North of Tyne and Gateshead Area Prescribing Committee
Minutes of a meeting held on Tuesday 9th January 2018 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Pat Bottrill	Lay Representative	
Ian Campbell		NUTH
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
Neil Gammack	Chief Pharmacist	GHFT
Tomal Karim		South Tyneside and Gateshead LPC
Steve Llewellyn	Medicines Optimisation Pharmacist	Newcastle Gateshead CCG
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Frank McAulay (FM)	Associate Medical Director	GHFT
Neil Morris (NM) (Acting Chair)	Medical Director	Newcastle Gateshead CCG
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Prescribing Lead	Northumberland CCG
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Susan Turner	Medicines Optimisation Pharmacist	NECS
Neil Watson	Clinical Director of Pharmacy and Medicines Optimisation	NUTH

Apologies

David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Sue White	Medicines Optimisation Pharmacist	Gateshead Public Health

GHFT	Gateshead Health NHS Foundation Trust
NoT LPC	North of Tyne Local Pharmaceutical Committee
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2018/01	**Apologies for absence** The committee was informed of the resignation of Martin Wright and Helen Coundon. DC has thanked them both for their contributions to the committee. NM also informed the committee of the death of Sarah Tulip and wished to acknowledge the contribution she has made to the committee and sub groups in recent years and to express publicly the sadness and shock felt by all her colleagues at the news of her death.
2018/02	**Declarations of interest** None.
2018/03	**Appeals against previous decisions** None.
2018/04	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 10/10/17. The decision relating to safinamide was noted as deferred in the October decision summary as, whilst the committee was minded to approve the use of safinamide in restricted groups of patients, they had asked for further information. This information was provided subsequent to the meeting and noted in the October minutes. This will be reflected in the January decision summary. • Minutes from 10/10/17.
2018/05	**Matters arising not on the agenda or Action Log.** None.
2018/06	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2016/26 Shared Care Guidelines for immunosuppressive therapy following paediatric renal transplantation. Agenda item (MGUG). Remove from action log. • 2016/56 Tafluprost 15mcg/ml (Taptiqom®) UDVs, Tafluprost/timolol 15mcg/5mg/ml (Taptiqom®) UDVs, Mydriasert® and Rituximab. Agenda Item (FSC). Remove from action log. • 2016/57 Pain Guidance. Work complete, remove from action log. • 2016/58 Osteoporosis guidelines. Agenda item (MGUG). Remove from action log. • 2017/55 Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®). Agenda Item (FSC). Remove from action log. • 2017/58 Interdependency of reference groups, decision making bodies and forums. Agenda item. Remove from action log. • 2017/55 Lidocaine patches – agenda item. Remove from action log • 2017/41 - Povidone-iodine 0.35% sterile aqueous solution - The request for povidone-iodine sterile aqueous solution was previously approved subject to an evaluation, with defined end points guided by WHO guidance, being returned to FSC 6 months following approval. Northumbria clinicians have agreed to undertake this audit but it was agreed to extend the deadline for completion of this audit to 30/6/18 due to delays in implementation.

