

Network Formulary

Version 8.5

December 2011

NICE approved drugs.....	2
Formulary principles.....	10
Formulary approved drugs.....	12
Formulary exclusions.....	17
Routine use.....	18
Drugs approved by the cancer drugs fund.....	19

Updated content

- Due to a current worldwide shortage of liposomal doxorubicin, commissioners have agreed to fund Myocet as alternative liposomal preparation as an option for the second-line (or subsequent) treatment of women with partially platinum-sensitive, platinum-resistant or platinum-refractory advanced ovarian cancer, and for women who are allergic to platinum-based compounds. (See page 15).

NICE approved drugs

The following drugs are currently available following approval by NICE in line with the indications as detailed below. Users should refer to the specific Technology Appraisal Guideline (TAG) (available at: www.nice.org.uk) for the exact terms and conditions of use.

Within Pan Birmingham there are different arrangements covering the funding mechanism for cancer drugs. Those PCTs that are part of the Pan Birmingham LCCB fund through their subscriptions. **This arrangement excludes Walsall PCT and South Staffordshire PCT (Burntwood Lichfield Tamworth population) where funding comes directly from the PCT.**

The drugs approved by NICE and the LCCB are monitored by the Cancer Network.

The use of high cost cancer drugs is audited to ensure that these are only prescribed in line with their NICE or Network Formulary indication. It is **essential** that Trusts provide the information requested by the Cancer Network working on behalf of Primary Care Trusts. **Trusts may not receive reimbursement unless they can demonstrate that drug expenditure is in line with NICE or agreed Network Formulary indications.**

Drug	NICE Indication	NICE – TAG
Aromatase Inhibitors: Anastrozole, Examestane, Letrozole	The aromatase inhibitors anastrozole, exemestane and letrozole, within their licensed indications, are recommended as options for the adjuvant treatment of early oestrogen-receptor-positive invasive breast cancer in postmenopausal women.	112
Azacitidine	Azacitidine is recommended as a treatment option for adults who are not eligible for haematopoietic stem cell transplantation and have: <ul style="list-style-type: none"> • intermediate-2 and high-risk myelodysplastic syndromes according to the International Prognostic Scoring System (IPSS) or • chronic myelomonocytic leukaemia with 10–29% marrow blasts without myeloproliferative disorder or • acute myeloid leukaemia with 20–30% blasts and multilineage dysplasia, according to the World Health Organization classification and • if the manufacturer provides azacitidine with the discount agreed as part of the patient access scheme. 	218
Bendamustine	Bendamustine is recommended as an option for the first-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.	216

Drug	NICE Indication	NICE – TAG
Bortezomib	<p>Bortezomib monotherapy is recommended as an option for the treatment of progressive multiple myeloma in people who are at first relapse having received one prior therapy and who have undergone, or are unsuitable for, bone marrow transplantation, under the following circumstances:</p> <ul style="list-style-type: none"> • the response to bortezomib is measured using serum M protein after a maximum of four cycles of treatment, and treatment is continued only in people who have a complete or partial response (that is, reduction in serum M protein of 50% or more or, where serum M protein is not measurable, an appropriate alternative biochemical measure of response) and • the manufacturer rebates the full cost of bortezomib for people who, after a maximum of four cycles of treatment, have less than a partial response (as defined above). 	129
Bortezomib	<p>Bortezomib in combination with an alkylating agent and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma if:</p> <ul style="list-style-type: none"> • high-dose chemotherapy with stem cell transplantation is considered inappropriate and • the person is unable to tolerate or has contraindications to thalidomide. 	228
Capecitabine	For the treatment of locally advanced or metastatic breast cancer.	62&CG81
Capecitabine	Oral therapy with either capecitabine or tegafur with uracil (in combination with folinic acid) is recommended as an option for the first-line treatment of metastatic colorectal cancer.	61
Carmustine Implants: Gliadel Wafers	Carmustine implants, within their licensed indications, are recommended as an option for the treatment of newly diagnosed high-grade glioma only for patients in whom 90% or more of the tumour has been resected.	121
Cetuximab (in combination with radiotherapy)	Cetuximab in combination with radiotherapy is recommended as a treatment option only for patients with locally advanced squamous cell cancer of the head and neck whose Karnofsky performance-status score is 90% or greater and for whom all forms of platinum-based chemoradiotherapy treatment are contraindicated.	145
Cetuximab	<p>Cetuximab in combination with 5-fluorouracil (5-FU), folinic acid and oxaliplatin (FOLFOX), within its licensed indication, is recommended for the first-line treatment of metastatic colorectal cancer only when all of the following criteria are met:</p> <ul style="list-style-type: none"> • The primary colorectal tumour has been resected or is potentially operable. • The metastatic disease is confined to the liver and is unresectable. • The patient is fit enough to undergo surgery to resect the primary colorectal tumour and to undergo liver surgery if the metastases become resectable after treatment with cetuximab. • The manufacturer rebates 16% of the amount of cetuximab used on a per patient basis. 	176
Docetaxel	For the treatment of advanced breast cancer where initial cytotoxic chemotherapy (including an anthracycline) has failed or is inappropriate.	30&CG81

