# North of Tyne Area Prescribing Committee

**Minutes of a meeting of the Area Prescribing Committee held on Tuesday 8th January 2013 at Northumbria House, Cobalt Business Park, North Tyneside**

## Present

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| 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 |
| Helen Coundon | GP and Prescribing Lead | NHS North Tyneside CCG |
| Sue Dickinson | Director of Pharmacy | RDTC |
| Rosie England (RE) | Associate Director of Medicines Management | NHS NoT |
| Sue Gordon (SG) | Executive Director Public Health | NHS NoT |
| Matt Grove (MG) | Consultant Rheumatologist, NTGH | NHCT |
| Matthew Lowery (ML) | Formulary and Audit Pharmacist | NUTH |
| Peter McEvedy (PMcE) | GP and Prescribing Lead | NHS Northumberland CCG |
| John Ross (JR) | Patient Representative | |
| Wendy Ross | GP and Prescribing Lead | NHS Newcastle North and East CCG |
| Simon Thomas | Consultant Clinical Pharmacologist | NUTH |
| 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

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| Tim Donaldson (TD) | Trust Chief Pharmacist/Associate Director of Medicines Management | NTWT |
| Zahra Irannejad | Head of Prescribing | NHS NoT Provider |
| Janet Kelly (JK) | Nurse Clinical Manager | NHCT |
| Tamsin Oswald (TO) | Consultant Microbiologist | NHCT |

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| 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 |

**2013/01** Wendy Ross, a GP from Newcastle, was welcomed to her first meeting as the APC representative for NHS Newcastle North and East CCG.
The chairman wished members a Happy New Year and outlined some of the challenges facing the committee during 2013 including:

- NHS Architectural changes
- Boundary and cluster changes
- Northumbria Foundation Trust acquisition of North Cumbria NHS Trust
- Impacts of restructuring on NETAG, NECDAG and the cancer network
- Changes to the IFR process
- Responsibilities of the Local Area Team of the NHS Commissioning Board and the impact of this on current processes

**2013/02 Declarations of interest**
ML - has participated in the assessment of representatives from Napp Pharmaceuticals Ltd, the manufacturers of Flutiform.

**2013/03 Appeals**
No appeals had been lodged with the secretary.

**2013/04 Minutes and decision summary from the meeting held on Tuesday 13th November 2012.**
These were accepted as a true record, subject to the altering of the word "was" to "is" under the dementia drugs decision on page 7.

**2013/05 Matters arising not on the agenda**

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

At the November meeting **(2012/87)** It was noted that formulary application forms should capture more financial and contracting data including the tariff position, estimated usage figures and funding arrangements for drugs. DC highlighted that it would also now be useful to include information around which organisation would have the responsibility for the commissioning of a technology in the new NHS structure.
The need for improved post approval audit was also discussed further and SD stated that the RDTC could look at ePACT data in situations where the committee feel think there is an issue with a particular medicine and provide some comparisons with elsewhere. Alternatively, where there are concerns at the point of approval that prescribing could outstrip initial modelling, information could be examined at 6 or 12 months post approval to check uptake compared with expectations.

**2013/06 Report from the Formulary Sub-committee**

**Minutes and recommendations from the meeting held on Thursday 17th December 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 for further consideration:

**Infatrini Peptisorb**
This request was for the use of this enteral feed in short bowel syndrome; intractable malabsorption, inflammatory bowel disease, bowel fistulae, disease related malnutrition; intolerance of whole protein feeds. An algorithm outlining the place in therapy has been provided and the applicant has confirmed that Infatrini Peptisorb would be prescribed by only two senior dieticians. The Formulary Subcommittee recommends the inclusion of Infatrini Peptisorb in the Formulary for use in this indication but had requested that Mr. Lowery provide information on the total anticipated usage for consideration by the APC. The estimate of costs across the North East Region is £113,000 per annum and it is realistic to anticipate that about 30% of this will relate to prescribing in the North of Tyne area.

**Decision: Infatrini Peptisorb**
**Approved** for use in short bowel syndrome; intractable malabsorption, inflammatory bowel disease, bowel fistulae, disease related malnutrition; intolerance of whole protein feeds.
To be used in line with the treatment algorithm provided to the committee

**Fluticasone and formoterol (Flutiform)**
Flutiform has been requested for the maintenance treatment of asthma. It has been requested on the grounds that it is cheaper than Seretide when higher strengths are used, and that it may aid patient compliance. At the Formulary subcommittee meeting it was noted that Flutiform is not a direct replacement for Seretide Evohaler and it was also noted that there were likely to be further licensed indications for Flutiform in the future (e.g. COPD).

