

**North of Tyne and Gateshead
Area Prescribing Committee
Minutes of a meeting held on
Tuesday 11th July 2017
at Northumbria House, Cobalt Business Park, North Tyneside**

Present:

David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	Prescribing Lead	North Tyneside CCG
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
Neil Gammack	Chief Pharmacist	GHFT
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Tomal Karim		South Tyneside and Gateshead LPC
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Frank McAulay (FM)	Associate Medical Director	GHFT
Neil Morris (NM)	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 Management	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE

Apologies

Pat Bottrill	Lay Representative	
Martin Wright	Medical Director	North Tyneside CCG

In attendance

Nirmalan Arulanantham	North Cumbria University Hospitals
Andrea Loudon	North Cumbria CCG
Bill Glendinning	North Cumbria University Hospitals

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

2017/35	DC welcomed Cumbria representatives who were joining the meeting in an observing role to help inform their future local decision making processes. He also informed members of the resignation from the committee of Sandy Dyker. DC had written to Dr Dyker to thank him for his valuable contribution to the committee and subcommittees over the years.
2017/36	Declarations of interest No relevant declarations were made.
2017/37	Appeals against previous decisions Appeals were due to be heard in relation to safinamide and Insulin Degludec. These have now been deferred to the October meeting.
2017/38	Minutes and decision summary from previous meeting. The following documents were accepted as a true record: <ul style="list-style-type: none"> • Decision summary from 11/04/17. • Minutes from 11/04/17.
2017/39	Matters arising not on the agenda or Action Log. None.
2017/40	Action Log The action log was reviewed and will be updated to reflect completed work and the following progress: <ul style="list-style-type: none"> • 2016/26: Shared Care Guidelines for immunosuppressive therapy following paediatric renal transplantation. ML to chase. • 2016/42: Heart Failure Guidelines - chair's approval taken. Action complete. • 2016/56: Rituximab – ML updated the committee on the review of previous approvals being undertaken to ensure legacy commissioning decisions are in line with national policy statements. The outcome of the review will be presented at the September FSC. • 2016/58: Osteoporosis guidelines - A final draft has been circulated for comments but, before approving, the commissioning implications in relation to DEXA scanning capacity need explored. Reference to strontium will need to be removed from the final guideline as this is being discontinued by the manufacturer • 2016/58: Thyroid Regional Assessment and Management Plan. Guidance has previously been approved for the North of Tyne footprint. Gateshead clinicians have now agreed in principle to the joint guideline and all parties are now being brought together to clarify the patient pathways and reference ranges. Closed from an APC perspective. Chairs action can be taken to add Gateshead to the area the guideline covers once this is resolved.
2017/41	Report from the Formulary Sub-committee The new formulary website is now active and accessible at North of Tyne and Gateshead Area Prescribing Committee Formulary . Minutes and recommendations from the North of Tyne & Gateshead FSC meeting held on 25/5/17: 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:

Glycopyrronium bromide 1mg/5ml

The use of glycopyrronium bromide 1mg/5ml for drying excessive oral secretions in patients with motor neurone disease (MND) was recently approved. An extension for use in home ventilation patients has been now received. Glycopyrronium liquid is significantly more expensive than the alternatives however the committee recognised that it would be difficult to refuse its use in other patient groups with this problem. The home ventilation service is a regional service currently with 48 patients across 11 CCG areas.

Decision: Approved

The request for glycopyrronium bromide oral solution SF 1mg/5ml for home ventilation patients was approved. This will be first line in patients with cognitive impairment and second line in patients who have failed other treatment options such as hyoscine patches or who have intolerance to other agents.

Povidone-iodine 0.35% sterile aqueous solution

Povidone-iodine sterile aqueous solution has been requested for the prevention of surgical site infection in arthroplasty. The WHO suggests that this approach should be considered in clean surgery.

