

Cancer Drugs Fund Policy WM/CDF/39

Pemetrexed Maintenance after Pemetrexed-containing First Line Treatment in stage IIIB/IV Non- Squamous Non-Small Cell Lung Cancer

Version 1 – February 2012

1. The policy

1.1 This policy applies to any patient for whom a West Midlands PCT is the Responsible Commissioner

1.2 Pemetrexed has been accepted by the West Midlands Cancer Drugs Fund Panel for funding from the Cancer Drugs Fund for maintenance treatment of stage IIIB/IV non-squamous non-small cell lung cancer after pemetrexed-containing first line therapy

Pemetrexed will not be funded by the Cancer Drugs Fund for non-squamous non-small cell lung cancer in any other setting (unless covered by a separate policy). Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through an individual funding application.

The following criteria must be fulfilled for funding:

- The patient must have stage IIIB/IV non-squamous non-small cell lung cancer previously treated with a first line pemetrexed and cisplatin, for at least two cycles, but 4 cycles recommended.
- At 4 cycles of first line treatment the patient should be in Complete Response, Partial Response or Stable Disease as defined by RECIST 1.1 compared to base line and not be progressing compared to post cycle 2 CT scan
- The patient must have performance Status 0-1 at time of consideration of maintenance pemetrexed

- The patient must have a GFR > 50 mL/ min by Wright-CK or 51-Cr-EDTA. (note Cockcroft underestimates GFR by around 20%).
- Maintenance should begin no longer than 5 weeks post last dose of pemetrexed and cisplatin

Clinicians must comply with the following:

- CT scans should be at a frequency of every 8 weeks until 24 weeks then 12-weekly
- The patient should be treated to disease progression or until drug intolerance
- Patients must be made aware that there are stopping criteria before treatment is initiated
- Make data of eligibility criteria and the results of associated CT scans available for audit

1.3 The fund is cash limited, therefore funding may not be allocated if a higher than expected level of uptake is evident. A proportion of the budget will be allocated for maintenance pemetrexed in stage III B/IV non-squamous non-small cell lung cancer which will be monitored and used to review the policy when usage information becomes available. Once a patient starts on pemetrexed the funding will continue providing all the criteria listed above still apply.

2. Background information

Interim Cancer Drugs Fund – October 2010 to March 2011

The interim cancer drugs fund (ICDF) was announced by the Chief Medical Officer at the Department of Health in July 2010. Many cancer drugs were already available for patients in the West Midlands. This included drugs that were considered by the National Institute for Health and Clinical Excellence (NICE). However, for a number of different reasons, some new cancer drugs were not available on the NHS.

From 1st October, an extra £50 million was made available to help patients get access to new cancer drugs. The fund for the West Midlands was £5.4 million for the period of October 2010 – March 2011 inclusive and was used to help those cancer patients who need access to new cancer drugs recommended by doctors.

Cancer Drugs Fund – April 2011 to April 2014

The Cancer Drugs Fund was established under terms detailed in the NHS Operating Framework¹ in December 2010. This made £200 million available in each of the following three years for the Cancer Drugs Fund. Regional Strategic Health Authority (SHA) shares of the £200 million were calculated

¹ The Operating Framework for the NHS in England 2011-12, Gateway reference 15216

using the national weighted capitation formula. Further information on the financial arrangements for 2011-12 is contained in Sir Bruce Keogh's letter of 1 March 2011 to Medical Directors and Directors of Finance in Strategic Health Authorities in England²

Each SHA will put in place a transparent, published process for allocating the funding. This process will build on the arrangements put in place in 2010-11 to manage allocation of the additional £50 million funding for cancer drugs. As in 2010-11, applications for funding from the Cancer Drugs Fund should be made by clinicians on behalf of their patients and decisions on the appropriate use of resources should be taken by a clinically-led panel. The clinically-led panels should take into account this guidance in coming to their decisions.

NHS West Midlands (NHSWM) was responsible for ensuring that appropriate arrangements were in place on 1st October 2010 to manage the Interim Cancer Drug Fund. It will continue to ensure that arrangements are in place to manage the Cancer Drugs Fund in 2011-12. Arrangements for 2012 and beyond will be the subject of discussions with the shadow NHS Commissioning Board.