The Subcommittee had not been minded to approve the request for Flutiform. Whilst it was appreciated that there is the potential for cost savings at higher doses, it is anticipated that this cost advantage could be diminished when Seretide comes off patent. It was also noted that a significant amount of work had gone into switching patients from the Seretide Evohaler to the Accuhaler, and that Flutiform is more expensive than the Accuhaler.

**Decision: Fluticasone and formoterol (Flutiform)**
**Refused**
The request for Flutiform was not approved but may be reconsidered if it gets a licence for COPD.

**Aclidinium bromide & Glycopyrronium bromide - COPD**
These long acting antimuscarinic antagonists had been requested for the maintenance treatment of COPD on the grounds that

- both agents are cheaper than tiotropium
- an increased choice of inhalers may aid patient compliance

It was noted that aclidinium has a lower rate of anticholinergic side effects, such as dry mouth, but the evidence for glycopyrronium is slightly stronger than that for Aclidinium, and that, although it is claimed that aclidinium is better for the control of night time symptoms, specialists within the NUTH have stated that this is not a major concern.
Since the Formulary subcommittee met NICE have published evidence summaries relating to both these products. These have been considered but do not change

the recommendations made by the subcommittee.
Mr. Lowery stated that both agents have been requested in addition to tiotropium but there is a preference for glycopyrronium if only one were to be approved.

**Decision: Aclidinium bromide**
**Refused** - The request for aclidinium bromide was not approved.

**Decision: Glycopyrronium bromide**
**Approved** - Glycopyrronium bromide should be included in the Formulary as a second line option for the maintenance treatment of COPD.
The positioning of Glycopyrronium as a second line choice after tiotropium, despite being slightly cheaper, is due to the lack of long term data on exacerbation reduction.

**Cefixime – Irinotecan induced diarrhoea**
Mr. Lowery stated that NECDAG had recently been asked to consider the use of cefixime to prevent diarrhoea in children undergoing treatment with irinotecan. NECDAG had refused the request but stated that Trusts might wish to make a decision locally, hence the application. Irinotecan is thought to reduce diarrhoea by reducing the intestinal flora that cleave the inactive irinotecan glucuronide metabolite reforming the active metabolite which has a direct cytotoxic action on the lumen of the intestine.

The applicant wishes to use cefixime in patients participating in a clinical trial, but also hopes to extend the use to other patients not enrolled in the trial.
Following the formulary subcommittee meeting the secretary of that committee had been asked if there had been oncology specialist input to the decision. There had not and therefore the APC was asked to consider if that altered the original recommendation to refuse the application. SW informed the committee that there had been oncology advice given at the NECDAG level (albeit in relation to use in adults).
The committee felt that there was not enough current evidence to support this use, indeed the ongoing clinical trial may provide some additional evidence once completed. It was also felt that there are other approaches available to managing such severe diarrhoea.

**Decision: Cefixime – Irinotecan induced diarrhoea**
**Refused**

The committee endorsed the remainder of the recommendations made by the subcommittee and these will be incorporated in the next formulary update.

**2013/07 Report from the Shared Care Group (SCG).**
No meeting has been held since the last APC meeting.

**2013/08 Report from the Anti-microbial Chemotherapy subcommittee.**
No meeting has been held since the last APC meeting.
The chairman had approved the antibiotic diagram supporting document which is now available on the website for members to use and disseminate.

**2013/09 Quality, Improvement, Productivity and Performance (QIPP)**
Draft minutes from the meeting on 14th November were received.
The following points were highlighted:

- Behaviour change project: Four key areas for intervention have been identified:
  1. Valuing medicines media campaign
  2. Promotion of repeat dispensing
  3. Optimise face to face medication reviews
  4. Consider how to deliver a domiciliary medicines taking support service to the hidden housebound

The summary document relating to this project will be forwarded to members.

DC emphasised that the QIPP workplan was subject to the approval of the APC but documents produced to support primary care implementation of the QIPP workplan were not necessarily developed/issued under the auspices of the APC. He emphasised that it was incumbent on authors of such documents to ensure the appropriateness of the guidance, compatibility with the formulary and that relevant approval by an appropriate authority is obtained before circulating.
The QIPP group needs to be clear on the appropriate governance structure when requests are made for documents to be produced.