Drug	NICE Indication	NICE – TAG
Docetaxel	For the treatment of stage III or IV non small cell lung cancer (NSCLC) in patients with a good performance status (WHO 0, 1 or a Karnofsky score of 80–100).	26 & CG24
Docetaxel	Docetaxel, when given concurrently with doxorubicin and cyclophosphamide (the TAC regimen) as per its licensed indication, is recommended as an option for the adjuvant treatment of women with early node-positive breast cancer.	109
Docetaxel	Docetaxel is recommended, within its licensed indications, as a treatment option for men with hormone-refractory metastatic prostate cancer only if their Karnofsky performance-status score is 60% or more.	101
Erlotinib	Erlotinib is recommended, within its licensed indication, as an alternative to docetaxel as a second-line treatment option for patients with non-small-cell lung cancer (NSCLC) only on the basis that it is provided by the manufacturer at an overall treatment cost (including administration, adverse events and monitoring costs) equal to that of docetaxel.	162
Erythropoietin	<p>Erythropoietin analogues are recommended in combination with intravenous iron as an option for the management of cancer treatment-induced anaemia in women receiving platinum-based chemotherapy for ovarian cancer who have symptomatic anaemia with a haemoglobin level of 8 g/100 ml or lower. The use of erythropoietin analogues does not preclude the use of existing approaches to the management of anaemia, including blood transfusion where necessary.</p> <p>Erythropoietin analogues in combination with intravenous iron may be considered for people who cannot be given blood transfusions and who have profound cancer treatment-related anaemia that is likely to have an impact on survival.</p>	142
Fludarabine (oral)	<p>Oral fludarabine is recommended as second line therapy for B-cell chronic lymphocytic leukaemia (CLL) for patients who have either failed, or are intolerant of, first line chemotherapy, and who would otherwise have received combination chemotherapy of either:</p> <p>1.1.1. cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)</p> <p>1.1.2. cyclophosphamide, doxorubicin and prednisolone (CAP) or</p> <p>1.1.3. cyclophosphamide, vincristine and prednisolone (CVP)</p>	29
Gefitinib	Gefitinib is recommended as an option for the first-line treatment of people with locally advanced or metastatic non-small-cell lung cancer (NSCLC) if they test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and the manufacturer provides gefitinib at the fixed price agreed under the patient access scheme.	192
Gemcitabine	Gemcitabine in combination with paclitaxel, within its licensed indication, is recommended as an option for the treatment of metastatic breast cancer only when docetaxel monotherapy or docetaxel plus capecitabine are also considered appropriate.	116
Gemcitabine	Gemcitabine may be considered as a treatment option for patients with advanced or metastatic adenocarcinoma of the pancreas and a Karnofsky performance score of 50 or more, where first line chemotherapy is to be used.	25

