Policy For The Management Of Cancer Patients For Whom Drugs Their Clinicians Have Recommended Are Not Available On The NHS.

Department / Service:	Cancer Services	
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Accountable Director:	Associate Medical Director for Cancer Services	
Approved by:	TOC	
Date of Approval:	9th April 2014	
Extension approved:	6th June 2022	
Review Date: This is the most current document and is to be used until a revised version is available	6th December 2022	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust	
Target Departments	Haematology/Oncology Directorate, Pharmacy, Finance	
Target staff categories	All Haematology/Oncology Clinical Staff, Pharmacy staff and Finance	

Policy Overview:
This document is to inform practice when cancer patients wish to pay privately for cancer medications and related services not funded by the NHS (top up payments), whilst the care which would normally be funded by the NHS will continue

The purpose of this policy is to ensure the Trust has procedures and protocols in place to ensure all staff know how to proceed in situations where NHS patients choose to pay for additional private care medications and related services that the NHS does not fund.

The policy ensures that individual patient cases are managed in a way that supports good clinical practice and is fully consistent with the fundamental principles of the NHS

The care of patients who wish to fund all of their treatment and related services privately is covered by a separate policy.

Key amendments to this Document:
Formerly entitled NHS patients who wish to pay for additional private care

Date	Amendment	By:
3.8.09	References to Medical Director changed to Clinical Director. Removed paragraph relating to process for agreeing when NHS care cannot be separated from private care.	Phil Milligan
18.08.09	Added purpose of document and definitions	Anne Sullivan
19.8.09	Flowchart at 10.1 – removed 'permission from clinical director' and added illustrative case studies	Adel Makar
20.8.09	10.3 – replaced Arrangements for Dealing with Private Patients 2006, with current version	Anne Sullivan / Chris West
1.9.09	Minor amendments	Phil Milligan
1.9.09	Comments re drug and consumable costs added	Nick Hubbard
2.9.09	10.1 Add to flowchart – DM to send form for costing 10.2 Referral form added	Katie Little
15.8.11	Amendments made by Sue Sharp and Anne Sullivan	Sue Sharp/ Anne Sullivan
20.10.11	Document made cancer specific	Sue Sharp
13/3/14.	Revision of document in response to Trust and NHS changes and change of title to "Policy for the management of Cancer patients for whom drugs their clinicians have recommended are not available on the NHS." to reflect the contents accurately	Sue Sharp
9/4/14	Revised document ratified by cancer board	Sue Sharp
10/08/16	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
August 2017	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
June 2018	Document extended for 3 months as per TLG recommendation	TLG
07/08/2019	Document extended for 6 months whilst Lynsey Pye reviews and approves document	Lisa Rowberry/ Lynsey Pye
10/02/2020	Document extended for 6 months whilst undergoing review and approval process	Lisa Rowberry
22nd May2020	Document extended for 6 months whilst review process is finalised during COVID-19 period	Lisa Rowberry
February 2021	Document extended as per Trust agreement 11.02.2021.	
28th September 2021	Document extended for 6 months whilst finalising review and approval process	Lynsey Pye
6th June 2022	Document extended for 6 months whilst finalising review and approval process	Lisa Rowberry

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Appendices

1. Introduction

In March 2009 “Guidance on NHS patients who wish to pay for additional private care” (top up payments) was published for immediate implementation, gateway ref 11512. The key driver for this was to enable patients who wished to pay for additional private healthcare unavailable on the NHS to do so whilst still having access to NHS care for elements which were widely available. For cancer patients this offered the opportunity to pay privately for treatment which their clinician supported but which was not available on the NHS at that time.

The publication of “Equity and excellence: Liberating the NHS” (Department of Health 2010) pledged to establish a fund to support cancer patients to access the drugs their clinicians recommended but were not available on the NHS. The funding was initially via the Interim Cancer Drugs Fund (ICDF), in April 2011 this was replaced by a substantive Cancer Drugs Fund (CDF) established for 3 years with the intention that patients no longer need to seek private healthcare for elements of their treatment.

In March 2013 with the reorganisation of the National Health Service, NHS England took on responsibility for the operational management of and accountability for the Cancer Drugs Fund under the guidance provided in the “Standard Operating Procedures: The Cancer Drugs Fund 2013-14.”

