North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 13th November 2012 at Northumbria House, Cobalt Business Park, North Tyneside

Present

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Lindsay Caulfield (for Zahra Irranejad)	Prescribing Advisor	NHS NoT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker (AD)	Consultant Physician	NUTH
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Paul Fieldhouse (for Sue Dickinson)	Principal Pharmacist	RDTC
Sue Gordon (SG)	Executive Director Public Health	NHS NoT
Matt Grove (MG)	Consultant Rheumatologist, NTGH	NHCT
Janet Kelly (JK)	Nurse Clinical Manager	NHCT
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
John Ross (JR)	Patient Representative	
Susan Turner (STu) (Professional Secretary)	Medicines Management Advisor	NHS NoT
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Amy Gall	GP and Prescribing Lead	NHSNNE CCG
Sue Dickinson	Director of Pharmacy	RDTC
Zahra Irannejad	Head of Prescribing	NHS NoT Provider

NoT LPC	North of Tyne Local Pharmaceutical Committee
NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NTWT	Northumberland Tyne and Wear NHS Foundation Trust

NUTH Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC Regional Drugs and Therapeutics Centre

2012/83 John Ross, a public Governor from Northumbria Healthcare Foundation Trust, was welcomed to his first meeting as a lay member of the committee.

2012/84 Declarations of interest

No declarations relevant to the meeting were made.

2012/85 Appeals

Hyalofemme

ML presented the appeal on behalf of the original applicant.

The following points were highlighted:

- Atrophic vaginitis occurs when there is a drop in oestrogen levels. The first line therapy for the treatment of atrophic vaginitis in menopause patients is hormone replacement therapy or topical oestrogen however these products are contraindicated in oestrogen dependant cancer.
- Due to radiotherapy women being treated for gynaecological malignancy can experience more severe symptoms than those experienced post menopausal women.
- Currently in these situations patients are advised to use lubricating gel, despite the fact that this is not intended for such use, as there are no other alternatives available in the NoT Formulary. Experience by the specialist team is that lubricating jelly does not provide relief from soreness and does not reduce discharge.
- The original application was refused on the grounds that Hyalofemme is expensive compared to lubricating jelly. It is, however, cost neutral compared to the first choice topical oestrogen preparation on the formulary and it was acknowledged that the wrong comparator had been used in the original application. Lubricating jelly has not been studied in atrophic vaginitis and is only indicated for use in intercourse.
- Hyalofemme has been compared to topical estriol (0.1%) and has been shown to be non inferior for symptoms of vaginal dryness. It is licensed, as a device, for this indication.

Decision:
Hyalofemme is approved for restricted use for the relief of symptoms of atrophic vaginitis, in women who have had treatment for gynaecological malignancy and where topical estriol is not a treatment option.

2012/86 Minutes and decision summary from the meeting held on Tuesday 11th September 2012.

These were accepted as a true record.

2012/87 Matters arising not on the agenda

2012/69 Lay Representation

Notification to the Governing Bodies of membership organisations of lay representation has been tasked to representatives of those organisations.

2012/69 Member attendance

DC has had discussion with NHSNWCCG and NHSNNECCG members about the importance of securing appropriate representation at the APC. He informed them of the difficulty in changing scheduled meeting dates of the committee and relayed the offer from Dr McEvedy to include them in his update bulletin that he produces for Northumberland CCG.

The members thanked the committee for giving due consideration to alternative arrangements and accepted the difficulties this presented.

They noted the offer from Dr McEvedy and accept this offer.

They stressed that where they were unable to attend they were satisfied that their organisation's needs were met by representatives of the medicines management teams.

2012/74 Newer Oral Anticoagulants

The RDTC agreed at the September meeting to produce 2 leaflets:

1. A patient info leaflet – this is still in development.
2. Advice for primary care prescribers.

This document had been circulated to the committee for consideration. PF informed the committee that a separate document outlining licensed indications, and outlining where approved North of Tyne use may be off-label, had also now been produced. This will be circulated to members and comments on both documents are requested within 2 weeks. Chair's approval will be given subject to comments received.

