

NORTH OF ENGLAND CANCER DRUG APPROVAL GROUP (NECDAG)

Executive Summary

The North of England Cancer Network Drug Approval Group (NECDAG) was established in May 2006 to ensure 'all patients with cancer in the North East receive equitable access to a clinically defined appropriate range of cancer medicines.'

The NECDAG considers applications for curative and palliative drugs which are not in the National Institute for Clinical Excellence (NICE) system and also those drugs which are more than six months away from being considered by NICE. Drugs that are scheduled to have final guidance published by NICE within three months of the meeting are not discussed. The group meets 4 to 5 times per year dependent on workload of applications to process. Each meeting is preceded by a 'Gateway Group' where the applications are prioritised and cost effectiveness evidence added to the application by the Network Pharmacist(s).

The NECDAG Committee serves all of the North of England Cancer Network organisations, encompassing 9 Acute Trusts, 5 Primary Care Organisations, several Hospices/Specialist Palliative Care services and spans 2 Strategic Health Authority areas. North Yorkshire and York PCT representatives also attend these meetings as an observer.

The NECDAG has delegated authority from strategic commissioners to financially approve or reject drugs presented for consideration. Decisions on affordability are made by PCT representatives on the day of the meeting. Following each meeting a 'Decision Summary' document is prepared for each drug considered and issued to stakeholders throughout the Network within seven days and subsequently posted on the website with the minutes of the meeting. This report details the background to the formation of NECDAG, describes the operation of the group, lists its decisions and comments on the challenges faced in this area.

In conclusion NECDAG represents a workable model for local NHS decision making on cancer medicines, the key elements to NECDAG success are:

- The backing and support of the Strategic Health Authorities in the North East and in Cumbria
- Close integration of the North of England Cancer Network with the SHA and the expertise and support of the Network in running the NECDAG
- Clinical involvement from Oncologists, both in supporting applications and as members of the committee
- Buy in from PCTs to collective decision making to ensure equity for patients
- Strong leadership and close links with the NHS senior management

Background to Development of Group

In 2005 there were two North East Cancer Networks each with a Drug and Therapeutic Committee making decisions on cancer medicines. The merger of the North East Strategic Health Authority (SHA) and the ongoing media scrutiny of the decisions of the Cancer Networks highlighted the need consistency of decision making across the North East. At this time there were two high profile public media campaigns for cancer medicines in the North East, adjuvant Herceptin and Alimta for mesothelioma, which ensure that this was a high priority area for executive action.

If equity of access to cancer drugs was to be ensured across the whole of the new SHA it was essential that a joint drugs approval process is established across the two cancer networks. This process had to enable clear and consistent advice to be given to all NHS organisations within the North East. The establishment of the NECDAG was the first step in the eventual merger of the two cancer networks which commenced in January 2007.

Role of NECDAG

NECDAG was established in May 2006 to provide NHS commissioners with clear advice, bringing together clinical and pharmacological experts from cancer network, senior public health physicians, PCT top management, SHA representatives and patient panel members. Its function is primarily to approve or reject requests for the clinical approval and funding of new cancer pharmaceuticals. Its aim is to ensure 'all patients with cancer in the North East receive equitable access to a clinically defined appropriate range of cancer medicines.' A summary of all the decisions made by the group can be found in appendix one, and the terms of reference of NECDAG and its Gateway subgroup are given in appendix 2 and 3.

Role of Network in NECDAG

The network team manages the functioning of the NECDAG. The network pharmacists give advice based on robust clinical evidence, undertake assessments of cost effectiveness and provide estimates of drug usage per population and associated costs at Network and PCT level. Horizon scanning is undertaken to identify cancer drugs due for NICE approval, licence extension, significant new clinical evidence or award of new licence. The Network Director Acts as vice chair and Network Consultant Pharmacist act as professional secretary to the group.

Role of commissioners in NECDAG

³ The role of commissioners is to manage resources and identify funding priorities as members of NECDAG. Following receipt of advice from NECDAG, PCTs agree to commission these drugs. While PCTs would not formally be bound to accept the advice of CDAG as it is not a statutory body, it is strongly recommended that they should do so and make collective decisions that ensure equity of access to all patients in the new SHA. Any PCT that decided not to accept the recommendation of CDAG would need to explain and justify its position to its public and the SHA. The commissioners on the group have the final say in approval of medicines.