In September 2013 the CDF was extended until March 2016 at the current value of £200m per year.

NHS England whilst maintaining overall accountability, have devolved the operational responsibilities for the CDF to four area teams, who oversee the administration of the CDF for their region, including coordinating the work of the regional clinically-led panels.

There is now a single, national CDF cohort policy list including the chemotherapy agents and indications that the CDF will routinely fund. The list of drugs and indications has been compiled by the NHS England Clinical Reference Group (CRG) for Chemotherapy to ensure consistency across the country.

If the treatment or indication required does not fulfill the National criteria of an agreed cohort policy then an application can be made by the clinician for consideration by the regional CDF panels as an Independent Cancer Drugs Fund Request (ICDFR). Prior to submitting an ICDFR the clinician needs to establish that the treatment has not been approved as part of the Early Access to Medicines Scheme (EAMS). This scheme commencing in April 2014 enables treatments that have not yet been licensed but have demonstrated efficacy and safety which potential outweighs any potential risks to be prescribed by the supporting clinician in discussion with the patient.

However for a percentage of cases where an ICDFR has been declined, there is no EAMS in place, and all appeal processes have been explored, if the treating clinician is still of the opinion that it is clinically appropriate to commence the treatment, a patient may wish to consider paying privately for the chemotherapy drugs and reasonable costs for delivery of the elements of the regime which the NHS does not provide

For these patients who wish to pay privately for elements of their treatment, the key principles of the top up guidance issued in March 2009 remains in effect:

- NHS organisations should not withdraw NHS care simply because a patient chooses to buy additional private care.
- Any additional private care should normally be delivered separately from NHS care.
- The NHS must never charge for NHS care (except where there is specific legislation in place to allow charges) and the NHS should not subsidise private care.
- The NHS should continue to provide free of charge all care that the patient would have been entitled to had he or she not chosen to have additional private care.
- NHS Trusts and Foundation Trusts should have clear policies in place, in line with these principles, to ensure effective implementation of this guidance in their organisations. This includes protocols for working with other NHS or private providers where the NHS Trust or Foundation Trust has chosen not to provide additional private care.

2. Scope of this document

This policy relates to all NHS Cancer patients who choose to pay privately for elements of their care which the NHS does not provide and health care professionals caring for these patients within Worcestershire Acute Hospitals NHS Trust.

3. Definitions

Cancer Drugs – This term including radiopharmaceuticals conjugated with drugs. For the purpose of this policy, a cancer drug is considered to be a systemic anticancer therapy with direct anti-tumour activity that is used for the treatment of malignant disease in adults and paediatrics (however CDF application in paediatrics will be undertaken by the primary treatment centre (PTC).

Cancer Drugs Fund (CDF) - Fund established in April 2011 by the government to replace the interim cancer drugs fund. The aim of the fund is to enable patients to access the cancer drugs recommended by their consultant cancer specialist which are not funded by the NHS

Co-funding (Top Up) additional treatment/care is used to describe the purchase of treatments or services not normally funded by the NHS but which are carried out in addition to NHS care.

Early Access to Medicines Scheme (EAMS) - Early Access to Medicines Scheme (EAMS) which commences in April 2014 is to support access in the UK to unlicensed or off-label medicines in areas of unmet medical need. Pharmaceutical companies can apply to be designated as part of the scheme where a new agent has been developed which meets the criteria that the medicine is targeting life threatening, or seriously debilitating conditions which are either:

- Conditions for which there is no treatment, or
- Conditions for which the available treatment options are not satisfactory e.g. in the advanced cancer setting where the tumour is unresponsive to currently authorised medicinal products.

If the Medicines and Safety Health regulatory agency are of the opinion that the evidence demonstrated efficacy and safety which potentially outweigh any potential risks then the prescriber will be able to make a decision with the patient on using this medicine, when still unlicensed or used off-label. The medicine will be made available free of charge by the pharmaceutical company.

Individual CDF Request (ICDFR's) – Can be submitted by consultant oncologist/haemato-oncologist (adult or paediatric) endorsed by the provider Trust chemotherapy lead or equivalent to the regional CDF panel if there is no cohort policy for the drug indicated and whose condition is particularly rare (i.e. likely to present is less than 20 cases in England per year) or clinical exceptionality for a patient.

