

Present

Ca) Chief Pharmacist/Clinical Director for Medicines	NHCT NHCT
0	NHCT
C) GP representative from Engage Clinical Commissionir	
	RDTC
) Trust Chief Pharmacist/Associate Director of Medicine	
	NHS NoT
Executive Director Public Health	NHS NoT
Head of Prescribing (Provider)	North of Tyne PCTs
Nurse Clinical Manager	NHCT
L) Formulary and Audit Pharmacist	NUTH
GP and Prescribing Lead Northumberland CCG	NHS Northumberland CCG
Consultant Microbiologist	NHCT
) Consultant Clinical Pharmacologist	NUTH
	NHS NoT
Clinical Director of Pharmacy and Medicines Management	NUTH
SW) Consultant Pharmacist in Cancer Services	NECN
Consultant Physician/Chair of NUTH D&T panel	NUTH
Assistant Director of Pharmacy	NUTH
orth of England Cancer Network orthumbria Healthcare NHS Foundation Trust	
	 Ca) Chief Pharmacist/Clinical Director for Medicines Management C) Formulary Pharmacist C) GP representative from Engage Clinical Commissionin Group Director of Pharmacy Trust Chief Pharmacist/Associate Director of Medicine Management Associate Director of Medicines Management Executive Director Public Health Head of Prescribing (Provider) Nurse Clinical Manager IL) Formulary and Audit Pharmacist GP and Prescribing Lead Northumberland CCG Consultant Microbiologist Consultant Clinical Pharmacologist Medicines Management Advisor tary) Clinical Director of Pharmacy and Medicines Management SW) Consultant Pharmacist in Cancer Services Consultant Pharmacist in NUTH D&T panel

Committee members who had not yet returned their Annual Declarations of interest form were reminded to complete this and return directly to the Professional Secretary.

It was confirmed that declarations at regular meetings need only be declared if they relate to an agenda item at that meeting. Other declarations and memberships of organisations will be covered by the Annual Declaration.

2012/67 Appeals

Hyalofemme

An intent to appeal the decision to reject the application for the above product was received within 4 weeks of the decision but will be heard at the next meeting.

2012/68 Minutes and decision summary from the meeting held on Tuesday 10th July 2012.

These were accepted as a true record, subject to the inclusion of the attendance of Sue Gordon at that meeting.

2012/69 Matters arising not on the agenda

2012/61:Terms of Reference

Paediatric Representation – Arpita Bhattachayra, a consultant community paediatrician from Northumbria Healthcare Foundation Trust, was welcomed to the meeting. She will share membership responsibilities between the APC and Formulary Subcommittee with Mark Anderson, a consultant paediatrician from the Newcastle Upon Tyne Hospitals Foundation Trust.

Lay representation – David Campbell had been approached by John Ross, a public Governor from Northumbria Healthcare Foundation Trust, to offer his services as a lay member of the committee.

The committee accepted this offer. SC will offer him some initial support in understanding the processes and responsibilities of members.

In order to enable broad representation from lay members it was agreed that the membership term for lay members should be restricted to 1 year initially.

DC will write to other Governor Bodies of membership organisations to inform them of this decision.

DC informed the committee that whilst he had initially committed to send the draft Terms of Reference to CCGs he had decided against this as CCG members on the committee were responsible for communication within their CCG and they had been included in the circulation.

The updated terms of reference were approved, subject to the membership term for lay members being stated as 1 year.

Member attendance – RE informed the committee that two of the GP CCG committee members were unable to attend Tuesday lunchtime meetings and had suggested alternative times for meetings be considered. The committee considered this request but noted the difficulties that alternative arrangements would create for other members and a potential lack of continuity in decision making with ad hoc attendance. It was agreed that CCGs be asked to seek alternative representatives who could regularly attend on behalf of their

organisation,

DC agreed to write to CCG chairs to communicate the importance of securing appropriate representation at the APC, citing existing arrangements within Northumberland as an example for how it can be achieved without involving the designated prescribing lead for the CCG.

2012/70 Report from the Formulary Sub-committee

Minutes and recommendations from the meeting held on Tuesday 28th August 2012.