Decision: Approved

The request for povidone-iodine sterile aqueous solution was approved subject to an evaluation, with defined end points guided by WHO guidance, being returned to FSC in 6 months. Northumbria clinicians have agreed to undertake this audit.

Guanfacine

Guanfacine hydrochloride has been requested as a 3rd line treatment of ADHD in children and adolescents when 1st line stimulants and atomoxetine are contraindicated or ineffective. It has significant side effects such as sedation, syncope, hypotension and bradycardia. Concerns were raised regarding continued GP prescribing in patients as they transition in to adulthood.

Decision: Deferred until suitable arrangements for transitioning patients to adult services are in place and clarified within shared care guidance.

Zoledronic acid infusion

Zoledronic acid infusion has been requested for the adjuvant treatment of post-menopausal women with early breast cancer. Such use has been endorsed by a European consensus group.

Decision: The request for IV zoledronic acid for adjuvant treatment of post-menopausal women with early breast cancer was approved from a clinical governance point of view. Trusts will need to agree this increase in activity in contract discussions with commissioners before use.

Bendroflumethiazide

The committee was asked to review its choice of thiazide diuretic in treatment of hypertension. The existing North of Tyne and Gateshead APC hypertension guideline recommends that bendroflumethiazide is used as the first line thiazide. At a recent review of the local guideline it was decided that the

updated guideline should be revised in line with NICE. Indapamide is now available generically. It was noted that NICE recommendations are based on the most recently available clinical trial data, most of which relate to indapamide and chlorthalidone. Bendroflumethiazide trials are older and tended to use higher doses of bendroflumethiazide than seen in current clinical practice. Whilst the committee accept there is a class effect for both efficacy and side effects they agreed the local guidance should be in line with NICE.

Decision: the formulary will reflect NICE guidance - indapamide immediate release is the first line choice in new patients. The guideline should emphasise that stable patients on bendroflumethiazide should continue with their current treatment.

Lidocaine Patches

Lidocaine 5% plasters are licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults.

The current North of Tyne and Gateshead APC formulary position is that lidocaine 5% plasters are approved for use in the treatment of chronic neuropathic pain on the advice of pain specialists only, subject to an appropriate trial of efficacy in each individual patient.

NICE Clinical Guideline 173: Neuropathic pain – The pharmacological management of neuropathic pain in adults in non-specialist settings, does not make recommendations on topical lidocaine for localised neuropathic pain as there are very limited clinical data to support its use.

Given the

- (a) lack of evidence to support their use
- (b) high relative cost and
- (c) national moves to restrict their usage

the committee is minded to remove Lidocaine 5% plasters from the local formulary. Before making a final decision, the APC will consult with clinicians on the following options:

1. Lidocaine 5% plasters should be completely removed from the formulary.
2. Lidocaine 5% plasters should be restricted to specialist pain clinic initiation for its licensed indication of PHN only.
3. The current position of lidocaine 5% plasters on the formulary should remain unchanged, i.e. used in the treatment of chronic neuropathic pain on the advice of pain specialists only, subject to an appropriate trial of efficacy.

2017/42

Report from the Medicines Guidelines and Use Group

Minutes from the meeting on 26/6/17 were accepted.

The following points were noted:

Clinical Guidelines for approval:

- ENT – updated guidelines for the management of common ENT conditions in primary care - approved
- Menopause – approval dependent on confirmation from Gateshead clinicians that they also support this guidance – assurance has been given subsequent to the meeting.
- C.Diff – updated guidance for prescribers - approved

Shared Care Guideline(s) for approval:

- Guanfacine - Shared Care Guidance for the Management of ADHD in Children and Young People – deferred until suitable arrangements for transitioning patients to adult services are in place and clarified within