National CDF Cohort Policies – An agreed list of drugs/indications to be funded by the CDF through the Midlands and East Regional Cancer Drugs Fund. In order to commence one of these drug treatments a notification of an intention to commence treatment will need to be undertaken by a clinician on behalf of the patient using the relevant online prior notification system.
N.B. Consultant-led specialist oncology (adult & paediatric) and haemato-oncology clinicians can apply to the CDF on behalf of their patients. Applications can be made on behalf of the lead consultant by any senior doctor in their team. Provider trust specialist pharmacists must also be named in the request

NHS commissioned care- healthcare which is routinely funded by the patient's responsible NHS Commissioner

Private healthcare- medical treatments or medical services which are not funded by the NHS, whether provided as a private service by an NHS body
or by the independent sector. A patient may choose to seek treatment on a private basis even where that treatment is available from an NHS provider.

Regional Cancer Drugs Fund panels- act as an expert independent clinical decision-making body on behalf of the NHS England Commissioning Board; the panel make decisions about access to the CDF for patients who fall outside the agreed clinical criteria for the national CDF Cohort Policy Group. The core membership will consist of consultant oncology (adult and paediatric), haemato-oncology specialists and patient representatives from providers within the geographical region of the Area Team.

4. Responsibility and Duties

Chief Executive

Overall responsibility for ensuring the Trust has appropriate policies in place to ensure the organisation works to best practice and complies with all relevant legislation.

Accountable Directors

An 'Accountable Director' is responsible for identifying and overseeing the development and effective implementation of key documents relevant to their areas of responsibility. An 'Accountable Director' will be an executive, divisional or Clinical Director.

Line Managers
Ensure staff are aware of and have access to relevant key documents.
Ensure staff work within approved policies.
Ensure staff have read and understood the relevant policies and work within them.
Ensure systems exist to identify staff training needs on the implementation of policies and take necessary action to address these where necessary.
Monitor compliance with key documents within the service as defined in the document.

All Staff including visiting clinicians
Ensure that their practice is in line with key documents applicable to their work.
Information regarding a failure to comply with a policy must be reported to the line manager and the incident reporting system used where appropriate.

5. Policy detail

Principles for NHS patients co-funding additional private care
Patients may co-fund additional (top up) private healthcare while continuing to receive care from the NHS. However, in order to ensure that there is no risk of the NHS subsidising private care:

- It should always be clear whether an individual procedure or treatment is privately funded or NHS funded.
- Private and NHS care should be kept as clearly separate as possible.
- Private care should normally be carried out at a different time to the NHS care that a patient is receiving.
- The 'Top-Up' treatment should normally be carried out in a different place to NHS care, as separate from other NHS patients as possible. A different place would include the facilities of a private healthcare provider, a home care provider or part of an NHS organisation which has been permanently or temporarily designated for private care, such as a private wing, amenity beds or a private room. Putting in place arrangements for separation does not necessarily mean running a separate clinic or ward. As is the case now, specialist equipment such as scanners may be temporarily designated for private use as long as there is no detrimental effect to NHS patients.
- NHS organisations should not withdraw NHS care simply because a patient chooses to co-fund additional (top up) private care. Any additional care must be provided separately from NHS care. The fact that some NHS patients also receive private care separately should never be used as a means of downgrading the level of service that the NHS offers. The NHS should continue to provide free of charge all care that the patient would have been entitled to had he or she not chosen to have additional private care. In any circumstances in which this Trust chooses not to provide additional private care, this Trust will work with other NHS or private providers to ensure that the additional private care bought by the patient is delivered.

Departing from these principles of separation should only be considered where there are overriding concerns of patient safety, rather than on the basis of convenience. If this is the situation then there is a process that will need to be followed to demonstrate to the NHS commissioning board that the principles of separation of NHS and private patient care are being followed
(Commissioning Policy: Defining the Boundaries between NHS and Private Healthcare NHS England Commissioning Board 2013)

General arrangements for the treatment of private patients in NHS clinical areas should be agreed between the Medical Director and Clinical Director for Oncology/Haematology and be regularly reviewed and decisions recorded.