2012/76 Department of Health review of Local formulary processes and review of NPC Diagnostic Tool on Local Decision Making

RE informed the committee that a meeting to assess our local decision making processes and to consider the draft NICE Guidance had taken place and drew attention to the following points:

- Attendees of the meeting discussed various options for CCG local decision making in the future. Although not the only option it was recognised that the APC provided a robust platform which gave member organisations assurance about compliance with decision making processes.
- The NPC competency framework was used as a starting point to reflect on the current processes and consider the future needs of CCGs.
- Areas where further action could strengthen the already robust arrangements include
    - Finance and contracting – There is concern about 'creep' of medicines use once a product is formulary approved for a discrete group of patients. It was agreed there could be a strengthening of post-approval review/audit and this should be captured as a priority within the primary care Medicines Management Strategy. It was also suggested that formulary application forms should capture more financial and contracting data including the tariff position, estimated usage figures and funding arrangements for drugs. It was noted that the Formulary Sub Committee is responsible for assessing the cost-effectiveness of medications, not affordability but additional information would be helpful to inform final decisions. This will be discussed further with the chair of the FSC. Affordability needs to be considered prior to APC endorsement of a FSC recommendation.
    - External communication and engagement - CCG representation still needs strengthened although some progress has since been made with this. This is particularly important when there are discussions

around affordability. Decisions of the committee are binding on member organisations therefore appropriate representation with delegated authority for decision making is essential.

- Governance and safety - Further work is required to understand Gainshare and patient access schemes and the benefits to provider and commissioner organisations. Whilst it was recognised that The Hackett Report suggested 50:50 may be appropriate for Homecare supply it was agreed that each arrangement needed individual consideration and would vary depending on various factors including the burden on staff time to administer a scheme. Transparency relating to such schemes is paramount. The Regional Specialist Procurement pharmacist is involved in a National Workstream relating to such issues. It was acknowledged that an increased burden on one part of healthcare expenditure could generate efficiencies in others.
- Deliberation, reasoning and ethical judgement – The Terms of Reference for the APC should include an overarching statement about having regard for making ethical decisions (justice, autonomy, benevolence, non-maleficence). This will be incorporated at the next review.

The chairman thanked members for their input into the above discussions and welcomed any workplan that would further build on the robust platform we currently have. He reminded the committee that we are already considered as an exemplar nationally.

2012/88 Report from the Formulary Sub-committee

Minutes and recommendations from the meeting held on Thursday 18th October 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:

Tafluprost preservative free

This prostaglandin analogue has been requested for use in paediatric patients who are intolerant to other preservatives for the treatment of open angle glaucoma and ocular hypertension (unlicensed).
The Formulary Subcommittee had questioned whether 10 patients per annum was a realistic reflection of the potential population who would use this product. Mr Lowery had explained that these 10 patients were children and agreed that prior to consideration by the APC he was seeking to confirm the potential numbers of adult patients who would also meet the criteria for this product.
These figures had now been obtained and the committee were informed that the anticipated numbers of adults in whom the product may be intended for use was approx 60. Although the original application had been for use in children it was recognised that the clinical case was equally justified in a similar adult population.

Decision: Approved

The request for tafluprost was approved for use in adults and children. It will be initiated by specialists only and should be used third line after preservative containing latanoprost and preservative free timolol. The ophthalmologists must clearly document that signs and symptoms of preservative intolerance/allergy have been demonstrated in their patient prior to initiation. Use should be audited in 12 months.

Cinacalcet – primary hyperparathyroidism

Cinacalcet is currently included in the Formulary for primary hyperparathyroidism as a bridging agent to surgery and is classified as a red drug.

There has now been a request to consider it for use in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated based on serum calcium levels, symptoms and end-organ damage, but in whom parathyroidectomy is either not clinically appropriate or is contraindicated. This is an extension of the current NICE recommendation. Concerns were raised that this is an expensive treatment option that if made available, could potentially be used first line instead of a simple surgical option.

Decision: Approved - Amber

The request for Cinacalcet for use in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated based on serum calcium levels, symptoms and end-organ damage, but in whom parathyroidectomy is either not clinically appropriate or is contraindicated is approved subject to the production of an agreed Shared Care Protocol documenting the strict parameters for use and clearly documenting the reason as to why surgery is not an appropriate treatment option for the particular patient. Primary care monitoring requirements will be clearly stated within this protocol.

Cinacalcet – Secondary hyperparathyroidism in ESRD.

The renal team have requested that Cinacalcet is changed from red to amber for patients requiring haemodialysis, as these patients have the bulk of their medication already prescribed in Primary Care. Committee members did not feel that this was a sufficient reason for a change in status given that these patients have to attend Secondary Care regularly for follow ups. Further work to explore the options, including the possibility of setting up a Homecare service for these patients, still needs undertaken.