	<p>the shared care guidance.</p> <ul style="list-style-type: none"> • Shared Care Guidance for Immunosuppressive Treatment following Liver Transplantation in Adults – update – approved. <p>Information leaflets:</p> <ul style="list-style-type: none"> • High dose venlafaxine - approved • Agomelatine- updated information leaflet for primary care - approved • Modafinil – updated information leaflet for primary care – approved <p>The committee noted that the current guidance for blood glucose testing is being reviewed. It was agreed this could be progressed through MGUG & APC chairs action once finalised.</p>
2017/43	<p>RMOC</p> <p>The committee was pleased to note that it has good representation on the newly formed Northern Regional Optimisation Committee. The first topics on the agenda were</p> <ul style="list-style-type: none"> • Antimicrobial Resistance (AMR) • Biosimilars • Poly Pharmacy <p>The APC noted the draft documents from the initial meeting and await with interest the national summary recommendations.</p>
2017/44	<p>NICE Technology Appraisals</p> <p>The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary:</p> <ul style="list-style-type: none"> • TA440 Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine - negative appraisal • TA441 Daclizumab for treating relapsing–remitting multiple sclerosis • TA442 Ixekizumab for treating moderate to severe plaque psoriasis • TA443 Obeticholic acid for treating primary biliary cholangitis • TA444 Afatinib for treating advanced squamous non-small-cell lung cancer after platinum-based chemotherapy (terminated appraisal) • TA445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs <p>Noted post meeting - chairs action taken in line with NICE</p> <ul style="list-style-type: none"> • TA446 Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma • TA447 Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer • TA448 Etelcalcetide for treating secondary hyperparathyroidism • TA449 Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease • TA450 Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia • TA451 Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia
2017/45	<p>Northern (NHS) Treatment Advisory Group (N-TAG)</p> <p>The following recommendations were finalised by NTAG at their meeting on the 6th June and are now available on the website http://ntag.nhs.uk/html/latest_news.html</p> <p>The formulary will reflect the NTAG position.</p>

	<ul style="list-style-type: none"> • Draft Recommendation Qutenza® (updated) – recommended as per attached specialist pathway as a fourth line treatment option. • Draft Recommendation Sodium Oxybate (updated) –recommended only for continuation of treatment in adults if started by NHS E as a child. Not recommended for initiation in adults. • Draft Recommendation Pitolisant – not recommended • Draft Recommendation Rituximab Biosimilars – recommended where branded product would be used for new patients and switching of current patients.
2017/46	<p>NHS England</p> <p>The following NHS England communications were noted and will be reflected in the formulary:</p> <ul style="list-style-type: none"> • SSC1739 - Impact of the exclusion of trientine and chenodeoxycholic acid from tariff in 2017/18 • SSC1740 - NICE Technology Appraisal 431: Mepolizumab for treating severe refractory eosinophilic asthma • SSC1741 - NICE Technology Appraisal Final Appraisal Determination: Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia • SSC1742 - NICE Technology Appraisal Final Appraisal Determination: Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia • SSC1744 - NICE Technology Appraisal Final Appraisal Determination: Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma • SSC1746 - NICE Technology Appraisal 443: Obeticholic acid for treating primary biliary cholangitis • SSC1747 - NICE Multiple Technology Appraisal Final Appraisal Determination: Everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression • SSC1749 - NICE Technology Appraisal 432: Everolimus for advanced renal cell carcinoma after previous treatment • SSC1751 - NICE Technology Appraisal Final Appraisal Determination: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer • SSC1752 - NICE Technology Appraisal Final Appraisal Determination: Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma • SSC1753 - NICE Technology Appraisal Final Appraisal Determination: Carfilzomib for previously treated multiple myeloma • SSC1754 - NICE Technology Appraisal Final Appraisal Determination: Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma • SSC1755 - Early Access to Medicines Scheme – Cenegermin (Oxervate) in the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults • SSC1756 - NICE Technology Appraisal Final Appraisal Determination: trastuzumab emtansine for treating human epidermal growth factor receptor 2 (HER2) positive, unresectable, locally advanced or metastatic breast cancer in adults • SSC1758 - Early Access to Medicines Scheme – Idebenone