The above minutes and recommendations were received by the committee. The summary of decisions made by the committee on new product requests is listed in **Appendix 1**.

The following specific points were highlighted:

Sodium Hyaluronate 0.4% eye drops (Clinitas[®])

The Formulary Subcommittee had recommended that the request for Clinitas should be approved on the condition that Artificial Tears is removed from the Formulary. The applicant has subsequently agreed that this is appropriate.

Decision: Sodium Hyaluronate 0.4% eye drops (Clinitas®)

Approved.

Artificial Tears SDU will be removed from the Formulary.

Adapalene 0.1%, benzoyl peroxide 2.5% gel (Epiduo[®])

The Formulary Subcommittee wished to know whether alternative 2.5 and 5% benzoyl peroxide preparations were commercially still available and would not wish to recommend the inclusion in the Formulary of Epiduo if they are. Enquiries with manufacturers have now confirmed that such preparations are available.

Decision: - Adapalene 0.1%, benzoyl peroxide 2.5% gel (Epiduo[®]) Refused.

Infatrini Peptisorb[®]

A treatment algorithm for the above product is required before approval. This will be presented before the next meeting.

Decision: - Infatrini Peptisorb®	
Deferred.	

Dialysis Fluids

Future applications for the inclusion of intermittent and continuous dialysis fluids will be considered by a concensus group of appropriate expertise drawn from across the North of Tyne area. Recommendations will be brought back to the APC for final approval.

Emollient skin products

A review of the above products will be conducted, again ensuring appropriate expertise drawn from across the North of Tyne area and including primary care representation. Recommendations will be brought back to the APC for final approval.

Subject to the above, all other recommendations were endorsed by the committee and will be reflected in the North of Tyne Formulary.

The committee were advised that Formulary Version 3.9 is now available on the website.

2012/71 Report from the Shared Care Group (SCG).

Version 3.5 (July 2012) of the traffic light list is now available on the website.

There has been no meeting of the Shared Care group since the last APC meeting.

An update to the Blue information sheet for nebulised gentamicin was approved.

It was agreed that the information sheet for Dekristol (colecalciferol) would be removed from the website as the information included there has now been superceded by updated recommendations locally and nationally.

Melatonin Oral Liquid

PMcE highlighted concerns that GPs have around the increasing number of requests for primary care prescribing of melatonin for long term use in children. There is a view that this is not appropriate for primary care prescribing either long term or when in combination with other medications, including antipsychotics and methylphenidate.

TD informed the committee that he is currently undertaking some work relating to the extent of prescribing of melatonin in the area. It was agreed that the SCG group should review the position of melatonin, incorporating this information **as** part of that review and examining shared care agreements from other parts of the country.

2012/72 Report from the Anti-microbial Chemotherapy subcommittee.

The primary care guidelines, approved at the July meeting subject to minor alteration, have now been updated to reflect these comments and posted on the APC website.

The revised Terms of Reference for the group were approved. GP representation is currently lacking but the GP members of the APC agreed that they would seek appropriate input where required.

2012/73 Quality, Improvement, Productivity and Performance (QIPP)

Draft minutes from the meeting held on 5/9/12 were received. The following points were highlighted:

- **Special Order Products** expenditure on special order products continues to grow, despite work by practice staff, therefore steps have been agreed to continue work in this area.
- Behaviour change Project an update was given on work to date.
- MDS Local authorities have contracts with the care agencies for packages
 of care and it was felt it would be helpful if there was a route to influence
 the contracts with the local agencies to specify that medication prompting
 should usually be from original packs. DC suggested a lead needed to be
 identified to progress this work.

This was received and considered by the committee.

The use of dabigatran off-label in cardioversion was confirmed as an approved use in the North of Tyne area.

Actions agreed:

The RDTC would produce 2 leaflets:

1. A patient info leaflet.

This should be generic to allow prescribers from different organisations to use it and could include space for the prescriber to add in the point of contact for a patient if they had any concerns over unexplained bruising etc and what to look out for.

2. Advice for primary care prescribers.

This would primarily be based on a Cheshire and Merseyside document with acknowledgement to them. It was requested that this be supplemented with a front page showing licensed indications and outlining where approved North of Tyne use may be off-label.