Decision: Deferred

Cinacalcet when used for Secondary hyperparathyroidism in ESRD will remain as a red drug at present.

Smoking Cessation products

At a Formulary Subcommittee meeting, that was held in April 2012, it was agreed that there would be a review for the current nicotine replacement products that are included in the Formulary. This review has now been undertaken in conjunction with the Smoking Cessation Teams and the following recommendations have been made:

- Specify that Nicotinell is the 24 hour patch of choice (it is estimated that this could result in savings of up to £19,000 per annum)
- Specify that Nicorette is the gum of choice (2mg/ 4mg)
- Specify that Niquitin is the lozenge of choice (2mg/ 4mg)
- Remove the 1mg lozenge.
- Remove the nasal spray and replace with Quickmist (overall this may lead to

modest savings) and potentially more significant savings if replaces some of the inhalator usage.
- NRT products should be prescribed by brand to ensure the first choice products are supplied.
- Given the lack of evidence to support one preparation, of a similar type over another, the range of products on the Formulary should be reviewed annually on the basis of cost and taking into account the current trends in usage, that indicate patient preference.

Decision
The above recommendations should be incorporated into the Formulary.

It was noted that responsibility for Smoking Cessation services will transfer to the Local Authorities on 1st April 2013 and therefore links with those teams will need to be established.

Emollient skin products
The emollient section of the formulary has been reviewed taking into account current usage patterns, indicating patient preference, and dermatology opinion. The following has been proposed:

Aqueous cream*	Aveeno cream	Calmurid
E45 cream	Cetraben	Oilatum
Diprobase cream	Yellow soft paraffin	Dermol Bath***
DoubleBase Gel	Hydromol ointment	QV cream**
Dermol cream***	Emulsifying ointment BP	Aquamax**

*Not to be used as a *leave on* emollient but a soap substitute only due to SLS content.
**To be used in radiotherapy only (Red status).
***Specialist recommendation only (^{s} status).

It has also been recognised that the following alternatives to the listed generics would release savings whilst maintaining the required range of therapeutic options:
Aqueous cream could be substituted for ZeroAQS , which also has the benefit of being SLS free
E45 cream could be substituted with ZeroCream
Diprobase cream could be substituted with Zerobase
Hydromol/Epaderm ointment could be substituted with Zeroderm
The Oilatum range could be substituted with Zerolatum

A decision on whether this range of products should be recommended in addition to the current alternatives or instead of them, along with an implementation plan, will be sought from the QIPP subgroup at the November meeting and fed back to the APC.

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 4.0 is now available on the website.

2012/89 Report from the Shared Care Group (SCG).

Version 3.6 (September 2012) of the traffic light list is now available on the website.
Dr Wynne highlighted the following points from the SCG minutes:

Dementia drugs
The value of the current shared care arrangement which requires a six monthly review by a specialist, as stated in NICE guidance, has been questioned as such reviews add a significant burden to the overall cost of dementia treatment and usually there is not a clinical decision to be made at each review. As it is impossible to know on an individual basis what treatment benefit a patient is deriving from these treatments, the main assessments are of tolerability and when to stop drug treatment, noting that this would usually be beyond the point at which a patient had been admitted to a care home. The requirement for six monthly reviews erodes the capacity to see new patients, and, as a result, initiating drug treatment is being delayed for patients most likely to benefit.
The Shared Care group have accepted the clinical appropriateness of a change of traffic light status of these drugs from amber to blue and feel that this deviation from NICE guidance could be justified as being beneficial for patient care if guaranteed rapid access to specialist advice and clear criteria for specialist review were agreed.
The APC were asked to endorse this view, providing that they had assurance that Commissioning issues around referral back to secondary care, should patients need further specialist review, were contractually agreed before implementation of this proposal.

Decision
The status of dementia drugs will change from Amber to Blue after contractual agreement is reached regarding rapid access back in to the specialist services.

Melatonin
Melatonin is currently approved as a blue drug in the North of Tyne area for a number of specific indications. The APC had asked the group to consider whether the use of melatonin for sleep disorders in children would be better placed as a shared care drug due to limited evidence for its use and no long term safety data. Furthermore, the issues around the unlicensed nature of some of the co-prescribed drugs compound these concerns. The group agreed that work on developing this shared care agreement and on updating the Blue information sheet to reflect this change would be progressed.