2018/07	**Report from the Formulary Sub-committee** The formulary website is available at North of Tyne and Gateshead Area Prescribing Committee Formulary. **Minutes and recommendations from the North of Tyne & Gateshead FSC meeting held on 30/11/17:** 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: **Insulin Degludec (Tresiba®) – paediatrics** Insulin degludec was recently approved, at appeal, for patients with either nocturnal severe hypoglycaemia (in whom an insulin pump may otherwise be considered) or those with recurrent DKA secondary to insulin omission. An extension to use for insulin degludec has been received for children and young people with type 1 diabetes to improve compliance by offering a once daily alternative for patients unable to tolerate the sting of glargine and also to offer greater flexibility for children and teenagers patients requiring supervised administration. The FSC noted that the SPC states "there is no clinical experience with flexibility in dosing time of Tresiba® in children and adolescents". Concerns were raised regarding the implications of children prescribed insulin degludec for the indications requested as they transition into adulthood services given the restricted list of adult indications. **Decision: Deferred** The committee agreed the application could potentially be supported but would need a more precise description of the clinical characteristics of the patients who would be offered degludec and how numbers would be controlled to those stated in the application. The process for transitioning into adulthood also needs clarified. **Mydriasert pellets** The use of Mydriasert pellets, pre-operatively, was previously approved subject to a 6 month evaluation being submitted back to the FSC. This evaluation has shown that, whilst the pellets are efficacious, there are some concerns regarding use. The evaluation made no mention of the anticipated cost savings made with nursing time and actually reported that nurses often reverted back to using the drops particularly when busy. The report concluded that use should be restricted, and only considered for the following patients: • With pre-existing ophthalmic conditions that result in a small pupil as seen at pre-operative assessment. • With pre-existing systemic conditions that result in a potential floppy iris during surgery • Undergoing second eye surgery in which first eye demonstrated poor dilation with standard drops or required intra operative additional phenylephrine or pupil stretching device. **Decision: Refused** The committee was concerned that use on such a restricted basis may result in nursing staff not maintaining competence and was not persuaded that the evaluation showed any substantial advantage of this product over standard drops. The pellet formulation will be removed from the formulary.

Glaucoma preparations (Tafluprost UDV) review

In September 2016 the Subcommittee agreed to retain Tafluprost UDV on the formulary alongside Monopost (preservative free latanoprost) subject to a review of usage data after 1 year, after which time a decision would be made as to which preparation should remain. Prescribing data (ePact) from the last 12 months shows very low usage of both Monopost and Tafluprost preservative free preparations in relation to overall prescribing and it was agreed both could remain on formulary.

Decision: Approved
Given the low usage of these preparations, the committee agreed that Tafluprost/Taptiqom and Monopost could be retained on formulary.

Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®).

At the October 2017 meeting Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®) was considered as a 3rd line option for the treatment of erectile dysfunction. Its anticipated place in therapy would be as an alternative to intracaversonal alprostadil in patients who have failed PDE5 inhibitors and the request was approved subject to further clarification of the treatment sequence.

Clarification of the ED treatment sequence was received as follows:

- 1st line – phosphodiesterase inhibitors (if no contraindications) – sildenafil (avanafil or tadalafil if no response to sildenafil)
- 1st line – topical alprostadil (Vitaros) as an alternative to PDE5i
- 2nd line – penile vacuum device (patient preference)
  AND/OR
- 2nd line – Intracavernosal injections (patient preference).Try Invicorp (avaptidil/phentolamine) first, if no success then try Caverject (alprostadil)
- 3rd line – refractory ED – consider penile implant

Decision: Approved
The request for aviptadil/phentolamine (Invicorp®) was approved in line with the above treatment sequence.

Rituximab approvals

A review of the old North of Tyne APC approvals for rituximab compared with NICE and NHS England approvals was undertaken to see if any of the recommendations had been superseded. There are 3 previous approvals, approved in 2006, that are not currently covered by NICE /NHSE:

- Autoimmune haemolytic anaemia (AIHA): warm antibody Autoimmune Haemolytic anaemia, cold agglutinin syndrome (CDS) / cold Haemagglutinin disease (CHAD), Evans syndrome
- Pure red cell aplasia (PRCA)
- Thrombotic thrombocytopenia purpura (TTP).

It was suggested that these indications are still recommended by the Haematology Regional Network.

Confirmation that these indications remain in line with Network guidelines will allow these treatments to remain approved from a clinical governance point of view. A policy development request being made for these indications to NHS