**2013/10 Development and updating of local formularies and NICE Compliance**

Sir David Nicholson has written to all NHS organisations reminding them of the requirement that drugs approved by a NICE TA guideline should be included in local medicines formularies and these formularies should be published online and be patient and stakeholder accessible. PCT Clusters and Clinical Commissioning groups are required to ensure they are compliant with this guidance by 1st April 2013 at the very latest.
Keith Ridge, the DH Chief Pharmaceutical Officer has subsequently urged PCTs and CCGs to review their local formulary processes in order to begin to implement the IWH actions.

In order to ensure compliance with the IHW requirement relating to NICE Technologies the North of Tyne Area Prescribing Committee changed their processes and Terms of Reference during 2012 to ensure all TAGs are officially ratified by the APC and incorporated into the NoT formulary within 3 months of publication.
The formulary has been hosted on a public facing website for several years and therefore the requirement to be available to patients and stakeholders is already being met.
Work has now also begun to ensure previously published TAGs, and not just those moving forward, are incorporated into the formulary and this work will be complete early in 2013.

Member organisations were requested to confirm that the actions outlined above were sufficient to satisfy their obligations with regards to the requirements outlined by Sir David Nicholson and NICE Guidance on developing and updating local formularies and would enable them to declare compliance.
Members agreed that this was an appropriate response to the requirements but asked that there was also a statement inserted at the front of the formulary document making it explicit that if there was any anomaly found within the formulary that was contrary to a NICE TAG, then the NICE TAG was the position that was supported. Where NICE state that a technology is "available as an option" it shall be included in the formulary and it will then be a clinical decision on whether it is the most appropriate option for use in a particular patient.

Members need to be clear on the implications of Sir David Nicholson's requirement for their organisation.

**2013/14 North of England Specialised Commissioning Group Decision – Ivacaftor**

The four Specialised Commissioning Groups (SCGs) in England have confirmed that ivacaftor will be funded by the NHS in England for all patients aged 6 years and over with cystic fibrosis and the G551D gene mutation.
Funding for this will come from Specialist Commissioning.
The APC is required to endorse this decision and incorporate Ivacaftor into the formulary.
The full evaluation will be forwarded to members for information.
The implications of the expansion of national decision making were discussed. There is concern that in the transition period, where NETAG and NECDAG hand over responsibility for their work, there will be decisions needing to be made that become incumbent on the APC that would not previously have been in their remit.

**2013/15 Documents previously circulated by email**

- NETAG Treatment Appraisal: Decision Summary - Bevacizumab (Avastin®) for hereditary haemorrhagic telangiectasia
- NETAG Treatment Appraisal: Decision Summary - Perampanel (Fycompa®) for focal epilepsy
- NECDAG CDF Approval - Abiraterone in combination with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men whose disease is failing hormone therapy (chemotherapy naïve)
- NECDAG Gateway Decision – Approval – Aresenic trioxide in relapsed or refractory acute promyelocytic leukaemia
- NECDAG CDF Approval - Bevacizumab (Avastin®) in combination with irinotecan for the treatment of Low Grade Gliomas in paediatric patients
- NECDAG Decision document - Glucarpidase (Varoxase®) For the treatment of toxic plasma methotrexate concentrations (>1 micromole per litre) in patients with delayed methotrexate clearance due to impaired renal function, in the following situations:
    - Delayed elimination of methotrexate
    - Impaired renal function
    - Significant methotrexate toxicity
- NECDAG CDF Approval - Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours – confirmation of continued approval beyond NICE TAG 265.
- NECDAG Gateway Decision – Approval –Rituximab chemo induction 1st line NHL
- NECDAG Gateway Decision – Approval –Rituximab for the treatment of patients with hairy Cell Leukaemia (HCL) or Hairy cell Leukaemia variant (HCL-v) who:
    - Relapse early after purine analogue therapy (< 2 years post treatment)
    - Are refractory to purine analogues.

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

**2013/16 APC Guidelines and Statements for review**

- Agomelatine – this Blue information sheet will be updated to reflect recent MHRA advice relating to liver function testing. ST will make suggested changes and forward to HW for approval through the shared care group and then the APC.
- Denosumab – ML will work with the author of this information sheet to update and forward to HW as above.

**2013/17 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 November and December:

- TA266: Cystic fibrosis - mannitol dry powder for inhalation – Bronchitol
- TA 267: Chronic Heart Failure - Ivabradine
- TA268: Melanoma (stage III or IV) - ipilimumab
- TA269: Melanoma (BRAF V600 mutation positive, unresectable metastatic) - vemurafenib

NB. The recommendation within TA 267 extends the use of ivabradine as an option beyond the previous North of Tyne approval. The formulary will now reflect the NICE position.