Drug	NICE Indication	NICE – TAG
Gemcitabine	For the treatment of stage III or IV non small cell lung cancer (NSCLC) in patients with a good performance status (WHO 0, 1 or a Karnofsky score of 80–100).	26 & CG24
Imatinib	<p>Imatinib is recommended as first-line treatment for people with Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in the chronic phase.</p> <p>Imatinib is recommended as an option for the treatment of people with Philadelphia-chromosome-positive CML who initially present in the accelerated phase or with blast crisis.</p> <p>Additionally, imatinib is recommended as an option for people who present in the chronic phase and then progress to the accelerated phase or blast crisis if they have not received imatinib previously.</p>	70
Imatinib	<p>Imatinib treatment at 400 mg/day is recommended as first-line management of people with KIT (CD117)-positive unresectable and/or KIT (CD117)-positive metastatic gastro-intestinal stromal tumours (GISTs).</p> <p>Imatinib at 600 or 800 mg/day is not recommended for people with unresectable and/or metastatic gastrointestinal stromal tumours whose disease has progressed after treatment with 400 mg/day imatinib.</p>	86 and 209
Irinotecan	Irinotecan within the licensed indications, is recommended as a treatment options for people with advanced colorectal cancer in combination with 5-fluorouracil and folinic acid as first-line therapy, or irinotecan alone in subsequent therapy	93
Liposomal Doxorubicin	PLDH is recommended as an option for the second-line (or subsequent) treatment of women with partially platinum-sensitive, platinum-resistant or platinum-refractory advanced ovarian cancer, and for women who are allergic to platinum-based compounds. Due to a current worldwide shortage of liposomal doxorubicin, commissioners have agreed to fund Myocet as alternative liposomal preparation in this indication. (See page 15).	91
Mifamurtide	Mifamurtide in combination with postoperative multi-agent chemotherapy is recommended within its licensed indication as an option for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection in children, adolescents and young adults and when mifamurtide is made available at a reduced cost to the NHS under the patient access scheme.	235
Oxaliplatin	Oxaliplatin, within the licensed indications, is recommended as treatment options for people with advanced colorectal cancer as in combination with 5-fluorouracil and folinic acid as first-line or subsequent therapy.	93
Oxaliplatin	Oxaliplatin in combination with 5-fluorouracil and folinic acid is recommended as an option for the adjuvant treatment of patients with stage III (Dukes' C) colon cancer following surgery for the condition:	100
Paclitaxel	It is recommended that paclitaxel in combination with a platinum based compound or platinum-based therapy alone (cisplatin or carboplatin) are offered as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer.	55

Drug	NICE Indication	NICE – TAG
Paclitaxel	For the treatment of advanced breast cancer where initial cytotoxic chemotherapy (including an anthracycline) has failed or is inappropriate.	30 & CG 81
Paclitaxel	For the treatment of stage III or IV non small cell lung cancer (NSCLC) in patients with a good performance status (WHO 0, 1 or a Karnofsky score of 80–100).	26 & CG24
Pazopanib	Pazopanib is recommended as a first-line treatment option for people with advanced renal cell carcinoma who have not received prior cytokine therapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. The manufacturer provides pazopanib with a 12.5% discount on the list price, and provides a possible future rebate linked to the outcome of the head-to-head COMPARZ trial, as agreed under the terms of the patient access scheme and to be confirmed when the COMPARZ trial data are made available.	215
Pemetrexed	Pemetrexed is recommended as a treatment option for malignant pleural mesothelioma only in people who have a World Health Organization (WHO) performance status of 0 or 1, who are considered to have advanced disease and for whom surgical resection is considered inappropriate.	135
Pemetrexed	Pemetrexed in combination with cisplatin is recommended as an option for the first-line treatment of patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC) only if the histology of the tumour has been confirmed as adenocarcinoma or large-cell carcinoma.	181
Pemetrexed	Pemetrexed is recommended as an option for the maintenance treatment of people with locally advanced or metastatic non-small-cell lung cancer other than predominantly squamous cell histology if disease has not progressed immediately following platinum-based chemotherapy in combination with gemcitabine, paclitaxel or docetaxel.	190
Rituximab	Rituximab within its licensed indication (that is, in combination with cyclophosphamide, vincristine and prednisolone) is recommended as an option for the treatment of symptomatic stage III and IV follicular lymphoma in previously untreated patients.	110
Rituximab	Rituximab is recommended for use in combination with a regimen of cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) for the first-line treatment of people with CD20-positive diffuse large-B-cell lymphoma at clinical stage II, III or IV (see Section 2.3). Rituximab is not recommended for use when CHOP is contraindicated.	65