	England should be considered. ML informed the committee that he is awaiting details in relation to the garments formulary, at which point he will seek chairs approval.
2018/08	**Report from the Medicines Guidelines and Use Group** Minutes from the meeting on 4/12/17 were accepted. The following points were noted: **Clinical Guidelines for approval:** • Northern England Strategic Clinical Networks Guidelines for the Management of Adults with Asymptomatic Liver Function Abnormalities – update approved. • Guideline for the management of osteoporosis in primary care and review of patients taking bisphosphonates for 5 years– update approved. • North of Tyne and Gateshead Guideline for Blood Glucose Monitoring – minor update approved. **Shared Care Guideline(s) for approval:** • Immunosuppressive treatment for paediatric nephrotic syndrome – update approved. • Immunosuppressive Treatment following Paediatric renal transplantation – update approved. • Erythropoietin (Darbepoetin [Aranesp]) in the Treatment of Patients with Chronic Kidney Disease (CKD) – update approved. This guidance relates to monitoring rather than prescribing. CCG members stated that CCGs may need to engage with practices further in terms of implementation. **Information leaflets for approval:** • Acetylcholinesterase inhibitors: information for primary care – update approved. • Memantine: information for primary care – update approved. **Guideline(s)and information sheets for removal:** • None
2018/09	**Regional structures** The committee had previously acknowledged the increasing complexity of various reference groups, decision making bodies and forums across the region, all with a potential impact on prescribing, and had agreed to map out the current situation with a view to facilitating increased consistency of approach. The following relationships with the APC were discussed: • **RMOC & APC** – RMOC recommendations go to NTAG and the APC then accept NTAG recommendations. RMOCs will generally focus on systems rather than new drugs/technologies. • **AHSN, LA s and Strategic Clinical Networks** – there can be pieces of work undertaken by these groups where there is a potential for overlap, duplication or contradiction with APC guidance. It was agreed that DC would write to these organisations encouraging closer working and outlining that where medicines are to be used, or incorporated into guidance, the APC would expect to be involved. • **CCG prescribing Forum** – GS explained that this is a medicines optimisation forum with a focus on implementation of best practice

	across the region in a consistent manner. DC has accepted an invitation to attend the February meeting of the North East and Cumbria Prescribing Forum. It was agreed that any guidance produced should go through all Local Decision Making committees in the region to ensure consistency and to facilitate engagement/implementation. • **NESPM** – there is little overlap in the role of this group with the APC.
2018/10	**Draft NE&C Regional Guidelines for Diagnosing and Managing CMPA and Lactose Intolerance** The committee have received a letter from Dr. Punit Shah, Consultant Paediatrician with an interest in Allergy, University Hospital North Durham inviting comments on a draft standard regional guideline for the management of Non-IgE mediated Cow's Milk Allergy. Members are asked to pass any additional comments to ST by 19/1/18 so she can collate responses and forward these to the regional group.
2018/11	**Regional commissioning policy regarding the treatment of Age-related Wet Macular Degeneration** NM wished to inform the committee that CCGs believe the regional policy circulated in October is lawful, but recognised that this will be tested by the ongoing legal process. Implementation of the policy was intended to deliver significant savings across the healthcare economy and if these are not delivered by implementation of this policy other difficult decisions will need to be taken. NW reiterated the previously minuted trust position. He challenged the statement 5.2.in the supplementary document that chief executives and clinical leaders in the four main providers of this treatment in the North East (Newcastle Upon Tyne Hospitals, City Hospitals Sunderland, County Durham & Darlington Hospitals, and South Tees Hospitals) support a policy of offering Avastin as a first-line treatment option based upon the informed consent of patients, and robust clinical indemnity for their clinicians in the case of any legal challenge. He stated that this was not, and never had been, the position of NUTH and asked that the authors were contacted to remove this statement before any further distribution. He recognised the available evidence base around safety and efficacy, and the opportunities available from the implementation of the policy, but stated that the provision of indemnity for knowingly committing an "unlawful act" is untenable and therefore cannot progress until that position is legally clarified. He stated that the current advice from the Health Secretary is clear. If legal assurance around the policy is achieved the trust will be fully supportive of work to implement it and would work with commissioners to produce robust and clear patient information leaflets around the choices open to them.
2018/12	**Items which should not be routinely prescribed in primary care: Guidance for CCGs** https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/ The above consultation has now concluded. This guidance is addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources, to address unwarranted variation, and to provide clear national advice to make local prescribing practices more effective. The recommendations will be reflected in the formulary and work progressed to ensure prescribers reflect this in their prescribing practice.
2018/13	**Previously circulated** Correspondence relating to a request from North Cumbria to join the APC had been circulated to members. The committee is supportive of this move but

