

The commissioning of cancer drugs in England now and in the next 5 years

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Commissioning of cancer drugs

- Background
- New drugs
- NICE
- NHS England Specialised Commissioning
- Cancer Drugs Fund
- The economic climate in the NHS
- Affordability

Background to English healthcare



- The state directs almost all of health service supply (private health insurance held by 9%); total NHS England budget £102bn in 2015/16
- Commissioning of systemic therapy ('chemotherapy' but not hormone therapies prescribed by GPs for breast cancer and prostate cancer) in NHS England is central and in Specialised Commissioning (latter's total budget is £14bn)
- Spend on chemotherapy in NHS England is £1.75bn
- Drugs £1500m; tariff £250m
- Of £1500m, generic £175m; NICE approved on patent £910m; CDF £415m
- Baseline commissioning thus £1085m for drugs
- Demographic changes in cancer
- Pertuzumab CDF £50m, T-E CDF £40m; trastuzumab BC >£100m; rituximab BC >£100m; abiraterone/enzalutamide in CDF £60-70m

New cancer drugs

- 190 listed for potential licensing in next 2 years
- At least 40 will be licensed in next 2 years
- Neoadjuvant pertuzumab
- Palbociclib, LEE011
- Buparlisib
- Olaparib, talazoparib, nirapanib, veliparib
- Neratinib
- Bavituximab
- Glenbatumumab
- Etrinotecan
- Plus 3 trastuzumab biosimilars

Guidance re Commissioning of chemotherapy

- Via NICE Technology Appraisal guidance
- Via NHS England Specialised Commissioning policy
- Via the Cancer Drugs Fund

Background to NICE

- Drug regulatory framework has 3 common hurdles: safety, quality and efficacy
- NICE: clinical effectiveness – how well does something work in comparison with what we already use? NICE: cost effectiveness – how much more life or quality of life do we get for the extra money we have to pay?
- NICE thus added cost effectiveness as the 4th hurdle for reimbursement
- A positive NICE appraisal has to be funded by the NHS: as the budget is fixed, some other planned improvement has to be axed or delayed
- A negative NICE appraisal is rarely routinely funded
- NICE technology appraisals: yes in 75%, no in 25%; cancer drugs: yes in 60%, no in 40% but recently yes 33%, no 67%
- New cancer drugs: prices and costs rising and expensive vs other diseases
- Binary outcome of appraisal: cost reduction mechanisms (Patient Access Schemes) determined by and offered by most pharmaceutical companies

Current NICE cancer drug appraisals



- NICE continues to determine clinical and cost effectiveness but its role in guiding the NHS as to value and thus commissioning of cancer drugs has been undermined by the current CDF
- Outcomes of appraisals have been affected by drug pricing but also by necessary assumptions in economic modelling because of: short follow-up (survival, resource use, impact on patient pathway), cross-over design etc
- In ever greater number of appraisals, there are now more assumptions in the economic modelling, thus uncertainty is greater....and more negative appraisals
- NICE assesses evidence from clinical trial populations of patients more likely to over estimate gains to patients in every day practice
- There is no feedback loop of outcomes in the NHS back to NICE appraisal
- Most but not all cancer drugs are appraised by NICE
- NICE is barred from appraising off label drugs
- NICE approval is the best and most certain way for a drug to enter BC

NHS England Specialised Commissioning policy



- NHS E Specialised Commissioning: 75 Clinical Reference Groups
- Budget £14bn Chemotherapy £1.75bn
- Spec Comm (SC) budget has to first fund all relevant NICE TA approvals NB 95% NICE TAs are for specialised services NB Hepatitis C sofosbuvir
- Limited budget for service development (SD)
- New competitive prioritisation process for new policies
- Hundreds of new policies for consideration
- Cancer seen as favoured by fact that NICE appraises most cancer drugs and CDF budget exceeds SC SD

NHS England Specialised Commissioning policy: the process

- Annual process using ethical framework which guides decision making and prioritisation (new one due shortly)
- NHS E Specialised Commissioning horizon scanning for new - drugs, indications, devices, ways of working
- Clinical build into a policy proposal via CRG
- Spec Comm evidence review
- Spec Comm clinical panel and iteration with CRG
- Impact assessment: operational, service reconfiguration, financial etc
- Public consultation
- Consideration and decision re approval/not by SC