	<ul style="list-style-type: none"> • SSC1759 - NICE Technology Appraisal 439: Cetuximab and panitumumab for previously untreated metastatic colorectal cancer
<p>2017/47</p>	<p>Chair's action Approval of :</p> <ul style="list-style-type: none"> • North of Tyne and Gateshead Heart Failure Guidelines • North East and Cumbria Antimicrobial Guidelines endorsed for use in the North of Tyne and Gateshead area • 2016/17 APC Annual report
<p>2017/48</p>	<p>Any other business None</p>
<p>2017/49</p>	<p>Date and time of next meeting(s) Tuesday 10th October 12.30pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.</p>
	<p>Signed: (Chair of the APC)</p> <p>Date: 10.10.17</p>

North of Tyne & Gateshead Area Prescribing Committee



Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 11th July 2017**.




Classification of products:




R = 'RED' drugs for hospital use only



A = 'AMBER' drugs suitable for use under Shared Care arrangements

B = 'BLUE' drugs initiated in secondary care where an information sheet for GPs is recommended

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Alendronic Acid 70mg Effervescent Tablets (Binosto®)	✓ 			Alendronic acid 70mg effervescent tablets have been requested as there is no liquid formulation on the formulary. It was agreed that a formulation for patients unable to swallow tablets was necessary. Effervescent tablets are cheaper than liquid but significantly more expensive than standard tablets. Decision: The request for effervescent tablets was approved only for use in patients with documented swallowing difficulties.
Articaine 4% & adrenaline 1 in 100,000 injection (Septanest® & Espestesin®)	✓ 			Articaine & adrenaline has been requested for mandibular procedures in patients in whom nerve blocks are contraindicated. Articaine is similar to lidocaine for maxillary infiltration but is more effective for supplemental infiltration after successful block anaesthesia and for mandibular infiltration. Adverse events and costs are similar to comparators. Decision: The request for articaine & adrenaline for dental use was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
2) New Requests				
Dalbavancin 500 mg injection (Xydaiba®)	✓ 			Dalbavancin injection has been requested for use by infectious disease physicians for treating significant deep soft tissue infections such as joint, discitis and spinal infections. It is non-inferior to vancomycin and linezolid and given as a once weekly infusion, potentially leading to decreased in-patient stay. Decision: The request for dalbavancin was approved for use only on the advice of infectious disease physicians or microbiology.
Sucroferric oxyhydroxide 500 mg chewable tablets (Velphoro®)	✓ 			Sucroferric oxyhydroxide is a calcium free phosphate binder. It has been requested for haemodialysis or peritoneal dialysis patients who cannot tolerate alternative phosphate binders or where these have been ineffective. It is non-inferior to sevelamer in lowering serum phosphate but is less well tolerated, although the pill burden is lower. It was felt that this would offer a useful alternative in a small number of patients who have tried and failed other options. Decision: The request for sucroferric oxyhydroxide was approved for 3 rd line use, as a green plus drug.
Guanfacine Hydrochloride 1mg, 2mg, 3mg and 4mg prolonged release tablets (Intuniv®)			✓ 	Guanfacine hydrochloride has been requested as 3 rd line treatment of ADHD in children and adolescents when 1 st line stimulants and atomoxetine are contraindicated or ineffective. It has significant side effects such as sedation, syncope, hypotension and bradycardia. Concerns were raised regarding continued GP prescribing in patients as they transition in to adulthood. Decision: The request for guanfacine as a 3 rd line treatment for ADHD was deferred until suitable arrangements for transitioning patients to adult services are in place and clarified within shared care guidance.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Opicapone 50mg capsules (Ongentys®)	✓ 			Opicapone has been requested as an alternative to tolcapone in patients with Parkinson's disease in whom entacapone has not been tolerated or failed. Opicapone is non-inferior to entacapone and adverse events are similar to the other COMT inhibitors. Decision: The request for opicapone was approved, as a green plus drug, as a 2 nd line treatment in PD patients whom have failed or not tolerated entacapone.
3) New formulations & extensions to use				