**2013/18 Chair's action**

- Newer Oral Anticoagulants Comparison Document
- Newer Oral Anticoagulants Licensed Indications

Both these documents have been approved and are available on the APC website, under the Guidelines and Statements section, for members to use and disseminate within their organisations.

**2013/19 Any other business**

- Subgroup Terms Of Reference – it was agreed to delay the review of these until the changes in the NHS structure and the responsibilities of the new organisations become clearer.

**2013/20 Date and time of next meeting**

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

**Signed:** ..... **Date:** 12/3/13

**(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 8th January 2013.**

## 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** | | | | |
| **Infratini Peptisorb®** | √ | | | Infatrini 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. Previously deferred subject to the production of treatment algorithm. This has now been received, along with costing projections. The applicant has confirmed that Infatrini Peptisorb would be prescribed by only two senior dieticians.<br><br>**Decision :Approved**<br>To be used in line with the treatment algorithm provided to the committee |
| **2) New Requests** | | | | |
| **Argatroban** | √<br>R | | | Argatroban is a direct thrombin inhibitor which has been requested for patients with heparin-induced thrombocytopenia type II who require parenteral anticoagulation. Lepirudin, an alternative treatment, has been discontinued. Argatroban can be monitored using the standard ATPP test, unlike the alternative treatment, danaparoid. Argatroban has a shorter duration of action than danaparoid, and, unlike danaparoid, is not renally excreted.<br><br>**Decision: Approved***:* The request for argatroban for the treatment of HIT was approved. |
| **Steriflex 165** [u]<br><br>Potassium chloride 0.3% (20mmol); sodium chloride 0.9%; and glucose 5%<br><br>500ml | √<br>R | | | Use of this product is recommended in current guidelines from the British Society of Paediatric Endocrinology and Diabetes for the management of diabetic ketoacidosis.<br>This is an unlicensed product but avoids having to add potassium to standard bags of sodium chloride and glucose at ward level.<br><br>**Decision: Approved***:* The request for Steriflex 165 for the management of diabetic ketoacidosis was approved. |

| Product | Decision | | | Comments/notes |
|---|---|---|---|---|
| | Approved | Refused | Deferred | |
| **Fluticasone & Formoterol (Flutiform®)**<br><br>50mcg/5mcg<br>125mcg/5mcg<br>250mcg/10mcg | | √ | | Flutiform is licensed for the maintenance treatment of asthma. It has been requested on the grounds that it is cheaper than Seretide when higher strengths are used.<br>There is the potential for cost savings at higher doses but these savings could be diminished when Seretide comes off patent. It was also noted that a significant amount of work has already gone into switching patients from the Seretide Evohaler to the Accuhaler, and that Flutiform is more expensive than Seretide Accuhaler.<br><br>**Decision: Refused**: The request for Flutiform was not approved but may be reconsidered if it gets a licence for COPD. |
| **Aclidinium bromide** | | √ | | This long acting antimuscarinic antagonist had been requested for the maintenance treatment of COPD. It is cheaper than tiotropium and would offer increased device choice. Aclidinium has a lower rate of anticholinergic side effects, such as dry mouth but the evidence for improved efficacy compared with tiotropium was lacking.<br><br>**Decision: Refused**<br>The request for aclidinium bromide was not approved. |
| **Glycopyrronium bromide** | √ | | | This long acting antimuscarinic antagonist had been requested for the maintenance treatment of COPD. It is cheaper than tiotropium and would offer increased device choice. Although it is currently a cheaper option than tiotropium, tiotropium will remain the first line choice of LAMA due to the lack of long term data on exacerbation reduction with glycopyrronium.<br><br>**Decision: Approved**<br>Glycopyrronium bromide should be included in the Formulary as a second line option for the maintenance treatment of COPD. |
| **Mannitol (Osmohale®)** | √<br>R | | | Inhaled mannitol has been requested for diagnostic use when conducting spirometry and bronchial provocation testing as an alternative to methacholine on the grounds that it is cheaper and may be better tolerated in patients who are unable to tolerate the taste of methacholine.<br><br>**Decision: Approved**<br>The request for mannitol was approved. |