Darbo/Erythropoietin shared care guideline
The clinical content of the above guideline was agreed but there are still some commissioning details to be worked through before implementation.
It was recognised that much good work is undertaken by the Shared Care Group but that progress with the commissioning arrangements required to underpin much of the work continues to cause some delays. It was suggested that, whilst there has been some primary care commissioning management representation at the meetings, it may facilitate the process if there was representation from the corresponding contracting teams of constituent member organisations.
Dr Wynne expressed her thanks to the GP representatives and medicines management representatives who continue to support the work of the committee. It was recognised that the work undertaken to date by the group, despite the

above frustrations, had resulted in improvements in the quality of care for patients.

The changes in the NHS structure from 1st April will undoubtedly cause some additional uncertainty, specifically around the role of the Local Area Teams of the NHS Commissioning board in terms of commissioning of GP services and the role they may have in developing Shared Care and TD requested that previous work around commissioning arrangements would not be lost as organisational restructure took place.
JR expressed the hope that organisational changes would not have any adverse impact on the public.
NW said we must embrace the changes and focus on the positives that may come out of them.

2012/90 Report from the Anti-microbial Chemotherapy subcommittee.
There had been no meeting of this group.

2012/91 Quality, Improvement, Productivity and Performance (QIPP)
This group is due to meet on 14th November.
JR asked about the work previously referred to around the use of Special Order Products and asked what timescales had been set against this work.
An outline of work to date was given, including meetings with the LPC and discussions with the FSC secretary.
Concern was expressed that whilst there is a pressure to progress this work in order to make the most of potential financial savings, there must be assurance that all work and/or documentation coming from subgroups of the APC is subject to robust governance before it is shared with the wider health economy.

2012/92 Adcirca
Tadalafil 20mg tablets are currently available as two brands for two separate indications; Cialis® for erectile dysfunction and Adcirca® for pulmonary arterial hypertension (PAH).

The Adcirca® brand's indication has been classified by APC as a RED drug, approved "for the treatment of PAH in adults for whom treatment with sildenafil is not tolerated or effective".
It has been requested that the APC recommend that prescribing of tadalafil for PAH should be by brand name to ensure the correct dispensing and monitoring of the use of this drug for PAH.
The committee noted that all prescribing of tadalafil for PAH should be undertaken by secondary care. In the rare situation where patient care is compromised by this requirement secondary care colleagues will ensure that any request for a GP to undertake the prescribing will refer to the product by the appropriate brand name.
It was not felt necessary however to change the current recommendation relating to generic prescribing.

2012/93 Primary Care Rebate Schemes for medicines
The Regional Procurement Specialist has produced a draft paper outlining some principles to be adhered to before entering into any such arrangement.
Comments were received on this and will be fed back to the author.

It was noted that :

- The London Procurement Group has sought legal advice on the use of such schemes and this advice will be considered before any final local guidance is produced.
- The paper does not relate to community pharmacy rebate schemes
- Any prescribing data to be released must be volume based only
- There may be difficulties ensuring appropriate choices are made when one

product has gained local approval for an additional off-label use, that is secondary to the main approval and the alternative product is not suitable for such an indication – it was stressed that any decision to use a particular product must be made on a clinical basis first.

- There needs to be a clear ethical framework in place that ensures transparency, governance and adherence to organisational Codes of Business Conduct.

2012/94 Documents previously circulated by email

- NECDAG Cancer Drug Fund Decision Document - Clofarabine (Evoltra®) for patients with refractory of relapsed AML who are non-responders to FLAG prior to allograft
- NECDAG Cancer Drug Fund Decision Document - Everolimus (Afinitor®) for unresectable or metastatic advanced pancreatic neuroendocrine tumours.
- NECDAG Cancer Drug Fund Decision Document - Everolimus (Afinitor®) for the treatment of hormone receptor-positive HER2 -ve advanced breast cancer, in combination with exemestane.
- NECDAG Gateway decision – Gemcitabine - Ovarian cancer
- NECDAG Gateway decision - PEG Asparginase for adult patients with ALL
- NECDAG Gateway decision - Rituximab + salvage chemotherapy for patients relapsing > 12 months post 1st line therapy with R-CHOP
- NECDAG Gateway decision – Rituximab for rising EBV viral copy numbers in patients after allogenic bone marrow transplant to pre-empt development of Post Transplant Lymphoproliferative disorders (PTLD)
- NECDAG Decision Document - Intravesical Mitomycin C combined with thermotherapy (Synergo®)
- NECDAG Decision Document - Rituximab in combination with bendamustine for CLL.
- NECDAG Decision Document - Rituximab in combination with bendamustine for the treatment of low grade Non Hodgkin's lymphoma (NHL).
- NECDAG Decision Document - Rituximab in combination with bendamustine for the treatment of High Grade Non Hodgkin's lymphoma (NHL).