Role of Patients and Public in NECDAG

NECDAG has a patient participation. Feedback from patient groups indicates that there is great value in patients seeing the thought that goes into the process of approving or not approving new drugs. Patients know that drugs must be cost effective, but often, due to media hype, the public is left with the notion that cost is the prime consideration. NECDAG strives to increase understanding of the issues surrounding cancer medicine approval.

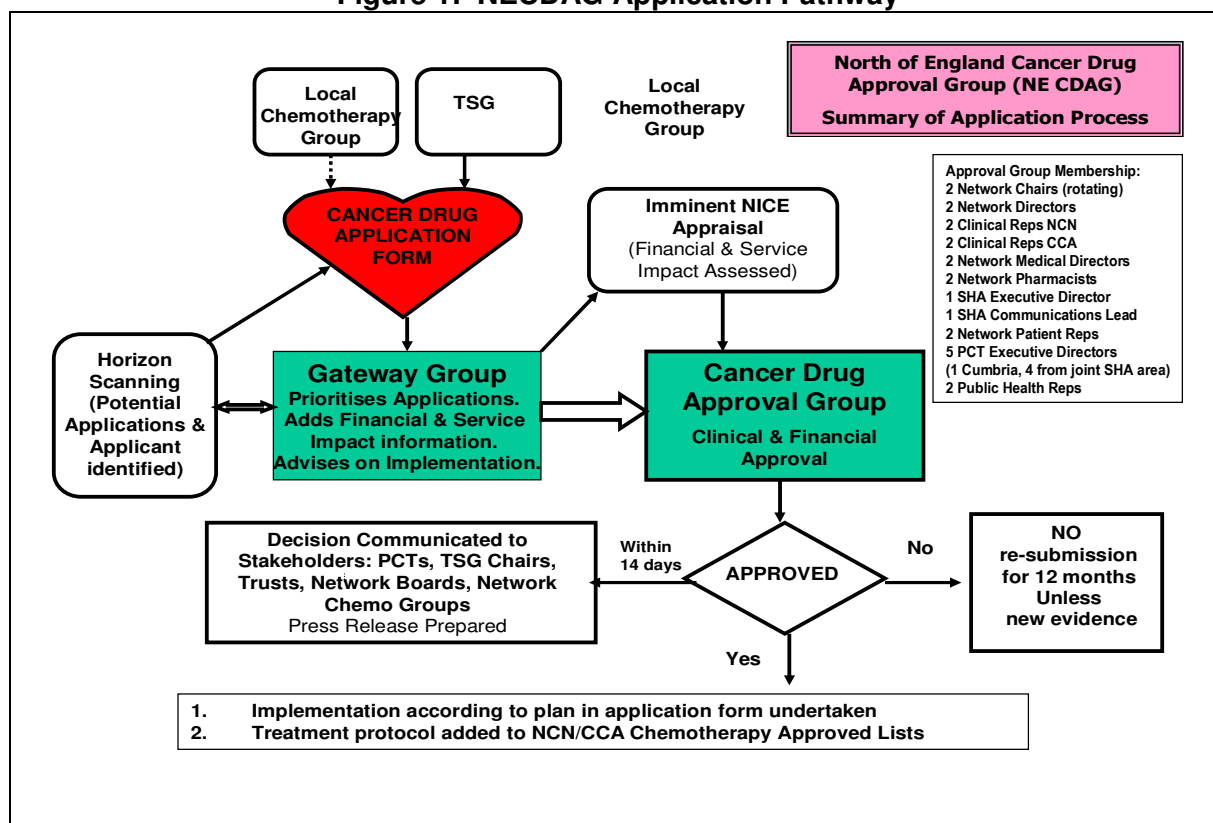
Role of Pharmaceutical Industry

NECDAG does not receive applications directly from the pharmaceutical industry. The Network pharmacists will liaise with industry and once an application is received invite industry to submit supporting evidence of cost effectiveness and budget impact models where available. The group recognises the value of maintaining close links with industry and has worked with Pharma on risk share schemes to support applications, making drugs more affordable and hence increasing likelihood of gaining access for North East patients.