Drug	NICE Indication	NICE – TAG
Rituximab	<p>Rituximab, within its marketing authorisation, in combination with chemotherapy, is recommended as an option for the induction of remission in people with relapsed stage III or IV follicular non-Hodgkin's lymphoma.</p> <p>Rituximab monotherapy as maintenance therapy, within its marketing authorisation, is recommended as an option for the treatment of people with relapsed stage III or IV follicular non-Hodgkin's lymphoma in remission induced with chemotherapy with or without rituximab.</p> <p>Rituximab monotherapy, within its marketing authorisation, is recommended as an option for the treatment of people with relapsed or refractory stage III or IV follicular non-Hodgkin's lymphoma, when all alternative treatment options have been exhausted (that is, if there is resistance to or intolerance of chemotherapy).</p>	137
Rituximab	Rituximab in combination with fludarabine and cyclophosphamide is recommended as an option for the first-line treatment of chronic lymphocytic leukaemia in people for whom fludarabine in combination with cyclophosphamide is considered appropriate.	174
Rituximab	<p>Rituximab in combination with fludarabine and cyclophosphamide is recommended as a treatment option for people with relapsed or refractory chronic lymphocytic leukaemia except when the condition:</p> <ul style="list-style-type: none"> • is refractory to fludarabine (that is, it has not responded to fludarabine or has relapsed within 6 months of treatment) or • has previously been treated with rituximab, unless: <ul style="list-style-type: none"> – in the context of a clinical trial, at a dose lower than the dose currently licensed for chronic lymphocytic leukaemia or – in the context of a clinical trial, in combination with chemotherapy other than fludarabine and cyclophosphamide. 	193
Rituximab	Rituximab maintenance therapy is recommended as an option for the treatment of people with follicular non-Hodgkin's lymphoma that has responded to first-line induction therapy with rituximab in combination with chemotherapy.	226
Sunitinib	<p>A first-line treatment option for patients with advanced and/or metastatic renal cell carcinoma who are suitable for immunotherapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.</p> <p>The manufacturer of sunitinib (Pfizer) has agreed a patient access scheme with the Department of Health, in which the first treatment cycle of sunitinib is free to the NHS.</p>	169
Sunitinib	Sunitinib is recommended, within its licensed indication, as a treatment option for people with unresectable and/or metastatic malignant gastrointestinal stromal tumours if imatinib treatment has failed because of resistance or intolerance, and the drug cost of sunitinib (excluding any related costs) for the first treatment cycle will be met by the manufacturer.	179
Tegafur Uracil	Oral therapy with either capecitabine or tegafur with uracil (in combination with folinic acid) is recommended as an option for the first-line treatment of metastatic colorectal cancer.	61

Drug	NICE Indication	NICE – TAG
Temozolomide	Patients with recurrent malignant glioma (brain cancer) who have failed first-line chemotherapy treatment with other agents (either because of lack of efficacy or because of side effects) may be considered for treatment with temozolomide. Such patients must have a histologically proven malignant glioma (WHO grades III and IV, or transformed grade II) at first relapse, recurrence or progression (as assessed by imaging), Karnofsky performance status greater than or equal to 70 and a projected life expectancy of 12 weeks or more, at initiation of temozolomide treatment.	23
Temozolomide	Temozolomide, within its licensed indications, is recommended as an option for the treatment of newly diagnosed glioblastoma multiforme (GBM) in patients with a World Health Organization (WHO) performance status of 0 or 1.	121
Thalidomide	Thalidomide in combination with an alkylating agent and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma in people for whom high-dose chemotherapy with stem cell transplantation is considered inappropriate.	228
Topotecan	Topotecan is recommended as an option for second-line (or subsequent) treatment only for those women with platinum-refractory or platinum-resistant advanced ovarian cancer, or those who are allergic to platinum-based compounds, for whom PLDH and single-agent paclitaxel are considered inappropriate.	91
Topotecan	Topotecan in combination with cisplatin is recommended as a treatment option for women with recurrent or stage IVB cervical cancer only if they have not previously received cisplatin.	183
Topotecan	<p>Oral topotecan is recommended as an option only for people with relapsed small-cell lung cancer for whom:</p> <ul style="list-style-type: none"> • re-treatment with the first-line regimen is not considered appropriate and • the combination of cyclophosphamide, doxorubicin and vincristine (CAV) is contraindicated (for details of the contraindications to CAV see the summary of product characteristics for each of the component drugs). 	184
Trabectedin	Trabectedin is recommended as a treatment option for people with advanced soft tissue sarcoma if treatment with anthracyclines and ifosfamide has failed or they are intolerant of or have contraindications for treatment with anthracyclines and ifosfamide and the acquisition cost of trabectedin for treatment needed after the fifth cycle is met by the manufacturer.	185
Trastuzumab	Trastuzumab, given at 3-week intervals for 1 year or until disease recurrence (whichever is the shorter period), is recommended as a treatment option for women with early-stage HER2-positive breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable).	107