The above documents were noted and the recommendations endorsed by the APC. Amendments will be made to the formulary where necessary.
It was also confirmed that the previous recommendation relating to use of palonosetron will be reflected in the formulary.

2012/95 APC Guidelines and Statements for review
None received

2012/96 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 September and October:

- TA264 - Stroke (acute, ischaemic) - Alteplase

- TA265- Bone metastases from solid tumours - Denosumab

2012/97 Chair's action

- Exenatide Information sheet – approved and on website
- Tacrolimus information sheet - approved and on website
- Melatonin - information for primary care (updated)

2012/98 Any other business

IFR Processes

Concerns were raised about communication and consistency regarding IFR applications. It was agreed that any such concerns should be raised directly with the chair of the IFR panel as the APC has no remit in this.

Buccal Midazolam

The APC had previously endorsed the continued use of unlicensed buccal midazolam in the belief that a licence was imminent. This has not yet been granted and the committee therefore feel unable to support continued use of this product when a licensed alternative is available. ML informed the committee that work was underway to scope the work involved in changing over to the licenced alternative. It was agreed this would be raised at the QIPP meeting to determine GP opinion on the appropriate level of input to any such change.

2012/99 Date and time of next meeting

Tuesday 8th January 2013 at 12:30pm
Room 2 and 3 ,Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... 8/1/13 **Date: .....**

(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 13th November 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				
Tadalafil – post radical prostatectomy			√	Awaiting further information
Infratini Peptisorb®			√	Awaiting further information
Follitropin alfa (Gonal – F®)			√	Awaiting further information
2) New Requests				
Fluenz®	√			Fluenz is a live attenuated influenza vaccine that is administered by a nasal spray. The DoH Green Book states that Fluenz is the preferred vaccine for children aged two to less than 18 years in clinical risk groups except those with certain immunodeficiencies (see contraindications), with severe asthma (British Thoracic Society and Scottish Intercollegiate Guidelines Network (BTS SIGN) step 4 or above), active wheezing at the time of vaccination or when pregnant (see precautions). However, supplies of this vaccine for the 2012/13 influenza season will be limited. **Decision:** Fluenz nasal spray should be added to the Formulary, for use in line with DoH guidance.
Palifermin			√ R	Palifermin is a recombinant form of human keratinocyte growth factor (KGF). It has been requested for the prevention of mucositis post HSCT in SCIDs (severe combined immune deficiency) patients. It is unlicensed for this indication and in children. In adult patients studies have shown that it prevents / decreases the severity of mucositis reducing the need for parenteral nutrition and opioids. It may also reduce the severity of acute Graft versus Host disease (aGvHD). There is currently no alternative preventative intervention for oral mucositis. **Decsision:** The committee was minded to recommend approval but clarification was required as to whether other SCIDs centres are using palifermin and, if so, what experience had been gained by using palifermin for this indication.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tafluprost	√			Tafluprost is the first preservative free (PF) prostaglandin analogue in its class. It has been requested for the treatment of open angle glaucoma and ocular hypertension in children who are intolerant to preserved eye drops although it is not licensed for use in children. Tafluprost has been shown to be non inferior to other, more established prostaglandin analogues. It is anticipated that by improving patient tolerability, it will result in an increase in patient compliance thereby reducing the need for surgery. **Decision: Approved** The request for tafluprost was approved for use in children and adults. It was recognised that the clinical case was equally justified in a similar adult population. It will be initiated by specialists only and should be used third line after preservative containing latanoprost and preservative free timolol. The ophthalmologists must clearly document that signs and symptoms of preservative intolerance/allergy have been demonstrated in their patient prior to initiation. Use should be audited in 12 months.
3) New formulations & extensions to use				
Cinacalcet – Primary hyperparathyroidism	√ A			Cinacalcet is currently included in the Formulary for primary hyperparathyroidism as a bridging agent to surgery and is classified as a red drug. The committee has now been asked to consider it for use in patients with primary hyperparathyroidism for whom parathyroidectomy is indicated, but in whom parathyroidectomy is either not clinically appropriate or is contraindicated. This is an extension of the current NICE recommendation. Concerns were raised that this is an expensive treatment option that if made available, could potentially be used first line instead of a simple surgical option. **Decision: Approved as an Amber drug** for use in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated based on serum calcium levels, symptoms and end- organ damage, but in whom parathyroidectomy is either not clinically appropriate or is contraindicated. Approval is subject to the production of an agreed Shared Care Protocol documenting the strict parameters for use and clearly documenting the reason as to why surgery is not an appropriate treatment option for the particular patient. Primary care monitoring requirements will be clearly stated within this protocol.
Cinacalcet – Secondary hyperparathyroidism in ESRD.			√	The renal team have requested that Cinacalcet is changed from red to amber for patients requiring haemodialysis. **Decision : Deferred** pending further information