It was noted that there is a primary care rebate scheme in place that makes dabigatran slightly cheaper than rivaroxaban. The committee noted this and agreed this information could be included in the information for prescribers, whilst protecting commercially sensitive information.

The RDTC will liaise with the Cardiac Network as appropriate.

2012/75 Dipeptidyl peptidase-4 (DPP-4) Inhibitors

Saxagliptin is currently the DPP-4 inhibitor on the North of Tyne formulary for use in all new patients.

The committee was asked to reconsider this position following license changes which allow sitagliptin to be used in severe renal failure.

Sitagliptin's licensed therapeutic indications would now appear to fit better both with NICE and local North of Tyne guidelines.

This proposed change has been requested by specialists across North of Tyne. They are in agreement that if just one DPP-4 inhibitor is to be included in the formulary, their choice would be sitagliptin, because of its broader (more appropriate) licensed indications, greater clinical experience and more established safety profile.

There is little cost difference.

Decision:

Sitagliptin will be the Dipeptidyl peptidase-4 (DPP-4) Inhibitor of choice on the NoT formulary.

Saxagliptin can be retained for existing patients only.

2012/76 Department of Health review of Local formulary processes

- DoH letter Gateway reference 17879 9/8/12
- DoH letter Gateway reference 17880 16/8/12
- These were discussed and the following points noted:

There is a requirement to demonstrate rapid adoption of NICE TAG recommendations into local formularies. Although the evidence behind the conclusion that rapid adoption onto formularies translates into wider use is not

robust, it was agreed that it was important to support this work so that further barriers to availability may become apparent. Current APC processes ensure adoption of NICE TAGs within 3 months. This is also now reflected in the Terms of Reference for the group. It was noted that RE had convened a meeting to review the fitness of purpose of the APC (on the request of the APC). It was agreed that a review of APC processes against (draft) NICE best practice guidance on local formularies be undertaken at the same time and be reported back to the APC for consideration.

2012/77 Documents previously circulated by email

- NETAG Decision Summary Pasireotide (Signifor®) for Cushing's disease
- NETAG Decision Summary Bevacizumab (Avastin®) for diabetic macular oedema

The above documents were noted and the recommendations endorsed by the APC. Amendments will be made to the formulary where necessary.

2012/78 APC Guidelines and Statements for review

None received

2012/79 NICE

The following NICE TAGs were noted. The recommendations within them were endorsed by the committee and the North of Tyne Formulary will be updated to reflect these decisions.

NICE Technology Appraisals published in July and August:

- TA261 Venous thromboembolism (treatment and long term secondary prevention) rivaroxaban
- TA262 Ulcerative colitis (moderate to severe, second line) adalimumab (terminated appraisal)
- TA263 Bevacizumab in combination with capecitabine for the first-line treatment of metastatic breast cancer. This has been rejected by NICE but has been approved by NECDAG for use under the terms of the Cancer Drugs Fund.

2012/80 Chair's action

2012/81 Any other business

NICE Consultation on local formularies.

NICE have issued a draft document for consultation on the development and updating of local formularies.

The consultation period runs from 10th September until 8th October.

The professional secretary will circulate this consultation document to members. Any comments should be returned to her by 21st September for collation and response to NICE.

MHRA August Drug Safety Update

HW asked committee members to ensure that the organisations they represented had noted the above bulletin and were compliant with its recommendations. ZI agreed to include additional reference to this in communications with primary care colleagues.

Manufacturer supplied emollients for use in cancer patients.

ML asked the committee for endorsement of the use of 2 emollient products, supplied free of charge by manufacturers of chemotherapy regimes, in patients undergoing cancer treatment. These would not be included in the formulary. The committee requested a short paper outlining the request to be presented at

the next meeting before a decision could be made.

2012/82 Date and time of next meeting

Tuesday 13th November 2012 at 12:30pm Room 2 and 3 ,Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

13/11/12 Signed: Chair of the APC)

North of Tyne Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 11th September 2012.**

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
 T = 'RED' drugs used in Tertiary Care only.