Process

- Clinicians are responsible for establishing whether NICE has approved a specific treatment for the patient's indication. If a treatment is NICE approved, it must be made available on the NHS.
- Clinicians must establish whether the relevant Clinical Commissioning Group (CCG) and NHS Commissioning board has a local policy to fund the treatment, or in the case of cancer drugs, advice from pharmacy as to whether it is an approved regime. If so, it should be made available on the NHS
- Clinicians are responsible for ensuring that all potential funding options have been explored including the Cancer Drugs Fund (process for a request to the CDF Appendix 4)
- Clinicians are responsible for establishing whether the treatment/indication has been approved as part of the Early Access to Medicines Scheme (EAMS)
- Clinicians should consider whether there are specific aspects of the patient's case which justify an Individual Cancer Drugs Fund Request (ICDFR)
- Only once these funding streams have been explored should a clinician inform the patient that they may wish to consider co-funding the additional treatment and related services which are not funded by the NHS.
- Clinicians are responsible for advising the patient of the various types of care available to them and providing impartial advice about that care.
- Clinicians and directorate managers are responsible for ensuring the separation of NHS and "co-funded additional care".
- If a patient decides they wish to co-fund their treatment dependent upon the treatment required there are different processes that need to be followed (see appendix 6)
- Clinicians are responsible for ensuring that where clinical responsibility for a patient changes, that effective risk management processes are in place to safeguard the patient and ensure continuity of care.
- Where Clinicians provide care and advice for "co-funded additional care patients", but do not make a charge then Clinicians are covered for negligence claims under existing Clinical Negligence Scheme for Trust arrangements. However where a charge is levied against the patient by the Clinician then this is classified as private work and the Clinician is responsible for providing clinical negligence insurance cover.

Therefore, in exceptional cases, if a clinician has received notification that a patient's treatment has been declined by the Cancer Drugs Fund and the patient is not eligible to receive the care requested under the NHS, but wishes to co-fund additional treatment and care, the directorate manager should be informed. A referral form for co-funding will then need to be completed by the general manager and clinician and sent to finance for a price to be prepared to enable the patient to make a decision about whether to proceed with co-funding (appendix 5).

Once the patient has confirmed that they wish to pay for the cost of the additional treatment, including drug(s) plus assembly on costs which the Trust needs to recover, the relevant private patient documentation should be completed.

The general manager will be responsible for notifying the head of finance for the relevant division that this has been done.

6. Training and awareness

It is the responsibility of the individual professional to ensure that they are aware of the contents of this policy. It is the responsibility of managers to identify any training needs.

7. Monitoring and compliance

Approvals of clinician requests to Cancer Drugs Fund and patients who self fund (top up) their treatment will be maintained on a pharmacy database.

The Finance Department will maintain a register of all patients treated on the NHS who have chosen to pay for additional care.

The NHS Commissioning Board will maintain records of patients referred for individual funding requests and will routinely request from providers reports detailing the number of patients seeking co-funding for which indications and how the Trust adhered to the providing the care in a separate episode/facility.

8. Policy Review

This policy will be reviewed 2 years after the date of approval and then biannually unless a specific change is required

9. References

	Code
Interim Commissioning Policy – NHS & Private Healthcare NHS England April 2013	
Equity and excellence: Liberating the NHS Department of Health July 2010	
Guidance on NHS patients who wish to pay for additional private care	Gateway Ref 11512
Guidance to support operation of the Cancer Drugs Fund in 2011-12 Department of Health March 2011.	
Standard Operating Procedures: The Cancer Drugs Fund 2013-14 NHS England March 2013 (updated January 2014)	Gateway Reference 00485
Commissioning Policy: Defining the Boundaries between NHS and Private Healthcare April 2013	NHSCB/CP/12

10. Background

The following staff have been involved in the review of this document

- Chief Operating Officer
- Chief Medical officer
- Deputy Chief Operating Officer
- Divisional Director of Operations for Medicine
- Divisional Medical Director for Medicine
- Divisional Director of Nursing for Medicine
- Trust Core Cancer Team
- Head of Clinical Governance

- Assistant Director of Finance
- Pharmacy Director
- Directorate Manager for Oncology, Haematology and Palliative Care
- Lead Chemotherapy Nurse
- Trust Chemotherapy lead

11. Approval process

A policy ratification process has been completed (attached Appendix 3).