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Botulinum Toxin A – Paediatrics [u]	√ See Notes R			Botulinum toxin A is currently included in the Formulary (for adult patients) for the treatment of overactive bladders in patients who have failed to respond to conservative treatment. This is an unlicensed indication. It is also approved for the treatment of chronic anal fissures. It has been requested for use in these indications in paediatric patients. Evidence to support its use in paediatrics is limited to small case series. Botulinum toxin usually has an action of 3 – 6 months, and the recurrence of anal fissure is less easy to predict and is more likely to recur following constipation. Studies have shown that in adults, recurrence occurs at 3 – 30 months. **Decision:** **Anal fissures** – the request should be **approved.** There must be documented informed consent from patients/carers. **Bladder dysfunction** – **Deferred** until data can be provided on treatment outcomes for patients in whom this treatment has already been tried and the provision of a clear treatment pathway.
Mexiletine – Myotonic dystrophy [u]		√		Mexiletine is an orally active antiarrhythmic agent that was previously marketed in the UK for the treatment of ventricular arrhythmias. It was withdrawn in 2008 due to lack of demand and is now available as an unlicensed product. Myotonic dystrophy type 1 (DM1) is a progressive condition causing muscle weakness, myotonia, cataract or diabetes and cardiac disorders. The committee noted that the supporting data for use in this latter indication was poor. **Decision: Refused**
Trichloroacetic acid 50% [u]		√		The BASHH guidelines recommend 80-90% TCA for genital warts. A request for 50% has been submitted on the grounds that it is anticipated to cause less patient discomfort and is a safer treatment choice for the penis. There is no evidence to support the claim that it will cause less pain and still be as effective as the higher treatment strengths. The committee was concerned that this proposal was contrary to national guidance. **Decision: Refused**
4) Products considered by NECDAG and decisions endorsed by APC				
Clofarabine (Evoltra®)	See notes			NECDAG – Considered 26.09.12 – Unable to fund through normal route for patients with refractory of relapsed AML who are non-responders to FLAG prior to allograft due to lack of evidence of cost effectiveness therefore considered for CDF. **Rejected** from Standard NHS Funding **Approved** from Cancer Drug Fund.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Everolimus (Afinitor®)	See notes			NECDAG reviewed everolimus for this indication on 26th September 2012 and concluded that everolimus in this indication does not meet the normal NHS Cost Effectiveness Criteria. **Rejected** from Standard NHS Funding **Approved** from Cancer Drug Fund (subject to ongoing review) for the treatment of hormone receptor-positive HER2 -ve advanced breast cancer, in combination with exemestane, in postmenopausal women with symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.
Everolimus (Afinitor®)	See notes			NECDAG – Considered 26.09.12 – Unable to fund through normal route due to lack of evidence of cost effectiveness therefore considered for CDF. **Rejected** from Standard NHS Funding **Approved** from Cancer Drug Fund for the treatment of patients with unresectable or metastatic advanced pancreatic neuroendocrine tumours (PNETs), whose disease has progressed on or after treatment with VEGF-targeted therapy, as a 2nd line treatment option after somastostatin analogue therapy with the condition unable to give Sunitinib in succession.. A national audit must be undertaken within 12 months.
Gemcitabine 1000mg/m²	See notes			There is a global shortage of pegylated liposomal doxorubicin (Caelyx). Caelyx is the NICE recommended second line treatment for women with partially platinum-sensitive, platinum-resistant or platinum-refractory advanced ovarian cancer. A phase 3 trial showed that gemcitabine has similar efficacy to caelyx (see below) and it would be a very appropriate replacement for it. **Approved** by NECDAG 26.9.12
PEG Asparginase 1000IU/m2 for 6 doses	See notes			**Approved** by NECDAG 26.09.2012 for ALL
Rituximab in combination with bendamustine	See notes			**Approved** for the use in combination with bendamustine for patients with either first line or relapsed Low Grade Non Hodgkins Lymphoma. Approved from NHS funding (Note an application for use in High grade NHL was considered and rejected)
Rituximab in combination with bendamustine	See notes			Refused for the use in combination with bendamustine for patients with either first line or relapsed High Grade Non Hodgkins Lymphoma. **Rejected from NHS funding** **Rejected from Cancer Drug Fund due to lack of supporting evidence** (Note an application for use in low grade NHL was approved)