The purpose of the fund is to provide additional resources to support improved access to cancer drugs from 2010 to April 2014. It is intended to support patients who have been unable to access a clinically-recommended treatment following consideration by their PCT under existing arrangements.

The fund is available for the purchase of medicines (including radiopharmaceuticals) and for molecular diagnostic testing which is necessary to help optimally target the use of drugs for patients who are most likely to benefit; PCTs are expected to fund the service costs associated with the provision of these medicines including any additional treatment costs (such as non-cancer drugs and monitoring.)

The cancer drugs fund is an additional cash-limited in-year allocation from the Department of Health central budget and other budgets. Therefore NHS WM and WM SCG reserve the right to cease funding previously commissioned drugs if the fund is exhausted before the end of the period for which the fund was allocated.

Further information about the process and how to apply are on the WMSCG website - <http://www.wmsc.nhs.uk/clinical-networks/cancer-drugs-fund/> .

3. Key principles supporting this policy

- 3.1 Primary care trusts have legal responsibility for NHS healthcare budgets and their primary duty is to keep within the budget allocated to them.

²http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleague/letters/DH_124791 (also referenced in section 5)

- 3.2 PCT commissioners have a responsibility to make rational decisions in the way in which they allocate resources and to act fairly between patients.
- 3.3 The purpose of this policy is to ensure diversity and equality to all patients, irrespective of their gender, race, ethnic origin, disability, age, nationality, national origin, sexuality, religion or belief, marital status and social class. The commissioners involved with this policy oppose all forms of unlawful and unfair discrimination.

4. Local documents which have a direct bearing on this policy

Terms of reference for the West Midlands CDF Clinical Panel

The WMSCG and NHS WM Cancer Drugs Fund Policy, available at:
<http://www.westmidlands.nhs.uk/WhatWeDo/WestMidlandsCancerDrugFund/CancerDrugsFundPolicy.aspx>

Letter from NHS WM Chief Executive, dated 27 September 2010, to Chief Executives of PCTs and Chairs of Local Collaborative Commissioning Boards, headed *Interim Cancer Drugs Fund – Hosting, clinical decision panel & operation*.

Letter from NHS WM Medical Director, dated 1 October 2010, to Chief Executives of PCTs and provider trusts, headed *Interim Cancer Drugs Fund – Operational arrangements*.

5. Documents which have informed this policy

The National Health Service Act 2006.
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4134387

DH letter, Gateway reference: 14617, from the NHS Medical Director on *Interim Cancer Drugs Funding*.

DH paper, Gateway reference: 15865. *The Cancer Drugs Fund: Government response to consultation*. 1 April 2011.

DH guidance, Gateway reference: 15852. *The Cancer Drugs Fund: Guidance to support the operation of the Cancer Drugs Fund in 2011-12*. 23 March 2011.

DH letter, Gateway reference: 15699, from the NHS Medical Director on *The Cancer Drugs Fund*. 1 March 2011.

Scientific Discussion for Marketing Authorisation variation for Alimta (Pemetrexed) Procedure No.: EMEA/H/C/000564/II/0033

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/000564/WC500118770.pdf This reference details the PARAMOUNT study which has been published and reported in various conferences/publications.

6. Definitions

Interim Cancer Drugs Fund (ICDF) – the 6 month fund that was available from 1 October 2010 – 31 March 2011 as announced by the Secretary of State for Health, Andrew Lansley on 27 July 2010 and detailed in a Dear Colleague letter published on 28 July 2010 by Sir Bruce Keogh, NHS Medical Director.

Cancer Drugs Fund (CDF) – the fund that is available from 1 April 2011 following consultation and covered in the subsequent Department of Health guidance. .

Individual Funding Request (IFR) – funding request made under an existing PCT process and consistent with the regional generic commissioning policy “Individual funding requests” WM/9 published by the West Midlands Specialised Commissioning Team. *An individual funding request* is a request received from a provider, or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.

Individual Patient Application (IPA) - relates to individual applications to the Cancer Drugs Fund made by patient for drugs which have not already been identified in the CDF funding policy/priorities.