Drug	NICE Indication	NICE – TAG
Trastuzumab	<p>Trastuzumab in combination with paclitaxel (combination trastuzumab is currently only licensed for use with paclitaxel) is recommended as an option for people with tumours expressing human epidermal growth factor receptor 2 (HER2) scored at levels of 3+ who have not received chemotherapy for metastatic breast cancer and in whom anthracycline treatment is inappropriate.</p> <p>Trastuzumab monotherapy is recommended as an option for people with tumours expressing HER2 scored at levels of 3+ who have received at least two chemotherapy regimens for metastatic breast cancer. Prior chemotherapy must have included at least an anthracycline and a taxane where these treatments are appropriate. It should also have included hormonal therapy in suitable oestrogen receptor positive patients.</p>	34
Trastuzumab	<p>Trastuzumab, in combination with cisplatin and capecitabine or 5-fluorouracil, is recommended as an option for the treatment of people with human epidermal growth factor receptor 2 (HER2)-positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who:</p> <ul style="list-style-type: none"> • have not received prior treatment for their metastatic disease and • have tumours expressing high levels of HER2 as defined by a positive Immunohistochemistry score of 3 (IHC3 positive). 	208
Vinorelbine	For second line or later therapy treatment of advanced breast cancer when anthracycline-based regimens have failed or are unsuitable.	54 & CG81
Vinorelbine	For the treatment of stage III or IV non small cell lung cancer (NSCLC) in patients with a good performance status (WHO 0, 1 or a Karnofsky score of 80–100).	26 & CG24

Formulary principles

Combinations of NICE drugs or their use in alternative schedules

The Network Drugs and Therapeutics Committee and the Network Commissioning Group considered this to be appropriate as these alternative combinations and schedules often represent a cost saving over the duration of an individual patient's treatment. This is either because less drug is used as in the case of adjuvant docetaxel in breast cancer, or because the use of an agent in 1st or 2nd line setting precludes its use in subsequent line of chemotherapy.

Definition of intolerance

The Drugs and Therapeutics Committee has used the term 'intolerant to...' in a number of its decisions and it has become necessary to define this term. The diagnosis of intolerance is a complex patient specific judgement which reflects the development of unacceptable toxicity in relation to the perceived or intended benefit of the treatment. Intolerance is defined as follows;

A patient is deemed to be intolerant of a drug if they develop side effects which in the clinical judgement of the prescriber would prevent them from receiving further therapy. This toxicity will occur within 60 days of starting the new drug. Intolerance is not the failure to gain, or the loss of a clinical, physiological, molecular or cytogenic response.

Patients in Clinical Trials

The Drugs and Therapeutics Committee and the Network Commissioning Group accept the principle that enrolment in a clinical trial and thus the contribution to effective treatments, schedules or combinations for the future should not preclude the patient from receiving a NICE approved drug out of sequence with the NICE guidance when or if the patient requires further treatment.

Cancers of unknown origin

Patients with cancers of unknown origin will now be included in all of the formulary approved indications and costs, as by their very nature the treating clinician does not know exactly what to give and has to make a best guess based on clinical judgement informed by closest pathological fit, clinical characteristics and radiological evidence.

Improved Patient Experience

Two other general principles have been accepted and endorsed by the Network Drugs and Therapeutics Committee and the Network Commissioning Group. Both improve the experience of the patient and save the commissioners a day case or inpatient attendance cost.

1. Any regimen or therapy which has historically used infusional 5FU, with all the associated line costs (insertion, maintenance and removal), is cost neutral to oral outpatient Capecitabine or UFT.

2. The substitution of an oral agent for an IV preparation where no loss of efficacy has been demonstrated or increased patient tolerability or concordance has been shown. These patients should be initiated on the oral therapy. e.g. oral Vinorelbine c.f. IV

Formulary approved drugs

(Network Restricted Use Drugs – approved indication)

This is the list of drugs endorsed by the Network Drugs and Therapeutics Committee and funded by commissioners as part of their priority setting process. In line with the local commissioning arrangements those PCTs that are part of the Pan Birmingham LCCB will fund through their subscriptions. **Walsall PCT and South Staffordshire PCT (for Burntwood, Lichfield and Tamworth population) will fund direct from the PCT.**

These drugs are approved for use in these **specific indications** and will be funded by the PCT or LCCB High Cost drugs budget as appropriate. The use of these drugs will be monitored by the Cancer Network.