Operation of NECDAG

NECDAG is different from many Network groups in its integration into the local NHS and support from commissioners. Support for NECDAG has been integrated into local world-class commissioning competencies. NECDAG decisions are binding to the North East PCTs. Unlike some other local English groups, if NECDAG approve a drug it is guaranteed to be funded. In summary the NECDAG process involves applications from local clinicians, either via the Trust chemotherapy groups (or equivalent D&Ts) or the Network Tumour Groups. A summary of the process is shown in figure 1 below.

Figure 1: NECDAG Application Pathway



A key strength of the group is having a Trust Chief executive as Chair, this adds great credibility to the group, and has proven invaluable to having chair(s) able to bring the broad overview and vision of a CEO to the process.

NECDAG Decision Making

Introducing new cancer medicines is a challenge, NECDAG makes three key decisions;

1. Is the drug clinically effective?
2. Is the drug cost effective?
3. Can the local healthcare economy afford the budget impact?

Determination of Clinical Effectiveness

NECDAG members consider submissions along with accompanying evidence and judge if the treatments are considered clinically effective. The committee looks for published evidence from randomised clinical trials in peer reviewed journals that shows clear advantage over existing treatment, ideally with evidence of improvements in survival. Service impact is also considered.

Determination of Cost Effectiveness

NECDAG uses the same criteria as the National Institute of Clinical Excellence (NICE) to calculate cost effectiveness. The NECDAG uses QALY (quality adjusted life years) and LYG (life years gained) as measures of cost effectiveness. The cost limit per QALY is one the used by NICE.

Determination of Affordability

If clinical and cost effectiveness are proven NECDAG members then consider the issue of local affordability. NECDAG does not have a 'budget' but sets a limit on the number of new drug applications that can be processed in any financial year, currently 12 per year. The horizon scanning undertaken by the group is used by PCTs to inform the potential costs of NECDAG and NICE approvals each year.

Communication

NECDAG decisions are widely disseminated within seven days of a meeting. Decisions are expected to be implemented immediately unless any service development issues are identified during the application process. A press release is prepared and the media informed by the SHA/PCT communications lead who supports the group. NECDAG has tried to be proactive with media but recognises the ongoing challenges the media presents.

Membership

Membership of the committee includes representatives from the following:

- Chair (Chief Executive)
- Network Director
- Network Pharmacists
- 4 Clinical Representatives (oncologist/ Haematologist)
- 2 Patient and Carer Representatives
- Network Medical Director and Lead Clinician
- SHA Executive Lead & Public Health
- Communications Lead
- 5 PCO Executive Leads (1 N Cumbria, 4 from combined North East SHA area)

Governance

It is acknowledged that in the longer term the role of NECDAG may change as a result of the national approval process (NICE) being accelerated for cancer drugs. However, in line with the mandate from the Joint Chief Executives' Group the group will continue to meet as long as there is a local need. NECDAG is accountable to the Network Board and its constituent Trust and PCT members.

Dealing with Appeals

Once a decision is made the group will not review a decision within 12 months unless there is new evidence, which can include economic evidence. Appeals against a decision would only be heard if it was felt that the group had made a mistake in its interpretation of the evidence.

Exceptional Circumstances

The existence of NECDAG has discouraged the use of the exceptional circumstance route as way of routinely funding cancer medicines. It is recognized that in other parts of the UK this route is often used in the absence of NICE or local approval mechanisms. NECDAG will not deal with EC requests directly since there is a potential conflict of interest as the EC request could be for medicines NECDAG has rejected. The network pharmacists are available to provide expert clinical advice and give the position of the NECDAG to PCTs dealing individual EC requests. This ensures there is consistency in decision making, as far as possible, amongst PCTs dealing with EC requests.

Benchmarking and concordance with NICE Decisions

The group has a standing agenda item to review decisions from the Scottish Medicines Consortium and the London New Cancer Drugs Group. This acts as a benchmark for NECDAG decisions. One of the group's functions is to facilitate the implementation of NICE guidance in the North East. NICE appraisals of cancer medicines are carefully monitored, the group will not review a medicine if final NICE guidance is due within three months of a meeting.