Zoledronic acid 4mg infusion	✓ 			Zoledronic acid infusion has been requested for the adjuvant treatment of post-menopausal women with early breast cancer. While there were some concerns around the strength of evidence it was noted this had been endorsed by a European consensus group. Decision: The request for IV zoledronic acid for adjuvant treatment of post-menopausal women with early breast cancer was approved from a clinical governance point of view. CCGs will need to agree this increase in activity in contract discussions with the provider trusts before use.
Phenol 5% in Glycerol Injection; & Dehydrated alcohol 100% BP for Injection	✓ 			Dehydrated alcohol and phenol in glycerol have been requested for the treatment of intractable pain due to cancer in terminally ill patients. Case reports and local experience suggest that intrathecal neurolysis can lead to significant pain relief in some patients. However the procedure can lead to significant side effects such as motor loss. Whilst there are no comparative studies with other treatments it was felt that this is a reasonable treatment in the circumstances Decision: The request for dehydrated alcohol and phenol was approved for intrathecal neurolysis for the treatment of intractable pain due to cancer in terminally ill patients.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<p>Glycopyrronium bromide 1mg/5ml oral solution SF</p>	<p>✓</p> 			<p>Glycopyrronium bromide 1mg/5ml for drying for drying excessive oral secretions in patients with motor neurone disease (MND) was recently approved. An extension for use in home ventilation patients has been now received.</p> <p>Glycopyrronium liquid is significantly more expensive than the alternatives, however the committee recognised that it would be difficult to refuse its use in other patient groups with this problem. As the home ventilation service is a regional service the cost would be spread beyond the North of Tyne and Gateshead footprint.</p> <p>Decision: The request for glycopyrronium bromide oral solution 1mg/5ml SF for home ventilation patients was approved. This will be first line in patients with cognitive impairment and second line in patients who have failed other treatment options such as hyoscine patches or who have intolerance to other agents.</p>
<p>Povidone-iodine 0.35% sterile aqueous solution</p>	<p>✓</p> 			<p>Povidone-iodine sterile aqueous solution has been requested for the prevention of surgical site infection in arthroplasty. The WHO suggests that this approach should be considered in clean surgery. It was noted that, at NUTH, in addition to pulsed irrigation with normal saline povidone-iodine is frequently used to swab orthopaedic wounds prior to closure.</p> <p>Decision: The request for povidone-iodine sterile aqueous solution was approved subject to an evaluation being returned to FSC in 6 months.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tiotropium bromide 10 microgram inhalation powder capsules (Braltus®)		✓		<p>Tiotropium (Handihaler®) is the 4th choice LAMA on formulary (for patients unable to use the other LAMA devices). Braltus® is a branded generic version of tiotropium Handihaler® that is very similar in design and is 29% cheaper. A consultation with the inhaler review group has been conducted, with the majority of the respondents favouring adding Braltus® to formulary as the tiotropium device of choice. Braltus® could potentially be used for a large scale switching program, however unless patients receive face to face counselling these switches are not appropriate. The group discussed the various options and agreed there wasn't currently a strong argument to add Braltus® to the formulary.</p> <p>Decision: The request for Braltus® was not approved.</p>
4) NHS England Specialised Services communications noted and endorsed by APC				
SSCSSC1731 Childrens Policy - Provider Letter	See notes			The formulary will reflect the policy outlined in this circular
SSC1732 TKIs Untreated CML - Provider Letter	✓ R			The formulary will reflect the policy outlined in this circular
SSC1733 TKIs Imatinib resistant or intolerant CML - Provider Letter	✓ R			The formulary will reflect the policy outlined in this circular
SSC1734 Biosimilar Rituximab - Provider Letter	✓ R			The formulary will reflect the policy outlined in this circular
SSC1735 Ibrutinib for previously treated chronic and untreated chronic lymphocytic leukaemia - Provider Letter	✓ R			The formulary will reflect the policy outlined in this circular
SSC1736 Pomalidomide for multiple myeloma - Provider Letter	✓ R			The formulary will reflect the policy outlined in this circular
SSC1739 - Impact of the exclusion of trientine and chenodeoxycholic acid from tariff in 2017/18	✓ R			The formulary will reflect the policy outlined in this circular