Trusts may not receive reimbursement unless they can demonstrate that drug expenditure is in line with NICE or agreed Network Formulary indications.

Drug	Indication
Alemtuzumab	Relapsed or refractory B-cell chronic lymphocytic leukaemia (B-CLL) in patients who have: <ul style="list-style-type: none"> • Relapsed or are refractory to a first line fludarabine based regimen. • On genetic screening have been shown to exhibit the 17p deletion. • ECOG performance status 0, 1 or 2.
Alemtuzumab	1 st line treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL) in patients who: <ul style="list-style-type: none"> • On genetic screening have been shown to exhibit the 17p deletion. • Are going to receive consolidation with transplantation. • ECOG performance status 0 or 1.
Arsenic trioxide	Relapsed or refractory acute promyelocytic leukaemia (APL) in patients who: <ul style="list-style-type: none"> • No prolongation of their QT interval. • Normal renal and electrolyte function including magnesium levels. • No pre-existing pleural effusions. • No pre-existing peripheral neuropathy.
Bexarotene	Advanced or 2nd line treatment of cutaneous lymphoma in line with West Midland Specialised Commissioning Team guidance on Extra-Corporeal Photopheresis.
Capecitabine	As a replacement for the continuous 5FU in ECF (epirubicin, cisplatin & infusional 5FU) i.e. as ECX (epirubicin, cisplatin & capecitabine).
Capecitabine	For 1 st or 2 nd line chemotherapy in pancreatic or cholangiocarcinoma, when: <ul style="list-style-type: none"> • Used in combination with gemcitabine. • ECOG performance status 0 or 1.
Carmustine wafers	Recurrent localised glioma after initial surgery, radiotherapy and / or temozolomide: <ul style="list-style-type: none"> • In which the neurosurgical MDT believe it is amenable to further surgical resection (complete or partial). • In patients with performance status 0 or 1.

Drug	Indication
Clofarabine	In the treatment of paediatric Acute Lymphocytic Leukaemia (ALL) when the patient is: <ul style="list-style-type: none"> • Less than 21 yrs old. • Relapsed or are refractory after receiving at least two prior regimens. • Has had one previous transplant. • Where there is no other treatment option. • It is an intention to proceed to stem cell transplantation.
Dasatinib	The 2 nd line treatment of Chronic Myeloid Leukaemia (CML), in patients who are: <ul style="list-style-type: none"> • Either intolerant of Imatinib 400mg daily. • Or who have had a previous cytogenetic response to imatinib, and who would be dose escalated should be switched to either dasatinib or nilotinib. • This should not be as a third line therapy
Degarelix	As an alternative to a LHRH agonist such as goserelin in hormone sensitive advanced prostate cancer patients when the clinician believes rapid/immediate suppression of testosterone is important. E.g. impending spinal cord compression. Funded in line with routine drug use. See page 16.
Docetaxel	Second or subsequent line chemotherapy for metastatic breast cancer, in combination with a gemcitabine. In patients whom: <ul style="list-style-type: none"> • NICE TAG # 116 applies but who cannot tolerate paclitaxel.
Docetaxel	Relapsed or refractory soft tissue sarcomas. <ul style="list-style-type: none"> • After a 1st line Ifosfamide +/- anthracycline based regimen. In combination with gemcitabine. • ECOG performance status 0, 1 or 2.
Docetaxel	In combination with cisplatin and 5FU as first line treatment for oesophageal tumours.
Docetaxel	In neo-adjuvant early breast cancer patients having an inadequate response to anthracycline based chemotherapy. <ul style="list-style-type: none"> • This use is in line with the NICE TAG 109 but extends the use into neo-adjuvant patients.
Docetaxel	In combination with cisplatin and 5FU in patients with locally advanced head and neck cancer and where: <ul style="list-style-type: none"> • The tumour is inoperable • Squamous histology • Adequate renal function for cisplatin 75mg/m² • Adequate liver function for docetaxel 75mg/m² • ECOG performance status 0, 1 or 2.
Docetaxel	In gynaecological cancers as an alternative to Paclitaxel in patients with underlying neurological problems.
Erlotinib	For second line subsequent treatment of non-small-cell lung cancer (NSCLC), except for patients who have received gefitinib as a 1 st line treatment. Not for maintenance.
Erlotinib	As an alternative to Gefitinib (as per NICE TAG 192) for the first-line treatment of people with locally advanced or metastatic non-small-cell lung cancer (NSCLC) if they test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation.
Etoposide Phosphate	Previous hypersensitivity to non phosphate formulation of etoposide.