Late 2015 Cancer Drugs Fund: the drugs

- Political creation in 2010 with set budget
- Addition of new drugs required re-prioritisation and removal process
- 48 current approved drug indications: 4 different types of drugs
- NICE appraisal negatives: clinically effective but not cost effective despite common use of Patient Access Schemes – 17 indications
- Pre-NICE outcome: covers variable gap (3 months to >2 years) between licensing & NICE guidance – 10 indications
- Drugs below NICE's radar (rarer cancers) – 15 indications
- Off label drugs – 6 indications
- CDF: open prioritisation meetings: clinicians, pharma, patient groups, CDF panel
- CDF budget in 2015/16 £340m but likely expenditure £410m
- Current CDF an unsatisfactory way of 'commissioning': in/out
- Current CDF: early access at licensing, application by clinicians and/or pharma, rare cancers, off label usage, engagement, dialogue with manufacturers re prices, pressure on pricing, central rebating, pricing by indication

- All new cancer drug licensed indications are appraised by NICE
- NICE has 3 options re decisions: yes/no/conditional yes, latter based on uncertainty
- NICE appraisal process starts much earlier, first TA committee meeting before wording of license
- NICE issues final guidance within 90 days of MA
- NICE provisional & conditional yes drugs get access at MA
- CDF is mainly an evaluation fund for NICE uncertain drugs
- 2 year CDF funding whilst pharma ensure data collection
- Conditional yes: data maturity - NICE re-appraisal: yes/no
- Budget capped at £340m and reimbursement to pharma adjusted according to pressure on budget

Commissioning of cancer drugs in England

- Commissioning is central ie one policy for all England
- Cost of drugs and of cancer drugs are by far the single greatest cost pressure in Specialised Commissioning
- Power of a positive NICE appraisal: must be funded by NHS England
- Baseline commissioning: the only safe place for commissioning – either via NICE approval or NHSE policy (but latter is a very competitive process within specialised commissioning)
- Political creation of the Cancer Drugs Fund
- New CDF: will help to deliver long term decisions as to availability or not for all cancer drug licensed indications

Commissioning of cancer drugs

- **Baseline commissioning.** The NHS must pay for NICE positive appraisals, within a fixed allocation funding and is at a cost of some other commissioned service. NICE is here to stay but no value-based pricing. Baseline commissioning also possible via NHS England policy but cancer drug policy has to compete with all other policy developments in specialised commissioning
- **Cancer Drugs Fund** - increasing new drugs, some exciting drugs, ever increasing drug costs to treat patients, £340m allocated for 2016/17 but permanent decisions re commissioning are required
- CDF has played its part in 2015 to focus on drug pricing: major reductions in costs, imaginative ways of reimbursement to pharma, how vital a NICE yes is
- New long term solution is for the fund to be used for '**Commissioning through Evaluation**' type of process to provide evidence to both NHS and NICE of mature 'real life' benefits for drugs
- Off label drugs

Economic climate and affordability

- Spending cuts for many government departments
- NHS E budget £102bn in 2015/16; NHS £115bn
- Gov't promise of extra £8bn whilst NHS E seeks £22bn efficiency savings in next 4-5 years
- 1.2m WTE staff with pay costing about £45-50bn and pensions accounting for 67% of typical NHS employer running costs
- Demographic pressures and drug discovery
- NICE does not yet consider affordability in its decision making.....
- Cancer is lucky to have elevated status vs other diseases: NICE workload, NICE EOL rules, CDF

Commissioning of chemotherapy in 2020

- General economic climate will remain tough
- NHS budget under ever greater pressure
- Increasing pipeline of new targeted drugs, many given in combination for longer
- NICE determines which cancer drugs are in BC
- Will NHS funding direction remain for NICE TAs?
- NHS E will consider affordability of NICE TA approvals
- Pricing of drugs has to align with non cancer drugs
- Personalised medicine; biosimilars; pharma competition
- PPRS re-negotiation