As NECDAG makes decisions before NICE there exists the potential for NICE to make a different decision to that made by NECDAG. In this situation the decision made by NECDAG would be reviewed in light of NICE guidance and updated to reflect the view of NICE. This would potentially mean withdrawing a treatment. As yet no treatments have been withdrawn but there have been three instances where NECDAG decisions made **before NICE** have differed from the initial draft NICE decisions;

- Pemetrexed for Mesothelioma – NECDAG approved, NICE rejected, eventually NICE decision changed following appeal and final NICE decision matched NECDAG position.
- Temozolamide for adjuvant glioma - NECDAG approved for PS 0 and PS 1 less 50 years. NICE initially rejected, eventually NICE decision changed following appeal and final NICE decision approved for PS 0 & 1.
- Erlotinib for NSCLC – NECDAG approved as an alternative to 2nd line docetaxel when obtained using a 'risk share' scheme to match price of docetaxel. NICE rejected but on appeal latest draft approved for limited use provided pricing deal used to ensure costs not greater than docetaxel.

Co-Payment

The group has provided advice for North East Trusts on difficult issues involving cancer medicines such as co-payment, including obtaining detailed legal advice.

Gateway sub group

NECDAG is supported by a gateway group which has been given delegated authority to discuss and make decisions on treatments that have very low financial impact. Provisional limit less than £200,000 for whole Network, approximately £20,000 per PCT. Low financial impact drugs with a QALY value greater than £25,000 or drugs that are deemed politically sensitive are still sent to NECDAG for consideration. A decision summary document is prepared for each of the Gateway decisions and taken to the main NECDAG for approval. This reduces the burden of work on NECDAG making the process more manageable.

Use of QALYS

NECDAG bases itself on NICE and uses QALYS, but has a pragmatic approach to working with QALYS as it is acknowledged that NECDAG does not have a health economist. The network pharmacists prepare basic in-house QALY models. NECDAG recognises that not all interventions easily assessed by basic QALYs and that QALYs have many limitations, not least of which is their sensitivity to small variations in cost and survival data. QALYS are seen as a guide only. Industry health economists can produce very comprehensive detailed economic models, but it has to be acknowledged that health economic models are based upon assumptions and NECDAG will review the assumptions behind any model it receives. Producing QALYS is not an exact science.

A great strength of NECDAG has been the willingness of the group to look at novel approaches to obtain access to medicines that would otherwise have too high a QALY to allow approval. For example adopting risk share schemes and limiting access of drugs to those patient groups that derive greatest benefit in order to maximize the cost effectiveness.

Challenges for Future

NECDAG faces many challenges, is has to learn to deal with phase trial II evidence and make cost effectiveness assessments when there is lack of survival data. NECDAG must learn to work with industry on prices and has to be mindful of managing the media.

Conclusions

The North East Cancer Drugs Approvals Group is effective and credible. NECDAG has achieved equity within the North East but acknowledge there are differences elsewhere. The groups immediate future looks secure as at national level NICE is increasing constrained by legal and process challenges which impact on its ability to deliver timely advice on new cancer medicines.

NECDAG represents a workable model for local NHS decision making on cancer medicines, the key elements to NECDAG success are:

- The backing and support of the Strategic Health Authorities in the North East and in Cumbria
- Close integration of the North of England Cancer Network with the SHA and the expertise and support of the Network in running NECDAG
- Clinical involvement from Oncologists, both in supporting applications and as members of the committee
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Appendix One Decisions: The Following table lists the decisions made by the group

Drug(s)	Indication	Date considered	Decision	Estimated Cost Impact (NECN)	Comments
Irinotecan	Advanced colorectal cancer	23 January 2008	Approved	Cost Neutral	Addition of weekly single agent irinotecan as option for treatment of advanced colorectal cancer, for those patients not suitable for NICE approved 3 weekly regimen
Topotecan (in combination with cisplatin)	Carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease.	23 January 2008	Approved with restrictions	£37,500 for the Network.	Restricted to patients who have been cisplatin free for a period of at least 12 months. Use without GCSF Support
2 nd line Sunitinib for GIST	Gastrointestinal Stromal Tumours (GIST) after Imatinib Failure	23 January 2008	Approved	£130,163 for the Network.	Approved using reduced costs from Sunitinib risk share scheme to achieve cost effectiveness.
2 nd Line FOLFIRI (Irinotecan Modified DeGramont)	Advanced colorectal cancer	7 November 2007	Approved	£38,400 for the Network.	FOLFIRI is approved as 2 nd line therapy following 1 st line treatment with FOLFOX.
Erlotinib (Tarceva)	Non Small Cell Lung Cancer 2 nd Line as an alternative to docetaxel (Taxotere)	7 November 2007	Approved as an alternative to 2 nd line docetaxel (Taxotere).	£4,931 per patient (125 days treatment)	In theory implementation is cost neutral since patients who would otherwise have received docetaxel will instead receive erlotinib at equivalent price. However the committee acknowledged that the convenience of the oral dose form and more favourable side effect profile may mean that patients eligible for docetaxel who would have not received it due to concerns over their ability tolerate it will receive erlotinib