Drug	Indication
Fulvestrant	Fulvestrant 500mg, by the most acceptable schedule for the patient, in patients with: <ul style="list-style-type: none"> Advanced oestrogen receptor positive advanced breast cancer. Progression after prior endocrine therapy.
Gemcitabine	In combination with a platinum (cisplatin or carboplatin) for adjuvant, neo-adjuvant, metastatic or locally advanced bladder cancer.
Gemcitabine	Relapsed or refractory soft tissue sarcomas. <ul style="list-style-type: none"> After a 1st line Ifosfamide +/- anthracycline based regimen. In combination with gemcitabine. ECOG performance status 0, 1 or 2.
Gemcitabine	As a single agent in leiomyosarcomas.
Gemcitabine	For the treatment of gynaecological tumours, in combination with either or both paclitaxel and carboplatin, after initial carboplatin based treatment.
Gemcitabine	In combination with paclitaxel in relapsed germ cell tumours.
Imatinib	New diagnosed C-kit positive sarcomas. <ul style="list-style-type: none"> As a 1st line therapy. Up to a dose of 600mg/day. For either unresectable or metastatic disease. ECOG performance status 0, 1 or 2.
Imatinib	Imatinib, for the treatment of patients with newly diagnosed or relapsed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukaemia (Ph+ ALL). <ul style="list-style-type: none"> Have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia or relapsed <i>or</i> Have refractory Philadelphia chromosome positive acute lymphoblastic leukaemia.
Lapatinib	Lapatinib as second line systemic treatment for patients with previously treated advanced breast cancer whose tumours express ErbB2 (HER2). Patients must fulfill the following criteria for funding: <ul style="list-style-type: none"> Should have progressive disease following prior therapy which must include anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. For advanced disease in patients at first relapse. Have a life expectancy of 12 weeks or greater. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Have histologically confirmed invasive breast cancer with stage IIIb or stage IIIc with T4 lesion, or stage IV disease.
Liposomal Cytarabine	For intrathecal use in aggressive diffuse B cell lymphoma, to decrease the number of lumbar puncture compared to non liposomal cytarabine. <ul style="list-style-type: none"> Patients should have confirmed B cell lymphoma in the CSF. Be fit enough to undergo the lumbar puncture / procedure.
Liposomal Daunorubicin	As an alternative to the non liposomal formulation in patients responding to the daunorubicin based therapy, but who has developed anaphylaxis/hypersensitivity to the non liposomal formulation.
Liposomal Doxorubicin	First line or relapsed treatment of AIDS related Kaposi's sarcoma as a single agent or in combination.

Drug	Indication
Liposomal Doxorubicin (Myocet)	<p>In patients with metastatic breast cancer who would benefit from anthracycline based chemotherapy but in whom non liposomal formulations would be contra- indicated. E.g. received a greater than the life time dose of Doxorubicin (450mg/m²) Epirubicin (950mg/m²). Or in patients with concurrent cardiovascular risk factors e.g.</p> <ul style="list-style-type: none"> • are over 65 years of age • have unstable cardiac dystrophy • have had prior anthracycline exposure in the adjuvant/ neo-adjuvant context • have received prior chest wall radiation to the heart
Liposomal Doxorubicin (Myocet)	As an alternative to caelyx in patients responding to the caelyx but who has developed anaphylaxis/hypersensitivity or grade three or four PPE to the caelyx.
Liposomal Doxorubicin (Myocet)	<p>PLDH is recommended as an option for the second-line (or subsequent) treatment of women with partially platinum-sensitive, platinum-resistant or platinum-refractory advanced ovarian cancer, and for women who are allergic to platinum-based compounds.</p> <p>Due to a current worldwide shortage of liposomal doxorubicin, commissioners have agreed to fund Myocet as alternative liposomal preparation in this indication. This decision will be reviewed regularly.</p>
Mitotane	First line chemotherapy for primary adrenal tumours, metastatic tumours or as adjuvant chemotherapy.
Nab Paclitaxel	Previous hypersensitivity to non albumin bound formulation of either paclitaxel or docetaxel in patients responding to chemotherapy, and who have tried or are unsuitable for a de-sensitisation regimen.
Nilotinib	<p>The 2nd line treatment of Chronic Myeloid Leukaemia (CML), in patients who are:</p> <ul style="list-style-type: none"> • Either intolerant of Imatinib 400mg daily. • Or who have had a previous cytogenetic response to imatinib, and who would be dose escalated should be switched to either dasatinib or nilotinib. • This should not be as a third line therapy
Nilotinib	<p>As an alternative to Imatinib (as per NICE TAG 70) in first-line treatment for people with Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in the chronic phase.</p> <p>Nilotinib is recommended as an option for the treatment of people with Philadelphia-chromosome-positive CML who initially present in the accelerated phase or with blast crisis. Additionally, nilotinib is recommended as an option for people who present in the chronic phase and then progress to the accelerated phase or blast crisis if they have not received nilotinib previously.</p>
Oxaliplatin	As a replacement for the cisplatin in ECF (epirubicin, cisplatin & infusional 5FU) i.e. as EOF (epirubicin, oxaliplatin & infusional 5FU) or EOX (Epirubicin, oxaliplatin & capecitabine).
Paclitaxel	Relapsed metastatic or locally recurrent germ cell tumours, as a single agent or as part of a combination regimen, e.g. TIP (Paclitaxel, Ifosfamide & Cisplatin).
Paclitaxel	In 1 st line or relapsed chemotherapy sensitive endometrial and cervical tumours.
Paclitaxel	In combination with a platinum in head and neck tumours.
Paclitaxel	In neo-adjuvant early breast cancer patients having an inadequate response to anthracycline based chemotherapy, either as a switch or as an addition to their current regimen.