Product		Decision		Comments/notes			
	Approved	Refused	Deferred				
1) Requests deferred from previous meetings							
AdCal D₃ caplets			V	The FSC has been asked to consider the inclusion of AdCal D_3 caplets in the Formulary. These were claimed to be considerably easier to take in comparison with existing products but as opposed to one tablet once daily, the equivalent dose is two caplets twice daily. It was reported that the savings that might be made by using AdCal D_3 caplets were not as great as had been suggested			
				Decision: A review of this entire section of the Formulary should be conducted. The position of AdCal D3 will be considered within this.			
2) New Requests							
Sodium Hyaluronate 0.4% eye drops(Clinitas®)				Sodium hyaluronate 0.4% single (SDU) dose unit eye drops (Clinitas) have been requested for the treatment of Keraconjunctiva sicca, post refractive surgery and corneal healing disorders. Sodium hyaluronate is a glycosaminoglycan found in significant amounts in synovial fluid and the vitreous humour. Owing to the large number of negative charges on the molecule, sodium hyaluronate is capable of holding large quantities of water, and thus lubricating surrounding structures. Studies have demonstrated that it is an efficacious and well tolerated treatment, and in vitro studies suggest that hyaluronate acid may improve epithelial healing. There are considerable savings to be made across North of Tyne if this product were used in place of some of the alternative SDU preparations. The Formulary Subcommittee recommended that the request for Clinitas should be approved on the condition that Artificial Tears is removed from the Formulary.			

Product		Decision		Comments/notes
TTOULCE	Approved	Refused	Deferred	Comments/notes
Adapalene 0.1%, benzoyl peroxide 2.5% gel (Epiduo [®])		V		Epiduo gel has been requested for the first line topical therapy (primarily in place of the topical antibiotic therapies) for acne vulgaris. It is applied once a day in the evening. There are no comparative studies between Epiduo and other retinoid or topical antibiotic formulations and there are no studies comparing Epiduo with dual therapy using the individual therapies. Adapalene alone is not currently approved for use in the North of Tyne area and the Formulary Subcommittee wished to know whether alternative 2.5 and 5% benzoyl peroxide preparations were available. Research following the FSC meeting confirmed that there are still commercially available benzoyl peroxide products in strengths lower than 10%. Decision: Refused
Sodium Hyaluronate (1.6%) / Sodium Chondroitin Sulphate (2%) (laluril [®])	R			laluril is the first product which combines a high concentration of hyaluronic acid and chondroitin sulphate that has been requested for the treatment of Interstitial cystitis. It is claimed to significantly reduce the production of pro inflammatory cytokines and allow correct repair of the protective layer of the urothelial coating. It has been requested as a second line treatment in patients who have failed on Cystistat (sodium hyaluronate 0.08%) although patients with severe symptoms may be started on laluril. Ialuril is cheaper than Cystistat but as there have been no studies comparing Cystistat to Ialuril, more experience of using Ialuril is needed before it could be considered as first line treatment. Decision: Approved as a second line treatment in patients who have failed on Cystistat
Biotin ^{sur}	R			Biotin has been requested for the treatment of multiple carboxylase deficiency. It is a water soluble vitamin that is a coenzyme for five mammalian carboxylases. Both holocarboxylase synthetase deficiency and biotinidase deficiency cause multiple carboxylase deficiency and biotin dependency. These conditions are rare and there are no alternative treatment options available. Published evidence is limited to individual case reports that have shown it to be effective, rapidly resolving some of the features of condition. No adverse effects were reported in the case studies. Decision: The request for Biotin was approved for the treatment of multiple carboxylase deficiency. It should be initiated only by a specialist and should be a red drug.