Drug(s)	Indication	Date considered	Decision	Estimated Cost Impact (NECN)	Comments
Cisplatin & Docetaxel	Advanced Oesophagogastric Cancer for patients unsuitable for ECX/ECF	7 November 2007	Approved	£12,420	Restricted to patients unsuitable for standard therapy with ECF or ECX regimens due to potential toxicity with fluoropyrimidine based chemotherapy.
Neulasta® (pegfilgrastim) 6mg solution for injection	Reduction in the duration of neutrophenia and the incidence of febrile neutropenia (FN) in chemotherapy patients	7 November 2007	Approved	Up to £502,634 (However potentially cost neutral dependant on current GCSF usage)	Certain Trusts in NECN purchase Neulasta via a price deal with Amgen based on replacing existing GCSF usage with Neulasta® (pegfilgrastim). NECN asked the manufacturers to provide the same offer of price deal to all Trusts in the Network. (Not for use in patients with the CML & MDS)
Oral Vinorelbine	A single agent or in combination for the treatment of advanced breast cancer	7 November 2007	Approved	£165,000	Used for patients with stage 3 and 4 relapsing after or refractory or anthracycline containing regimen.
Aprepitant (Emend®)	Prevention of Chemo Induced Nausea & Vomiting in patients receiving high dose cisplatin & patients who fail standard anti-emetic	23 July 2007	Approved	1 cycle of treatment costs £47.42+vat, with a typical cost per patient around – £280.	Costs are covered within tariff individual costs per PCT or Trust have not been calculated
Ritixumab (Follicular Lymphoma)	Relapsed/ refractory follicular lymphoma responding to induction chemotherapy with or without Rituximab.	23 July 2007	Approved	Year 1 - £268,514 Year 2 - £537,028	Further work ongoing defining the patient pathway for follicular lymphoma.

Drug(s)	Indication	Date considered	Decision	Estimated Cost Impact (NECN)	Comments
Sunitinib (Sutent®)	First line for Renal Cell Carcinoma	23 July 2007	Approved	£674,600 per year + (a non-recurrent cost of £202,620*)	*NE NHS Chief Executives agreed the small number of patients who have already received first line treatment with interferon may not be able to receive Sunitinib if clinically appropriate. (approximately 12). However, this was not a general approval for Second Line use of Sunitinib but recognition that there are some patients who may benefit from receiving it
Zevaline® (Yttrium-90 labelled Ibritumomab tiuxetan)	The treatment of adult patients with CD20+ follicular B-cell non-Hodgkin's lymphoma (NHL) resistant to/ relapsed after Rituximab.	7 March 2007	Rejected	£10,356.30 per patient per year. None – as not being implemented.	
Dasatinib (Sprycel®) for Chronic Myeloid Leukaemia	Adults with chronic, accelerated or blast phase chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate (Gilevec).	7 March 2007	Rejected	£31,714 per patient per year. None – as not being implemented.	
Bexarotene (Targretin™)	Skin manifestations of advanced stage (CTCL) cutaneous T-cell lymphoma patients refractory to at least one systemic therapy	7 March 2007	Approved with restrictions	£90,000 per year maximum. .	Likely to be £45K per year as a number of patients already treated

Drug(s)	Indication	Date considered	Decision	Estimated Cost Impact (NECN)	Comments
Sorafenib (Nexavar®) and Sunitinib (Sutent®)	Second line for Renal Cell Carcinoma	7 February 2007	Rejected	None -not being implemented.	No published cost effectiveness data was available
Pegylated-Cytarabine (Depocyte)	Intrathecal treatment of lymphomatous meningitis	7 February 2007	Approved	£29,275	Centre only treatment
Oral Uftoral® (tegafur/uracil)	Advanced Colorectal Cancer	1 November 2006	Approved	£3,500 for both Oral Uftoral & Folinic Acid.	Previously NICE approved. Unable to estimate uptake, likely to be small and instead of existing treatment option.
Temozolomide (Temodal)	Concomitant & adjuvant temozomide with radiotherapy for malignant glioma with good performance status	1 November 2006	Approved	£564,960 per year.	Subsequently NICE approved
Docetaxel (Taxotere) FEC-T	Adjuvant use in patients with Node Positive Breast Cancer	1 November 2006	Approved	Drug costs per patient £5.3K plus £3K. Totals of £169,600 and £96,000	NICE approved NICE estimates that 32 patients per million population will be eligible for treatment with this regimen.
Capecitabine	GI Cancers (ECX regimen etc)	5 July 2006	Approved	Cost Neutral	Delivery cost should be neutral and capacity from nursing and pharmacy time being freed would be able to be redeployed for delivery of NICE Adjuvant Colon Guidance.

