TA734 Secukinumab for treating moderate to severe plaque psoriasis in children and young people	The formulary will reflect the NICE position	R

6) Northern (NHS) Treatment Advisory Group (N-TAG)

Lurasidone (Latuda®) for the treatment of schizophrenia in adults and adolescents aged 13 years and over	✓ G+	Updated recommendation recommending use as an option as per criteria specified in recommendation, and also including use in adolescents. The formulary will reflect the N – TAG position. The APC agreed that lurasidone will have green plus formulary status.
Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer		Updated recommendation that once daily oral 5mg tadalafil may be considered as an option for the management of erectile dysfunction following treatment for prostate cancer. Oral 2.5mg tadalafil is not recommended by NTAG for this indication based on cost. The formulary will reflect the N – TAG position.
Buprenorphine prolonged release injection for opioid dependence		New recommendation that these products offer an alternative option for the management of opioid dependence after oral methadone and/or oral buprenorphine. The formulary subcommittee will approve the specific product to be used locally following discussion with appropriate clinicians.

7) Regional Medicines Optimisation Committee (RMOC)

No new guidance published

8) Appeals against earlier decisions by the APC

Product	Approved	Refused	Deferred	Notes
None				

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

Methylphenidate SCG	New guideline for use of methylphenidate secondary to brain injury
Continence product formulary	
Catheter formulary	
SGLT-2 in diabetes top tips document	Diabetes clinical network guidance to be hosted on APC website until March 2023, or until superseded by new evidence
IMD Guidelines	Review date extended to March 2022

10) Miscellaneous decisions by the APC

Codeine 15mg tablets	Codeine 15mg to be made first line formulary choice, with 30mg still available as a second line choice