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1740 - NICE Technology Appraisal 431: Mepolizumab for treating severe refractory eosinophilic asthma	✓ R			The formulary will reflect the policy outlined in this circular
SSC1741 - NICE Technology Appraisal Final Appraisal Determination: Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia	✓ R			The formulary will reflect the policy outlined in this circular
SSC1742 - NICE Technology Appraisal Final Appraisal Determination: Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia	✓ R			The formulary will reflect the policy outlined in this circular
SSC1744 - NICE Technology Appraisal Final Appraisal Determination: Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma	✓ R			Interim CDF funding
SSC1746 - NICE Technology Appraisal 443: Obeticholic acid for treating primary biliary cholangitis	✓ R			The formulary will reflect the policy outlined in this circular
SSC1747 - NICE Multiple Technology Appraisal Final Appraisal Determination: Everolimus, lutetium-177 DOTATATE and sunitinib for treating unresectable or metastatic neuroendocrine tumours with disease progression	✓ R			Interim CDF funding
SSC1749 - NICE Technology Appraisal 432: Everolimus for advanced renal cell carcinoma after previous treatment	✓ R			The formulary will reflect the policy outlined in this circular
SSC1751 - NICE Technology Appraisal Final Appraisal Determination: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer	✓ R			Interim CDF funding
SSC1752 - NICE Technology Appraisal Final Appraisal Determination: Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma	✓ R			Interim CDF funding
SSC1753 - NICE Technology Appraisal Final Appraisal Determination: Carfilzomib for previously treated multiple myeloma	✓ R			Interim CDF funding