Drug(s)	Indication	Date considered	Decision	Estimated Cost Impact (NECN)	Comments
Alemtuzumab (MabCampath)	Chronic Lymphocytic Leukaemia with disease less than 5 cm (Third Line)	5 July 2006	Approved	£12-13 per patient and approximately 15 patients per year in both networks (5 per million population) = £65,000	
Erlotinib (Tarceva)	Non Small Cell Lung (Second or Third Line)	5 July 2006	Rejected		The Committee noted that no published cost effectiveness data was available. An estimate Cost per Life Year Gained and QALY had been made. The Committee concluded that the economic case had not been demonstrated. SUPERCEDED by 7.11.07 DECISION
Oral Vinorelbine	Non Small Cell Lung (First Line) NSCLC		Approved		Equalising practice between CCA and NCN (previously approved in NCN)

Appendix Two

NECDAG Terms of Reference

North of England Cancer Drug Approval Group (NECDAG)

Purpose

To ensure that all patients with cancer in the North of England Cancer Network (NECN) receive equitable access to a clinically defined appropriate range of cancer medicines.

Terms of Reference

The NECDAG will:

- Act as an expert making body within the NECN and make decisions about availability of new and existing cancer drugs and treatments based on proven clinical outcomes, value for money and affordability.
- Accept all NICE recommended drugs.
- Drugs due to receive final NICE recommendation within 3 months of the meeting date will not be considered.
- The group has the capacity to deal with approximately 12 new applications per year and must therefore operate a system of prioritising applications. Drugs will be considered for approval in the following order of priority:
 - non NICE recommended potentially curative drug
 - non NICE Palliative (non curative)
- To receive on a six monthly basis from the Gateway Group a 'Horizon Scan' to identify potential new drugs and provide commissioners with advance notice of developments.
- Consider licensed new drugs for cancer; new indications for old drugs; new combinations of drugs; hormonal, supportive and other licensed new/novel treatments for cancer patients with associated protocols for local delivery such therapies.
- Unlicensed medicines will only be considered in exceptional circumstances as identified by the Cancer Network. Licensed medicines for unlicensed indications, the so called 'off label' use, will be considered, unless licensing is due within 3 to 6 months in which case they should be considered once licensed.
- Make recommendations on clinical effectiveness. Agree potential cost and service implications including cost effectiveness
- To give delegate authority to the Gateway/Chemotherapy Group to;
 - To discuss and make decisions on treatments that have very low financial impact. Provisional limit > £200,000 for whole Network approximately £20,000 per PCT. A decision summary document will be prepared for each of these decisions and taken to the main NECDAG for approval.

Note: There may be low financial impact drugs that the Gateway group will still send to NECDAG for consideration, e.g. drugs with a QALY value greater than £25,000 or drugs that are deemed politically sensitive.

- Give recommendations for good practice on supportive drugs that are potentially be included in tariff, eg anti-emetics. It is recognised that implementation of these therapies will be undertaken at trust level without additional funding from PCTs.
- Make changes to approved list of chemotherapy regimens where new regimens contain drugs previously approved for that indication or where financial impact is cost neutral in comparison with existing approved regimens.
- To receive audits and evaluations, including expenditure, of approved new drugs to be undertaken on a six monthly basis.
- To inform Drugs and Therapeutic Committees of acute trusts and PCTs, of its decisions and to support the appropriate implementation and monitoring by trusts.
- To make disinvestment decisions where appropriate based on clinical evidence and updated NICE recommendations.
- To encourage the use of new drug therapies in National Cancer Research Network clinical trials and to ensure suitable exit programmes for patients no longer involved in trials.