12. Equality requirements

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. The assessment confirms that there should be no patients, staff or visitors discriminated against with the use of this Policy (attached Appendix 1).

13. Financial risk assessment

There are no financial implications for the implementation of this Policy (attached Appendix 2).

Appendix 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	NO	
	• Ethnic origins (including gypsies and travellers)	NO	
	• Nationality	NO	
	• Gender	NO	
	• Transgender	NO	
	• Religion or belief	NO	
	• Sexual orientation including lesbian, gay and bisexual people	NO	
	• Age	NO	
	• Disability - learning disabilities, physical disability, sensory impairment & mental health problems	NO	
2.	**Is there any evidence that some groups are affected differently?**	NO	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	N/A	
4.	**Is the impact of the policy/guidance likely to be negative?**	NO	
5.	**If so can the impact be avoided?**	N/A	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

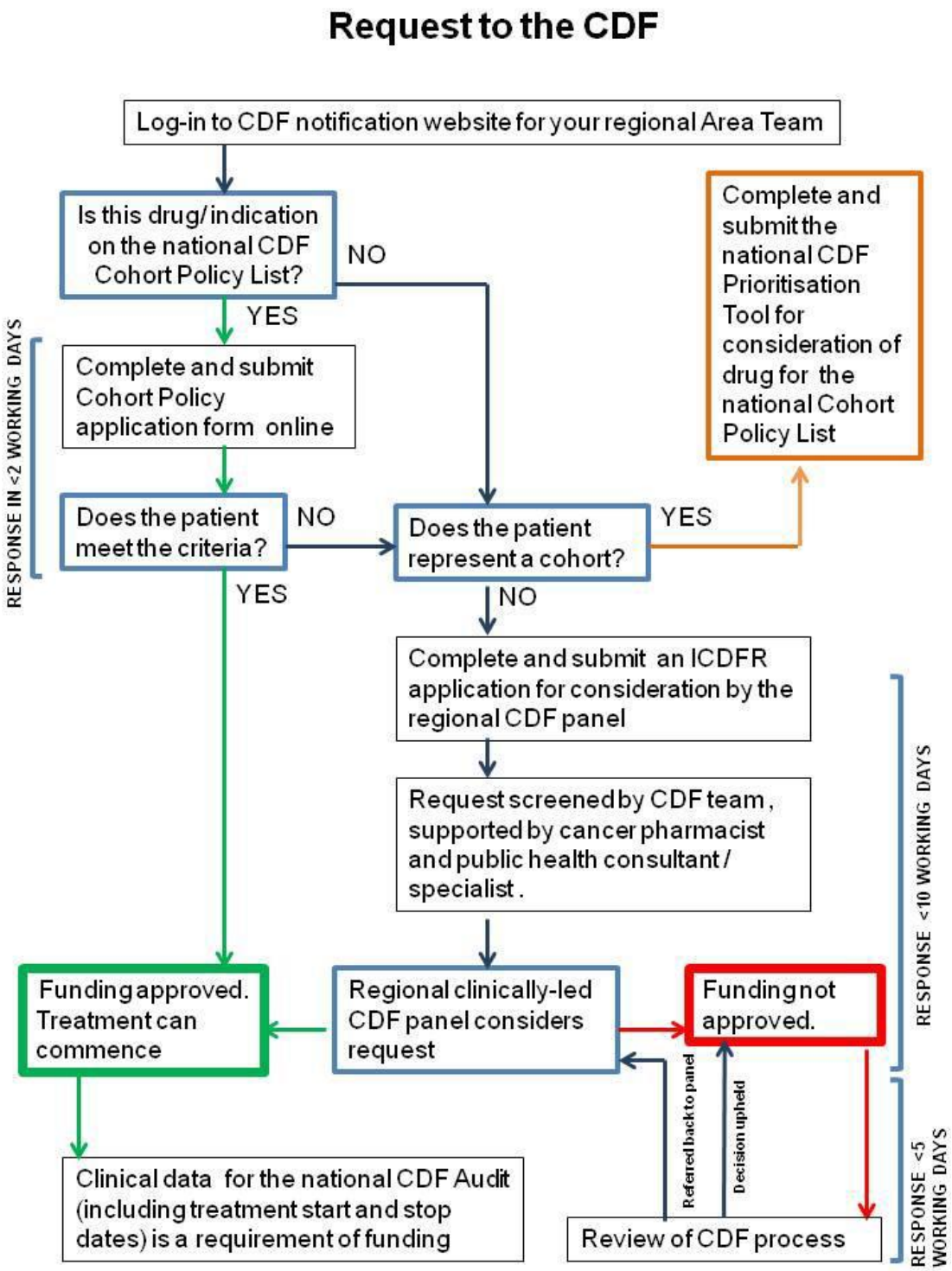
Appendix 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	NO
2.	Does the implementation of this document require additional revenue	NO
3.	Does the implementation of this document require additional manpower	NO
4.	Does the implementation of this document release any manpower costs through a change in practice	NO
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	NO
	Other comments:	