Product		Decision		Comments/notes
	Approved	Refused	Deferred	
ProZero [®] protein free milk replacement	V			Currently there are five milk replacements that are available on prescription for children requiring low protein diets. Three of these products contain phenylalanine, thereby restricting the amount that can be consumed each day. ProZero is protein free and higher in calories than other available products. It does not require dilution and it is well tolerated by children of all ages.
				Decision: The request for ProZero for children with metabolic diseases was approved.
Infratini Peptisorb [®]			V	Infratini Peptisorb is a nutritionally complete 1Kcal/ml extensively hydrolysed whey protein feed designed for infants from birth up to 18 months who are at risk of developing faltering growth caused by severe malabsorption and maldigestion of nutrients e.g. in short bowel syndrome. Pepti Junior will remain the first choice feed in these patients and Infratini Infatrini Peptisorb will only be used in those patients who require a higher calorie feed. WHO guidelines recommend that where available commercially sterile ready-to-feed liquid formula should be used for infants at greatest risk.
				Decision: The request for Infatrini Peptisorb, for patients that require a higher calorie feed, was deferred subject to an algorithm being produced for its use and agreeing that an audit of use being undertaken at 6 months.

Product	Approved	Decision Refused	Deferred	Comments/notes
Fidaxomicin (Dificlir [®])	R			 Fidaxomicin is a new antimicrobial that has been requested for the treatment of <i>C. difficile</i>. Studies have show it to be as effective as vancomycin but with a significantly lower recurrence rate. It is a non absorbed macrocyclic antibiotic with a narrow spectrum of action. It has little effect on the other organisms in the bowel. It has been suggested that the following patients will be treated with fidaxomicin: Patients with recurrent C. difficile Patients who need antibiotics which cannot be stopped Lung transplant or bone marrow transplant patients as they have much higher risk of colectomy. It will only be used on the advice of microbiology. Decision: Fidaxomicin was approved for third line use in the treatment of <i>C. difficile</i>. It will be a red
Follitropin alfa (Gonal – F [®])			√	use in the treatment of <i>C. difficile</i> . It will be a red drug. Gonal F has been requested for inclusion in the Formulary as an additional option to Menopur in IVF. As a prefilled pen it is anticipated that it will reduce wastage and improve patient compliance. A previous application for Gonal F was refused in 2010 because there was a lack of consensus on the use of this product between clinical teams across North of Tyne. It was felt that the advantage of a prefilled pen formulation was insignificant because this client group is sufficiently motivated to be fully compliant with treatment regimes although it has been suggested that it may bring some cost benefit. Decision: Deferred . It was noted that NICE guidance states that the most cost effective product should be used for this indication. It was agreed to defer a decision to allow the applicant time to present any evidence to demonstrate that using Gonal F could reduce waste which could make it price equivalent with Menopur.
Primasol 4mmol/I potassium [®]			V	Primasol 4mmol/L potassium is a continuous renal replacement therapy solution that has a similar electrolyte profile to the currently used solutions, Lactosol and Hemosol, but with 4mmol/l potassium. Using Primasol 4mmol/l potassium will reduce the need to add concentrated potassium to haemofiltration and haemodiafiltration solutions, therefore reducing risk. If approved, it would replace Lactosol. It was queried whether Phoxilium could be used in this indication since it would meet phosphate requirements. Decision: Deferred . The request was deferred pending the receipt of information from the applicant regarding the possibility of using Phoxilium .The application will then be discussed by the Dialysis Fluids Group before coming back to the APC for final approval.

3) New formulations & extensions to use

Product	Decision		1	Comments/notes
	Approved	Refused	Deferred	Commentariotes
Colesevelam (Cholestagel [®])	N			Colesevelam has been requested for the treatment of bile acid malabsorption that results in diarrhoea. This is often seen in patients with small bowel, Crohn's disease and post-cholecystectomy. It has requested for patients who cannot tolerate colestyramine. Decision: The request for colesevelam was
				approved for second line use after colestyramine. Usage should be reviewed after 6 months.
Pancreatin (Creon Micro [®])	√			Creon Micro has been requested for the treatment of pancreatic exocrine insufficiency in CF babies. Pancreatin 10,000, 25,000 and 40,000 unit capsules are included in the Formulary. Small children often require lower doses and hence a 5000 unit preparation has now been launched.
				Decision: The request for Creon Micro should be approved
Nystatin pessaries ^{su}	R			Nystatin pessaries have been requested for the treatment of vaginal non-albicans infection, for patients who have not responded to standard treatments such as azoles. Although only available as an unlicensed product it is a recommended treatment option in the BASSH: 2008 National Guideline on the management of vulvovaginal candidiasis. It has been claimed that existing treatment options do not work against non albicans candidal species or sachhromyces cerevisiae.
				a red drug. Prescribing will be restricted to the GUM clinics and supplies will be obtained from the RVI.
Acetic acid 5% - endoscopy	√			Acetic acid 5% (AA) diluted to 2.5% has been requested for the detection of dysplasia/ neoplasia in Barrett's oesophagus. It is used routinely in colposcopy, and when sprayed on mucosa, leads to reversible acetylation of nuclear proteins leading to an aceto white area, improving visualisation. This allows mucosal surface patterns to be assessed, improving the diagnosis of dysplasia or cancer. AA is very safe to use (table vinegar is approximately 5%). Decision: The request for acetic acid (5%) diluted to 2.5% was approved for endoscopy.