| Product | Decision | | | Comments/notes |
|---|---|---|---|---|
| | Approved | Refused | Deferred | |
| **3) New formulations & extensions to use** | | | | |
| **Ulipristal 5mg tablets** | √ R | | | Requested to shrink uterine fibroids and stop bleeding before surgery. GnRH agonists are used for indication but can cause bone density loss and menopausal symptoms. There is no data to demonstrate improved surgical outcomes but it is accepted that reducing the size of fibroids makes surgery more successful.<br><br>**Decision: Approved**<br>The request for ulipristal was approved. It will be classified as a red drug with the duration of use restricted to 3 months prior to surgery. |
| **Denosumab** [u] | √ B | | | Denosumab has been requested for use in men with osteoporosis who are not able to tolerate bisphosphonates or strontium ranelate. There is some evidence to suggest it has similar benefits to those seen in women. This is an unlicensed indication but it was noted that the manufacturer is in the process of applying for a licence.<br><br>**Decision: Approved**<br>The request for denosumab in men with osteoporosis was approved. It will be classified as a blue drug. |
| **Cefixime** [u] | | √ | | Requested to prevent irinotecan related diarrhoea. Evidence presented was from phase 1 studies only. The applicant wishes to use cefixime in patients participating in a clinical trial, but also hopes to extend the use to other patients not enrolled in the trial.<br><br>**Decision: Refused** |
| **Sublingual/buccal fentanyl** | √ R | | | The Palliative Care team has supported a previous request for sublingual/buccal fentanyl in patients undergoing radiotherapy and allayed the previously raised safety concerns. The Palliative Care Team has experience of using sublingual fentanyl in this indication and is highly involved in the treatment of these patients.<br><br>**Decision: Approved**<br>Abstral was approved for restricted use in patients who experience incident pain during radiotherapy:<br>• on positioning for treatment<br>• or who experience pain flare during the course of radiotherapy treatment.<br>The Palliative Care Team must ensure that the monitoring as outlined in the request is adhered to. |
| **4) Products considered by NECDAG and decisions endorsed by APC** | | | | |
| **Arsenic Trioxide for relapsed or refractory acute promyelocytic leukaemia (APL).** | √ R | | | Approved by NECDAG 28.11.12<br>For implementation at specialist Haematology Units Only |

| Product | Decision | | | Comments/notes |
|---|---|---|---|---|
| | Approved | Refused | Deferred | |
| **Abiraterone acetate (Zytiga®)** | | See notes | | 28.11.12 :NECDAG considered Abiraterone in combination with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men whose disease is failing hormone therapy (chemotherapy naïve) – (currently unlicensed)<br>**Decision:**<br>**Rejected from Standard NHS Funding**<br>**Provisionally Approved from Cancer Drug Fund** AFTER the MHRA have confirmed its safety and efficacy in this indication by granting abiraterone a product licence for this indication PROVIDED the NSSG agree a set of stopping rules which may include re-discussion at an MDT for some patients where there is a borderline evidence of benefit.<br>Note this approval is subject to ongoing review of priorities and along with all CDF approvals will be reviewed for 2013/14.: |
| **Bevacizumab (Avastin®) in combination with irinotecan for the treatment of Low Grade Gliomas in paediatric patients** | | See notes | | NECDAG – Considered 28.11.12 – Unable to fund through normal route due to lack of evidence of cost effectiveness therefore considered for CDF.<br>**Decision:**<br>**Rejected from Standard NHS Funding**<br>**Approved from Cancer Drug Fund** for the treatment of Low Grade Gliomas in paediatric patients that are resistant to standard therapies. To be used pre radiotherapy (Unlicensed indication)<br>(Note existing patients who have already received radiotherapy may receive treatment, for new patients treatment must be used prior to radiotherapy.) |
| **Rituximab 375mg/ m2 for 6 cycles in combination with a standard NHL induction regimen. (Frequency variable depending on regimen e.g. CVP / DECC/MACOP-B)** | √ R | | | Approved by NECDAG 28.11.12<br>Gold standard chemotherapy for patients with DLBCL is R-CHOP. Some patients who may be more frail or who have history of cardiac disease cannot be given Anthracycline. Rituximab with other chemotherapy regimens is an alternative treatment option e.g. DECC, CVP for this group of patients, as part of their first line therapy. Additionally, Rituximab would be added to the MACOP-B regimen for the small number of young patients with DLBCL, subtype Primary Mediastinal B cell Lymphoma. |