If the response to any of the above is yes, please complete a business case which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval

Appendix 3 - Request to the Cancer Drugs Fund (Standard Operating Procedures: The Cancer Drugs Fund 2013-14)



Appendix 4 - Referral form

This form should be completed by the Doctor and General Manager in cases where all other NHS funding streams have been exhausted and the patient is looking to fund an element of their care privately.

This form should NOT be used for private patients where the whole episode of care is undertaken privately. In these cases the Trust private patient process and documentation should be used.

All fields should be fully completed as far as possible to ensure that an accurate price can be prepared. If further details need to be included please attach as a separate sheet.

PLEASE COMPLETE IN BLOCK CAPITALS

Responsible Doctor / Lead Clinician			
Patient's Full Name			
Date of Birth		Hospital No.	

Description of element of care that will be paid for privately by the patient:

Site where care will be delivered: *(please state)*	

Location where care will be delivered: *(please tick as appropriate)*			
Outpatient Clinic		Theatre	
Ward Attender		Inpatient	
Treatment Room		ITU / HDU	

Description of how delivery of additional care will be separated from other NHS care:
Description of any additional cost to the Trust as a result of separating this care from other NHS work?
E.g. will the care be delivered out of normal working hours?

Resources used to deliver care: *(Please describe the input required as fully as possible)*			**Finance Use**
Staff Type	**Grade / Name**	**Time / Description of role in this case:**	**Costs £**
Consultant			
Consultant Anaesthetist			
Other Medical Staff			
Nursing			
Other Clinical Staff			
Admin / Non Clinical staff			
Non Pay Costs	**Type / Quantity**	**Cost / Description:**	
Consumable items			
High Cost items			
Equipment used			
Other			

Drug Administration:		**Finance Use - Costs £**
Name of Drug		Drugs:
Dosage Required		Dispensing:
To be administered by		Administering:
Associated Consumables		Consumables:
Drugs costing agreed with Lead Pharmacist:		

Details of tests / treatments: *(please tick as appropriate)*					
None					
Pathology		**Radiology**		**Other Depts.**	
Biochemistry		Plain Radiology		Audiometry	
Blood Bank		Ultrasound		ECG	
Cytology		Contrast Investigations		Occupational Therapy	
Haematology		CT Scanning		Physiotherapy	
Histology		MRI Scanning		Dietetics	
Microbiology					
Other (please specify)					

Other resources that will be used? / Other relevant Information: *(please use a separate sheet if necessary)*

In signing this form the Doctor and General Manager are confirming that they have explored and exhausted all other reasonable avenues for securing NHS funding, and that they have completed this form with all relevant facts about the element of the patients care that will be paid for privately.

The costing prepared by the Finance Team assumes that all material facts relating to the resources used in delivering this element of care have been disclosed and that the patient is undertaking to pay for this element of their care privately.

Consultant / Lead Clinician	General Manager
Name: Specialty: Signature: Date:	Name: Signature: Date:
Contact in case of queries:	

Once completed please forward to the Finance department for costing.

The form showing the total cost will be returned to the General Manager for notification to the patient. Once the patient has confirmed they wish to pay for this element of their care the relevant private patient documentation should be completed in the usual way.

For Finance Department use only:		Date received:	
Total calculated cost:		Costed By:	
G M Notified:			

Appendix 5: Flowchart for management of cancer patients for whom chemotherapy drugs their clinicians have recommended are not available on the NHS or through the cancer drugs fund.