	emphasised that there was an expectation that workload would be shared across all member organisations.
2018/14	**RMOC** National RMOC guidance is generally issued before regional minutes are collated and approved and it is the guidance that has the potential to impact the formulary or supersede previous local guidance. It was therefore agreed that the APC do not need to formally note RMOC minutes. The RMOC position statement with regards to FreeStyle Libre® Glucose Monitoring System was noted. This has been translated into NTAG guidance (2018/15).
2018/15	**Northern (NHS) Treatment Advisory Group (N-TAG)** The approved minutes from September 2017 were received by the committee. The following recommendation was finalised by NTAG at their meeting on the21 /11/17and are now available on the website http://ntag.nhs.uk/html/latest_news.html : • NTAG position statement FreeStyle Libre® Glucose Monitoring System – approved by APC chairs action An associated CCG commissioning policy to aid implementation of use in line with this position statement was also noted.
2018/16	**NICE Technology Appraisals** The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary: • TA480 Tofacitinib for moderate to severe rheumatoid arthritis • TA481 Immunosuppressive therapy for kidney transplant in adults • TA482 Immunosuppressive therapy for kidney transplant in children and young people • TA483 Nivolumab for previously treated squamous non-small-cell lung cancer • TA484 Nivolumab for previously treated non-squamous non-small-cell lung cancer • TA485 Sarilumab for moderate to severe rheumatoid arthritis • TA486 Aflibercept for treating choroidal neovascularization • TA487 Venetoclax for treating chronic lymphocytic leukaemia • TA488 Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours • TA489 Vismodegib for treating basal cell carcinoma • TA490 Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy • TA491 Ibrutinib for treating Waldenstrom's macroglobulinaemia • TA492 Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable • TA493 Cladribine tablets for treating relapsing–remitting multiple sclerosis • TA494 Naltrexone–bupropion for managing overweight and obesity – negative appraisal
2018/17	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC1793NICE Technology Appraisal Final Appraisal Determination:

	Ibrutinib for treating Waldenstrom's macroglobulinaemia • SSC1794 Tariff excluded drugs SNOMED terms FINAL • SSC1795 - NICE Technology Appraisal Final Appraisal Determination: venetoclax for the treatment of chronic lymphocytic leukaemia UPDATE • SSC1796 - NICE Technology Appraisal 479: Reslizumab for treating eosinophilic asthma • SSC1797 - Abiraterone for hormone-sensitive metastatic prostate cancer • SSC1798 - NICE Technology Appraisal Final Appraisal Determination: Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours • SSC1799 - NICE Technology Appraisal Final Appraisal Determination: Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy • SSC1800 - NICE Technology Appraisal 458: Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane • SSC1801 - NICE Technology Appraisal 457: Carfilzomib for previously treated multiple myeloma • SSC1802 - Revised guidance and principles on switching immunoglobulin (IG) products for existing patients on long-term treatments • Patient information letter • SSC1803 - NICE Technology Appraisal 476: Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer • SSC1804 - Improving value: Guidance on the timing of a repeat dose of intravenous immunoglobulin in the treatment of immune thrombocytopenic purpura • SSC1805 - NICE Technology Appraisal Final Appraisal Determination: Atezolizumab for the treatment of locally advanced or metastatic urothelial cancer in patients who are ineligible for cisplatin-based chemotherapy • SSC1808 - SPIRIT 2 Trial in chronic myeloid leukaemia. Transition of patients on dasatinib trial supply to NHS commercial supply • SSC1809 - NICE Technology Appraisal 463: Cabozantinib for previously treated advanced renal cell carcinoma • SSC1810 - NICE TA FAD: Palbociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer • SSC1811 - NICE TA FAD: Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer • SSC1812 - NHS England Individual Funding Request Policy and Standard Operating Procedures • SSC1813 - NICE Technology Appraisal 474: Sorafenib for treating advanced hepatocellular carcinoma • SSC1814 - Urgent clinical commissioning policy statement – cerliponase alfa for neuronal ceroid lipofuscinosis Type 2 (CLN2) in children • SSC1815 - NICE Technology Appraisal Final Guidance: Vismodegib for treating basal cell carcinoma • SSC1816 - NICE Technology Appraisal Final Appraisal Determination:

	Lenvatinib with everolimus for previously treated advanced renal cell carcinoma • SSC1817 - NICE Technology Appraisal Final Appraisal Determination: ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer
2018/18	**Chair's action** • Update to Diabetes stepped approach approved in October. • Freestyle Libre – approval of NTAG position.
2018/19	**Any other business** Regional AF card - Julie Fletcher, AHSN NENC Medicines Optimisation Programme Manager, has asked for comments on the draft update to the Thromboprophylaxis Anticoagulant Treatment card decks produced by the AHSN. The cards have been reviewed since the first version taking on board a lot of the comments received from the survey earlier this year. Members should forward comments to ST by 19/1/18. These will then be collated and returned.
	Date and time of next meeting(s) Tuesday 10th April 1.00pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.
	Signed: **Date:** 12 April 2018 Neil Morris (Acting Chair of the APC)

North of Tyne & Gateshead Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 8th January 2018.**

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.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Safinamide	✓ G+			At the appeal in October 2017 the committee was minded to approve the use of safinamide in restricted groups of patients but asked for further information that clearly defined •the criteria by which initiation would be defined and •the criteria by which an objective assessment of improvement, which included cessation criteria, would be measured This information was provided subsequent to the meeting and deemed satisfactory. Approval was therefore been given. Safinamide will be used in mid-late stage PD in patients on levodopa who are having fluctuations affecting their quality of life. All patients will have had to have tried rasagiline first but if ineffective or side effects then that will be stopped and treatment changed to safinamide. If the patient does not see an improvement in their motor fluctuations, that is providing an improvement in their movements and quality of life, at their next review (which is usually 6 months) or if they are suffering adverse effects then safinamide will be stopped. **Decision: Approved**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®).	✓			**Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®).** At the October 2017 meeting Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®) was considered as a 3rd line option for the treatment of erectile dysfunction. Its anticipated place in therapy would be as an alternative to intracaversonal alprostadil in patients who have failed PDE5 inhibitors and the request was approved subject to further clarification of the treatment sequence. Clarification of the ED treatment sequence was received as follows: • 1st line – phosphodiesterase inhibitors (if no contraindications) – sildenafil (avanafil or tadalafil if no response to sildenafil) • 1st line – topical alprostadil (Vitaros) as an alternative to PDE5i • 2nd line – penile vacuum device (patient preference) AND/OR • 2nd line – Intracavernosal injections (patient preference).Try Invicorp (avaptidil/phentolamine) first, if no success then try Caverject (alprostadil) • 3rd line – refractory ED – consider penile implant **Decision: Approved** The request for aviptadil/phentolamine (Invicorp®) was approved in line with the above treatment sequence.
2) New Requests				
Ceftazidime/avibactam 2.5g injection (Zavicefta®)	✓			**Zavicefta®** is a combination of ceftazidime and a new generation beta-lactamase inhibitor. It has been requested for the treatment of infections with carbapenemase-producing organisms for which the treatment options are very limited, toxic and not particularly effective.It is non-inferior to the carbapenems in the treatment of complicated intra-abdominal infections and in complicated UTI/pyelonephritis. Efficacy is similar in patients with ceftazidime resistant organisms vs. those with ceftazidime susceptible organisms. There is limited data in patients with carbapenemase producing organisms. It appears to be well tolerated. **Decision: Approved** The committee approved the inclusion of ceftazidime/avibactam (Zavicefta) onto the formulary as a Red drug to be used on microbiology / ID advice only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Insulin degludec 100 & unit/mL (Tresiba®) penfill cartridges and pre-filled pen - paediatrics			✓	**Insulin Degludec (Tresiba®) – paediatrics** Insulin degludec was recently approved, at appeal, for patients with either nocturnal severe hypoglycaemia (in whom an insulin pump may otherwise be considered) or those with recurrent DKA secondary to insulin omission. An extension to use for insulin degludec has been received for children and young people with type 1 diabetes to improve compliance by offering a once daily alternative for patients unable to tolerate the sting of glargine and also to offer greater flexibility for children and teenagers patients requiring supervised administration. The FSC noted that the SPC states "there is no clinical experience with flexibility in dosing time of Tresiba® in children and adolescents". Concerns were raised regarding the implications of children prescribed insulin degludec for the indications requested as they transition into adulthood services given the restricted list of adult indications. **Decision: Deferred** The committee agreed the application could potentially be supported but would need a more precise description of the clinical characteristics of the patients who would be offered degludec and how numbers would be controlled to those stated in the application. The process for transitioning into adulthood also needs clarified.
3) New formulations & extensions to use				
None				