Product		Decision		Comments/notes
Tadalafil 2.5mg - 5mg daily – post radical prostatectomy	Approved	Refused	Deferred √	Tadalafil has been requested for penile rehabilitation (i.e. restoration of erectile function) after radical prostatectomy (RP). Erectile dysfunction occurs in 80% of patients following RP and can persist for as long as 24 months. Regular dosing of tadalafil and other PDE5 inhibitors has
				been proposed for penile rehabilitation following RP on the basis that improved penile flow will reduce erectile tissue atrophy and apoptosis. Tadalafil has a long period of responsiveness, lasting up to 36 hours, whereas sildenafil has immediate response and a more pronounced side effect profile. It was noted that DH guidelines are that PDE5 inhibitors are used a maximum of once weekly for erectile dysfunction and that there is no evidence to support once daily Tadalafil for this indication.
				Decision: Deferred pending receipt of further evidence for the use of twice weekly Tadalafil in this indication, particularly around the number of patients who will regain normal erectile function. There also needs to be clarification on whether there is potential for using sildenafil in this indication due to its forthcoming expiry in 2013.
4) Products consid	lered by N	NECDAG	ì	
None received				
5) Products consid	lered by N	NETAG		
Pasireotide (Signifor®) for Cushing's disease		√ 10th July 2012		The NHS North East Treatment Advisory Group was not satisfied that pasireotide represents a cost- effective treatment in the management of Cushing's disease. Individual patients in exceptional circumstances may be suitable for treatment. Such cases must be referred via local individual funding request mechanisms.
Bevacizumab (Avastin®) for diabetic macular oedema		√ 10th July 2012		The NHS North East Treatment Advisory Group was requested to re-appraise bevacizumab (Avastin®) for the treatment of diabetic macular oedema in light of NICE not having recommended ranibizumab (Lucentis®) for the same indication. The group refused the application as they were concerned about the quality of clinical evidence supporting bevacizumab in DMO and in particular evidence relating to the durability of treatment effects.

Product	Approved	Decision Refused	Deferred	Comments/notes		
6)Products considered by NICE						
TA261 Venous thromboembolism (treatment and long term secondary prevention) - rivaroxaban	V			Approved in line with the NICE TAG.		
TA262 Ulcerative colitis (moderate to severe, second line) - adalimumab (terminated appraisal)				Termination of appraisal noted.		
TA263 Bevacizumab in combination with capecitabine for the first-line treatment of metastatic breast cancer		\checkmark		Refused from mainstream funding in line with NICE but approved for use under the Interim Cancer drugs fund.		
7) Appeals against	earlier de	ecisions	by the A	PC		
Hyalofemme				An intent to appeal was registered within the required timescale following the July meeting. This will be heard at a future meeting.		
8) Miscellaneous d	ecisions	by the A	PC			
Metformin – polycystic ovaries	V			Metformin has been included in NICE guidance for use in the treatment of polycystic ovaries. Decision: Approved for the treatment of polycystic ovaries.		
Melatonin oral liquid	V			Currently the Formulary recommends use of a melatonin suspension however a cheaper unlicensed solution has become available. Decision: Approved. The Formulary will be updated to recommend use of the solution.		
Sitagliptin and Saxagliptin				A request had been submitted for the committee to review the choice of DPPIV inhibitor on the formulary following licence changes. Decision: Sitagliptin will be added to the formulary in place of saxagliptin.		