| Product | Decision | | | Comments/notes |
|---|---|---|---|---|
| | Approved | Refused | Deferred | |
| **Rituximab – 375mg/m2 every 2 weeks, for 6 doses ( unlicensed indication ) for the treatment of patients with hairy Cell Leukaemia (HCL) or Hairy cell Leukaemia varian (HCL-v) who:**<br>• **Relapse early after purine analogue therapy (< 2 years post treatment)**<br>• **Are refractory to purine analogues.** | √<br>R | | | Approved by NECDAG 28.11.12.<br>To be implemented following agreement from the Haematology NSSG |
| **Glucarpidase (Varoxase®) (Unlicensed) for the treatment of toxic plasma methotrexate concentrations (>1 micromole per litre) in patients with delayed methotrexate clearance due to impaired renal function, in the following situations:**<br>• **Delayed elimination of methotrexate**<br>• **Impaired renal function**<br>• **Significant methotrexate toxicity** | See notes | | | **Decision:**<br>Approved for NHS funding subject to discussion with local commissioners.<br>Rejected for CDF funding |
| **Denosumab for the prevention of skeletal-related events in adults with bone metastases from prostate cancer** | | | | **Decision:** Approved for CDF funding<br>The NE CDF will continue to fund denosumab for patients with metastatic prostate cancer who have poor venous access and intolerance of oral bisphosphonate, or mild/moderate renal impairment and intolerance of oral bisphosphonate or intolerance of intravenous and oral bisphosphonate. |
| **5) Products considered by NETAG and decisions endorsed by APC** | | | | |
| **Bevacizumab (Avastin®) for hereditary haemorrhagic telangiectasia** | | √ | | 13/11/2012: The NHS North East Treatment Advisory Group does not recommend bevacizumab for hereditary haemorrhagic telangiectasia. |

| Product | Decision | | | Comments/notes |
|---|---|---|---|---|
| | Approved | Refused | Deferred | |
| **Perampanel (Fycompa®) for focal epilepsy** | √ | | | 13/11/2012: The NHS North East Treatment Advisory Group recommends perampanel for partial (focal) seizure epilepsy only when other treatment options recommended by NICE have been tried or fully considered.<br>The group recommends that perampanel should only be initiated by specialists. |
| **6) Products considered by NESCG and decisions endorsed by APC** | | | | |
| **Ivacaftor (Kalydeco) for cystic fibrosis** | √ | | | The four Specialised Commissioning Groups (SCGs) in England announced on 19th December that ivacaftor will be funded by the NHS in England for all patients aged 6 years and over with cystic fibrosis and the G551D gene mutation as set out in the licensed indication.<br>The APC therefore endorses this decision and Ivacaftor will be added to the North of Tyne Formulary in line with this decision. |
| **7) Products considered by NICE** | | | | |
| **TA266: Cystic fibrosis - mannitol dry powder for inhalation – Bronchitol** | √ | | | Approved in line with NICE TAG |
| **TA 267: Chronic Heart Failure - Ivabradine** | √ | | | Approved in line with NICE TAG. The previous restriction on the North of Tyne approval will be relaxed to match the NICE TAG. |
| **TA268: Melanoma (stage III or IV) - ipilimumab** | √ | | | Approved in line with NICE TAG. |
| **TA269: Melanoma (BRAF V600 mutation positive, unresectable metastatic) - vemurafenib** | √ | | | Approved in line with NICE TAG. |
| **8) Appeals against earlier decisions by the APC** | | | | |
| **None** | | | | |
| **9) Miscellaneous decisions by the APC** | | | | |

| Product | Decision | | | Comments/notes |
|---|---|---|---|---|
| | Approved | Refused | Deferred | |
| **Mesalazine 400mg MR (Octasa 400mg MR)** | √ | | | Mesren 400mg MR, which is currently the first choice mesalazine preparation, has been rebranded to Octasa but the price will remain unchanged. The Subcommittee noted that this could encourage use of the non formulary 800mg MR product of the same name.<br>**Decision: Approved**<br>Octasa 400mg MR will be added to formulary in place of Mesren. |
| **Topiramate** | √ | | | NICE CG150 recommends topiramate as a treatment option for migraine.<br>**Decision: Approved**<br>The Formulary will be updated to reflect the recommendation. |
| **Levetiracetam** | √ | | | Levetiracetam is included in the Formulary as an alternative treatment option for a number of epilepsy types however recently published NICE (CG137) guidance recommends it as first line option for some of the epilepsies.<br>**Decision: Approved**<br>The Formulary first and alternative choices for the different epilepsies will be updated in line with NICE CG137 |
| **Glyceryl Trinitrate 0.2% ointment** | | √ | | To be removed from the formulary. |