4) NHS England Specialised Services communications noted and endorsed by APC	
SSC1793 - NICE Technology Appraisal Final Appraisal Determination: Ibrutinib for treating Waldenstrom's macroglobulinaemia	The formulary will reflect the SSC
SSC1795 - NICE Technology Appraisal Final Appraisal Determination: venetoclax for the treatment of chronic lymphocytic leukaemia UPDATE	The formulary will reflect the SSC
SSC1796 - NICE Technology Appraisal 479: Reslizumab for treating eosinophilic asthma	The formulary will reflect the SSC
SSC1797 - Abiraterone for hormone-sensitive metastatic prostate cancer	The formulary will reflect the SSC
SSC1798 - NICE Technology Appraisal Final Appraisal Determination: Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours	The formulary will reflect the SSC
SSC1799 - NICE Technology Appraisal Final Appraisal Determination: Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy	The formulary will reflect the SSC
SSC1800 - NICE Technology Appraisal 458: Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane	The formulary will reflect the SSC
SSC1801 - NICE Technology Appraisal 457: Carfilzomib for previously treated multiple myeloma	The formulary will reflect the SSC
SSC1802 - Revised guidance and principles on switching immunoglobulin (IG) products for existing patients on long-term treatments	The formulary will reflect the SSC

Product	Decision: Approved	Refused	Deferred	Comments/notes
SSC1803 - NICE Technology Appraisal 476: Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer				The formulary will reflect the SSC
SSC1804 - Improving value: Guidance on the timing of a repeat dose of intravenous immunoglobulin in the treatment of immune thrombocytopenic purpura				The formulary will reflect the SSC
SSC1805 - NICE Technology Appraisal Final Appraisal Determination: Atezolizumab for the treatment of locally advanced or metastatic urothelial cancer in patients who are ineligible for cisplatin-based chemotherapy				The formulary will reflect the SSC
SSC1808 - SPIRIT 2 Trial in chronic myeloid leukaemia. Transition of patients on dasatinib trial supply to NHS commercial supply				The formulary will reflect the SSC
SSC1809 - NICE Technology Appraisal 463: Cabozantinib for previously treated advanced renal cell carcinoma				The formulary will reflect the SSC
SSC1810 - NICE TA FAD: Palbociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer				The formulary will reflect the SSC
SSC1811 - NICE TA FAD: Ribociclib in combination with an aromatase inhibitor for previously untreated advanced or metastatic hormone receptor-positive, HER2-negative breast cancer				The formulary will reflect the SSC
SSC1813 - NICE Technology Appraisal 474: Sorafenib for treating advanced hepatocellular carcinoma				The formulary will reflect the SSC
SSC1814 - Urgent clinical commissioning policy statement – cerliponase alfa for neuronal ceroid lipofuscinosis Type 2 (CLN2) in children				The formulary will reflect the SSC
SSC1815 - NICE Technology Appraisal Final Guidance: Vismodegib for treating basal cell carcinoma				The formulary will reflect the SSC
SSC1816 - NICE Technology Appraisal Final Appraisal Determination: Lenvatinib with everolimus for previously treated advanced renal cell carcinoma				The formulary will reflect the SSC
SSC1817 - NICE Technology Appraisal Final Appraisal Determination: ceritinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer				The formulary will reflect the SSC
5) Products considered by NICE				
TA480 Tofacitinib for moderate to severe rheumatoid arthritis				The formulary will reflect the NICE Guidance
TA481 Immunosuppressive therapy for kidney transplant in adults				The formulary will reflect the NICE Guidance
TA482 Immunosuppressive therapy for kidney transplant in children and young people				The formulary will reflect the NICE Guidance
TA483 Nivolumab for previously treated squamous non-small-cell lung cancer				The formulary will reflect the NICE Guidance
TA485 Sarilumab for moderate to severe rheumatoid arthritis				The formulary will reflect the NICE Guidance
TA486 Aflibercept for treating choroidal neovascularization				The formulary will reflect the NICE Guidance
TA487 Venetoclax for treating chronic lymphocytic leukaemia				The formulary will reflect the NICE Guidance