Operational Procedures of NECDAG

Membership:

Chair (Chief Executive)

Network Director

Network Pharmacists

4 Clinical Representatives

2 Patient & Carer Group Representatives

Network Medical Director and Lead Clinician

SHA Executive Lead

Communications Lead

5 PCO Executive Leads (1 N Cumbria, 4 from combined North East SHA area)

Public Health

Members' Responsibilities

No one can deputise on behalf of any members of the group without prior approval from the Network Director. PCO commissioning representatives to ensure any deputy must have financial decision making authority for the PCO. All members of the group and those asked to comment on work produced by the group will be asked to declare any conflicts of interest. Any action to be taken on the basis of these declarations will be at the discretion of the chair.

Organisation of Group

1. Committee to meet four to six times per year (there may be a need to meet more frequently on occasion to deal with the backlog issues).
2. To be quorate 3 out of the 5 PCT representatives must be present and there must be 75% agreement to carry the vote.
3. Requests for drugs/therapies for consideration by the committee to be submitted electronically on the 'New Product Request' form by given deadlines.
4. Requests may be presented by a nominated member of the Site Specific group or trust local chemotherapy group who will attend only for this part of the agenda.
5. Records will be kept of the proceedings, decisions and advice of the group including brief minutes of meeting and more detailed decision summary documents.
6. A decision summary with details of implementation issues will be circulated to all stakeholders, including SSGs, Network Groups, PCTs, and acute trusts and posted on the NECN website. These documents and minutes can be made available in the public domain. Actual applications remain confidential to ensure the protection of commercial interests and personal information.
7. Preparation of agendas and papers for the committee and day to day work generated by committee to be undertaken by Network team.
8. Circulation of papers/agendas by Network secretariat.

Authority of NECDAG

1. The NECDAG will have delegated authority from strategic commissioners to financially approve or reject drugs presented for consideration.
2. Commissioners within the group have delegated authority from strategic commissioners to approve or reject requests within agreed criteria and timescales
3. Decisions on affordability will be made by PCTs representatives on the day of the meeting. PCTs and trusts will be informed in writing of decisions within 7 days of the NECDAG meeting.

Revised November 2007

Appendix Three

Gateway Terms of Reference

North of England Cancer Drugs Approvals Group Gateway Sub-Group

The group will function as a sub-committee of the North of England Cancer Drugs Approvals Group with principle function to support the NECDAG process.

Membership

- 2 Clinical Leads
- 2 Network Pharmacists
- 2 Network Nurse Directors
- 2 Co-opted finance/commissioner representatives

Note in order to be quorate the group must have at least one of each of the all above members. Financial decisions cannot be made without commissioner representative.

Functions of the group:

1. To receive applications for new drugs for cancer, new indications for old drugs; hormonal; supportive and other novel treatments for patients on behalf of NECDAG.
2. To review applications for completeness and accuracy before they are escalated to the NECDAG. Prioritise the order in which drugs are considered
3. Work with a nominated commissioner / finance representative from a PCT in order to assist them to identify capacity impacts, and all associated costs. To provide the outcome of Quality Assessments to the NECDAG group including additional information to applications, and capacity and financial impact. Prioritise agenda items for the main committee using pre-agreed criteria.
 - non NICE recommended potentially curative drug
 - non NICE Palliative (non curative)
4. To have delegate authority from NECDAG to;
 - 6.1 To discuss and make decisions on treatments that have very low financial impact. Provisional limit less than £200,000 for whole Network approximately £20,000 per PCT. A decision summary document will be prepared for each of these decisions and taken to the main NECDAG for approval.

Note:
There may be low financial impact drugs that the Gateway group will still send to NECDAG for consideration, e.g. drugs with a QALY value greater than £25,000 or drugs that are deemed politically sensitive.
 - 6.2 Give recommendations for good practice on supportive drugs that are potentially be included in tariff, e.g. anti-emetics. It is recognised that implementation of these therapies will be undertaken at Trust level without additional funding from PCTs.
 - 6.3 Make changes to approved list of chemotherapy regimens where new regimens contain drugs previously approved for that indication or where financial impact is neutral in comparison with existing approved regimens.
5. To prepare horizon scanning information conjunction with appropriate stakeholders to provide warning to the NECDAG and stakeholders organisations of expected increased activity/ expenditure. Horizon scanning should be undertaken in depth, in advance of the LDP process and reviewed regularly.