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Rituximab (Mabthera®) with Bendamustine (BR regimem)	See notes			Approved for use in combination with bendamustine for patients with CLL not fit for FCR chemotherapy or for patients who relapse within 2 years of FCR chemotherapy and not fit for alemtuzumab (Campath®) **Approved** from NHS funding
Rituximab + salvage chemotherapy	See notes			**Approved** by NECDAG 26.9.12 for patients relapsing > 12 months post 1st line therapy with R-CHOP
Rituximab – 375mg/m2 weekly for up to four doses	See notes			**Approved** by NECDAG 26.9.12 For rising EBV viral copy numbers in patients after allogenic bone marrow transplant to pre-empt development of Post Transplant Lymphoproliferative disorders (PTLD) (An unlicensed indication)
5) Products considered by NETAG				
None to consider				
6) Products considered by NICE				
TA264 - Stroke (acute, ischaemic) - Alteplase	√			Approved in line with NICE TAG
TA265- Bone metastases from solid tumours - Denosumab	√			Approved in line with NICE TAG
7) Appeals against earlier decisions by the APC				
Hyalofemme®	√			**Decision:** Hyalofemme is approved for restricted use for the relief of symptoms of atrophic vaginitis, in women who have had treatment for gynaecological malignancy and where topical estriol is not a treatment option.
8) Miscellaneous decisions by the APC				
Octaplas® and Octaplas LG®	√			Pathogen reduced human Fresh Frozen Plasma (FFP) products are recommended by the DH for patients born after 1996. The two options available in the UK are methylene blue treated FFP (MB-FFP) & Octaplas. There have been long term problems obtaining MB-FFB, and as a result solvent detergent FFP is required. Octaplas is licensed as a medicine, is already in use and is a cheaper alternative. **Decision:** Octaplas and Octaplas LG should be added to the Formulary

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Vagifem 25 microgram vaginal tablets	√			Vagifem 25 microgram tablets have been discontinued as the manufacturer has confirmed that studies have shown that the lower strength is equally efficacious. **Decision:** Vagifem 10 microgram tablets will be added to the Formulary as a replacement.
Etravirine 200mg tablets	√			Etravine 100mg tablets are currently included in the formulary. Etravine 200mg tablets are cost equivalent. **Recommendation:** Etravine 200mg tablets should be added to the Formulary
Methylene Blue	√			Proveblue is a 0.5% methylene blue product that is currently included in the Formulary. The committee has been asked to consider the replacement of Proveblue with a 1% methylene blue product called Aggutenent. This is licensed as a device as opposed to a medicine. Colleagues at NHCFT would prefer to use the 1% methylene product as there would be less wastage and it is considerably cheaper. The committee noted that Proveblue is a purer product compared Aggutenent. **Decision:** Aggutenent will be added to the formulary in addition to Proveblue.
Nicotine Replacement Therapy Review	√ See notes			A review of the current nicotine replacement products that are included in the Formulary has been undertaken. The following decisions are agreed: - Specify that Nicotinell is the 24 hour patch of choice (it is estimated that this could result in savings of up to £19,000 per annum) - Specify that Nicorette is the gum of choice (2mg/ 4mg) - Specify that Niquitin is the lozenge of choice (2mg/ 4mg) - Remove the 1mg lozenge. - Remove the nasal spray and replace with Quickmist (overall this may lead to modest savings) and potentially more significant savings if replaces some of the inhalator usage. - NRT products should be prescribed by brand to ensure the first choice products are supplied. - Given the lack of evidence to support one preparation, of a similar type over another, the range of products on the Formulary should be reviewed annually on the basis of cost and patient preference.