Product	Decision Approved | Refused | Deferred	Comments/notes
TA488 Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours		The formulary will reflect the NICE Guidance
TA489 Vismodegib for treating basal cell carcinoma		The formulary will reflect the NICE Guidance
TA490 Nivolumab for treating squamous cell carcinoma of the head and neck after platinum-based chemotherapy		The formulary will reflect the NICE Guidance
TA491 Ibrutinib for treating Waldenstrom's macroglobulinaemia		The formulary will reflect the NICE Guidance
TA492 Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable		The formulary will reflect the NICE Guidance
TA493 Cladribine tablets for treating relapsing–remitting multiple sclerosis		The formulary will reflect the NICE Guidance
TA494 Naltrexone–bupropion for managing overweight and obesity – negative appraisal		The formulary will reflect the NICE Guidance
6) Northern (NHS) Treatment Advisory Group (N-TAG)		
FreeStyle Libre® Glucose Monitoring	✓ R	The formulary will reflect the NTAG position statement and the CCG commissioning policy
7) Appeals against earlier decisions by the APC		
None		
8) Miscellaneous decisions by the APC		
Mydriasert pellets	The use of Mydriasert pellets, pre-operatively, was previously approved subject to a 6 month evaluation being submitted back to the FSC. This evaluation has shown that, whilst the pellets are efficacious, there are some concerns regarding use. The evaluation made no mention of the anticipated cost savings made with nursing time and actually reported that nurses often reverted back to using the drops particularly when busy. The report concluded that use should be restricted, and only considered for the following patients: • With pre-existing ophthalmic conditions that result in a small pupil as seen at pre-operative assessment. • With pre-existing systemic conditions that result in a potential floppy iris during surgery • Undergoing second eye surgery in which first eye demonstrated poor dilation with standard drops or required intra operative additional phenylephrine or pupil stretching device. The committee was concerned that use on such a restricted basis may result in nursing staff not maintaining competence and was not persuaded that the evaluation showed any substantial advantage of this product over standard drops. The pellet formulation will be removed from the formulary.	
Glaucoma preparations (Tafluprost UDV) review	In September 2016 the Subcommittee agreed to retain Tafluprost UDV on the formulary alongside Monopost (preservative free latanoprost) subject to a review of usage data after 1 year, after which time a decision would be made as to which preparation should remain. Prescribing data (ePact) from the last 12 months shows very low usage of both Monopost and Tafluprost preservative free preparations in relation to overall prescribing and it was agreed both could remain on formulary.	

Product	Decision Approved | Refused | Deferred	Comments/notes
Rituximab approvals		A review of the old North of Tyne APC approvals for rituximab compared with NICE and NHS England approvals was undertaken to see if any of the recommendations had been superseded. There are 3 previous approvals, approved in 2006, that are not currently covered by NICE /NHSE: • Autoimmune haemolytic anaemia (AIHA): warm antibody Autoimmune Haemolytic anaemia, cold agglutinin syndrome (CDS) / cold Haemagglutinin disease (CHAD), Evans syndrome • Pure red cell aplasia (PRCA) • Thrombotic thrombocytopenia purpura (TTP). It was suggested that these indications are still recommended by the Haematology Regional Network. Confirmation that these indications remain in line with Network guidelines will allow these treatments to remain approved from a clinical governance point of view. A policy development request being made for these indications to NHS England should be considered.
Items which should not be routinely prescribed in primary care: Guidance for CCGs https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/		The national consultation has now concluded. The guidance is addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources, to address unwarranted variation, and to provide clear national advice to make local prescribing practices more effective. The recommendations will be reflected in the formulary and work progressed to ensure prescribers reflect this in their prescribing practice.