CDF Clinical Panel (CDF CP) - a clinically-led group that will consider and agree funding policies and priorities for the CDF.

Priority Drugs List – the list of cancer drugs which have been considered by the CDF CP and agreed to be a priority for funding from the CDF.

Cancer Drugs Fund Appeals Panel – a panel established by NHS West Midlands that will consider individual appeals on the grounds of failure to follow the agreed process.

Exceptional clinical circumstances refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient.

WMSCG – West Midlands Strategic Commissioning Group – the group of Primary Care Trusts (PCTs) who are responsible for overseeing the commissioning of specialised services.

WMSCT – the West Midlands Specialised Commissioning Team, staff employed on behalf of SCG.

Cancer drugs – This term includes radiopharmaceuticals. For the purpose of this policy a cancer drug is considered to be a systematic anticancer therapy with direct anti-tumour activity that is used for the treatment of malignant disease in children or adults (licensed or unlicensed for the proposed indications). A drug is said to be “licensed” if it has been given marketing authorisation by the European Medicines Evaluation Agency (EMA).

Cohort – A designated group of patients defined by particular characteristics such as a particular disease or specific criteria relating to that disease.

Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Commissioning Policy	Cancer Drugs Fund Policy (WM/CDF/39) Pemetrexed Maintenance after Pemetrexed containing First Line Treatment in stage IIIB/IV Non-Squamous Non-Small Cell Lung Cancer
<p>The policy sets out the West Midlands Cancer Drugs Fund funding criteria for the use of pemetrexed for maintenance therapy after pemetrexed containing first line treatment in stage IIIB/IV non-squamous Non-Small Cell Lung Cancer (NSCLC). Its use will be limited to those patients with non-squamous NSCLC who have had a complete response, partial response or stable disease after treatment with first-line pemetrexed and cisplatin. The document also specifies a number of additional conditions that clinicians are expected to adhere to for the treatment to be funded and an explanation of any changes to funding allocations if all the funding available has been taken up.</p>	

		Yes/No	Comments
1	<p>Does the policy/guidance affect one group less or more favourably than another on the basis of:</p> <ul style="list-style-type: none"> • Race • Ethnic origins (including gypsies and travellers) • Nationality • Gender • Culture • Religion or belief • Sexual orientation including lesbian, gay and bisexual people • Age • Disability - learning disabilities, physical disability, sensory impairment and mental health problems 	No	
2	Is there any evidence that some groups are affected differently?	No	The funding policy is solely based on clinical criteria relating to a patient's condition.
3	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	NA	
4	Is the impact of the policy/guidance likely to be negative? (If no, please go to question 5.)	No	This decision has been based on the best available evidence and the drug priorities have been assessed solely in relation to the funding available for the cancer drugs fund.

		Yes/No	Comments
	<ul style="list-style-type: none"> If so can the impact be avoided? 	No	
	<ul style="list-style-type: none"> What alternatives are there to achieving the policy/guidance without the impact? 	N/A	
	<ul style="list-style-type: none"> Can we reduce the impact by taking different action? 	N/A	Patients outside of the qualifying criteria will continue to be offered normally commissioned care for their condition.
5.	Health Inequalities	No	
6.	Outcome	No major change in the policy after the EIA and the evidence does not show any potential for discrimination.	

Human Rights Assessment Tool

The Human Rights Act, which came into force in October 2000, incorporates into domestic law the European Convention on Human Rights to which the UK has been committed since 1951. Section 6 of the Human Rights Act makes it unlawful for a public authority to act in a way, which is incompatible with a Convention right. The underlying intention of the Act is to create a Human Rights culture in public services.

We do not consider that infringes a person's human rights, however if it is considered that this policy does infringe on a person's human rights legal advice will be sought before proceeding.

Details (names and roles) of staff involved in this impact assessment

Name	Role	Date completed	Outcome
David Prayle	Associate Director, Pharmacy, Greater Midlands cancer Network. Clinical Panel member	February 2012	Initial EIA assessment now complete. To be posted on website once approved.
Richard Seal	Programme Consultant in Medicines Management, NHS West Midlands	February 2012	Approved