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1754 - NICE Technology Appraisal Final Appraisal Determination: Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma	✓ R			Interim CDF funding
SSC1755 - Early Access to Medicines Scheme – Cenegermin (Oxervate) in the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults	✓ R			The formulary will reflect the policy outlined in this circular
SSC1756 - NICE Technology Appraisal Final Appraisal Determination: trastuzumab emtansine for treating human epidermal growth factor receptor 2 (HER2) positive, unresectable, locally advanced or metastatic breast cancer in adults	✓ R			Interim CDF funding
SSC1758 - Early Access to Medicines Scheme – Idebenone	✓ R			The formulary will reflect the policy outlined in this circular
SSC1759 - NICE Technology Appraisal 439: Cetuximab and panitumumab for previously untreated metastatic colorectal cancer	✓ R			The formulary will reflect the policy outlined in this circular
5) Products considered by NICE				
TA440 Pegylated liposomal irinotecan for treating pancreatic cancer after gemcitabine - negative appraisal		✓		The formulary will reflect the position outlined in the TAG
TA441 Daclizumab for treating relapsing–remitting multiple sclerosis	✓ R			The formulary will reflect the position outlined in the TAG
TA442 Ixekizumab for treating moderate to severe plaque psoriasis	✓ R			The formulary will reflect the position outlined in the TAG
TA443 Obeticholic acid for treating primary biliary cholangitis	✓ R			The formulary will reflect the position outlined in the TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA444 Afatinib for treating advanced squamous non-small-cell lung cancer after platinum-based chemotherapy (terminated appraisal)				Terminated appraisal
TA445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs	✓ R			The formulary will reflect the position outlined in the TAG
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Rituximab biosimilars	✓ R			The formulary will reflect the position outlined in the decision notification <u>Rituximab Biosimilars</u>
Sodium oxybate for narcolepsy	See notes			The formulary will reflect the position outlined in the decision notification <u>Sodium oxybate(Xyrem®) for Narcolepsy with Cataplexy in adult patients (updated)</u> The Northern (NHS) Treatment Advisory Group only recommends the use of sodium oxybate in adult patients who have received and benefited from treatment with sodium oxybate as commissioned by NHS England. i.e. continuing treatment for those >19 years old. The strict NHS England criteria for starting and stopping must continue to be followed.
Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults.		✓		The formulary will reflect the position outlined in the decision notification <u>Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults</u>
Qutenza® (capsaicin) cutaneous patch for neuropathic pain	✓ R			The formulary will reflect the position outlined in the decision notification <u>Qutenza® (capsaicin patch) for neuropathic pain (updated)</u>
7) Appeals against earlier decisions by the APC				
None				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
8) Miscellaneous decisions by the APC				
Programme of formulary chapter review	Chapter 1 formulary review. Current actions: <ul style="list-style-type: none"> • Gaviscon Advance – remove • Antimuscarinics - list according to price as no differentiation in NICE • H-Pylori – change to reflect current antimicrobial recommendations • Sucralfate – remove from formulary • Esomeprazole – remove from formulary 			
Updated hypertension guidelines	The existing North of Tyne and Gateshead APC hypertension guideline recommends that bendroflumethiazide rather than a thiazide-like diuretic, as recommended by NICE, is used. At a recent review of the local guideline it has been noted that indapamide is now available generically and therefore the updated guideline should be in line with NICE. Whilst generic indapamide is cheap in comparison to the branded alternative it is still more expensive than bendroflumethiazide. Decision: the formulary will reflect NICE guidance - indapamide immediate release is the first line choice in new patients. Stable patients on bendroflumethiazide should continue with their current treatment.			
Fentanyl patch (Matrifen®)	Matrifen® is a branded generic fentanyl patch that is considered to be bioequivalent to the originator brand (Durogesic®) but it is 40% cheaper. Noting that fentanyl patches should be prescribed by brand it was agreed that Matrifen® would be approved as the formulation of choice. Decision: Matrifen® will be included on the formulary as the first choice fentanyl patch.			
Naloxone pre-filled syringes	In 2012 The Advisory Council on the Misuse of Drugs recommended that take-home naloxone should be made more widely available. As a result of a recent contaminated heroin alert, there has been a request that A&E supply naloxone pre-filled syringes to patients that present with opioid overdose. Naloxone pre-filled syringes can be provided under a PGD in these circumstances to allow drug users, family members/carers to administer naloxone in the event of an overdose. Decision: The committee agreed that, in accordance with national guidance, naloxone pre-filled syringes should be provided to patients who present at A&E with opioid overdose.			

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Lidocaine patches				<p>Lidocaine 5% plasters are licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults.</p> <p>The current North of Tyne and Gateshead APC formulary position is that lidocaine 5% plasters are approved for use in the treatment of chronic neuropathic pain on the advice of pain specialists only, subject to an appropriate trial of efficacy in each individual patient.</p> <p>NICE Clinical Guideline 173: Neuropathic pain – The pharmacological management of neuropathic pain in adults in non-specialist settings, does not make recommendations on topical lidocaine for localised neuropathic pain as there are very limited clinical data to support its use.</p> <p>Given the (a) lack of evidence to support their use (b) high relative cost, and (c) national moves to restrict their usage, the North of Tyne and Gateshead Area Prescribing Committee is minded to remove Lidocaine 5% plasters from the local formulary.</p> <p>Before making a final decision, the APC will consult with clinicians on the following options:</p> <ol style="list-style-type: none"> 1. Lidocaine 5% plasters should be completely removed from the formulary. 2. Lidocaine 5% plasters should be restricted to specialist pain clinic initiation for its licensed indication of PHN only. 3. The current position of lidocaine 5% plasters on the formulary should remain unchanged, i.e. used in the treatment of chronic neuropathic pain on the advice of pain specialists only, subject to an appropriate trial of efficacy