Drug	Indication
Paclitaxel	First line treatment of AIDS related Kaposi's sarcoma.
PEG Asparaginase	Previous hypersensitivity to non pegylated asparaginase.
Pemetrexed	As a single agent or in combination as an alternative to docetaxel or erlotinib in patients with relapsed NSCLC, but only in patients with tumours which show histology that is predominantly non squamous.
Platinum(s)	Cisplatinum or oxaliplatin: For 1 st or 2 nd line chemotherapy in pancreatic or cholangiocarcinoma, when: <ul style="list-style-type: none"> • Used in combination with gemcitabine. • ECOG performance status 0 or 1.
Porfimer	1st line treatment of localised NSCLC and oesophageal cancer in line with The West Midlands Specialised Commissioning Team guidance on Photodynamic therapy in NSCLC and Oesophageal cancer.
Rituximab	Waldenstrom's macroglobulinaemia; <ul style="list-style-type: none"> • With relapsed or refractory disease when alternative treatment options have been exhausted (that is, if there is resistance to or intolerance of chemotherapy). • To allow the use of rituximab in patients with isolated neuropathy due to an M-protein. • To allow the use of rituximab in combination with chemotherapy in patients considered eligible for an autologous or allogeneic peripheral blood stem cell transplant.
Rituximab	Marginal zone lymphomas; <ul style="list-style-type: none"> • With relapsed or refractory disease when alternative treatment options have been exhausted (that is, if there is resistance to or intolerance of chemotherapy). • To allow the use of rituximab in patients with isolated neuropathy due to an M-protein. • To allow the use of rituximab in combination with chemotherapy in patients considered eligible for an autologous or allogeneic peripheral blood stem cell transplant.
Rituximab	In combination with chemotherapy for newly diagnosed Burkitt's lymphoma patients.
Rituximab	In combination with chemotherapy for newly diagnosed mantle cell lymphoma patients.
Rituximab	For the first line use of rituximab in post-transplant lymphoproliferative disorders (PTLDs).
Streptozotocin	For the first line chemotherapy of carcinoid or related GI tumours. <ul style="list-style-type: none"> • In combination with 5FU • Patient capable of tolerating the 5 day schedule
Temoporfin	As part of the package of care for the treatment of head and neck patients according to the Pan-Birmingham Cancer commissions approval of Photodynamic therapy.
Thalidomide	In combination with an alkylating agent and corticosteroid for the 1st line treatment of multiple myeloma. Funded in line with routine drug use. See page 16.
Trastuzumab	In neo-adjuvant early breast cancer patients who are HER II positive and receiving chemotherapy the trastuzumab is administered as part of their overall 18 doses of adjuvant treatment, as described in the NICE guidance TAG # 107.

Vinorelbine	As a single agent for mesothelioma in patients unable to tolerate cisplatin based chemotherapy.
-------------	-------------------------------------------------------------------------------------------------

Formulary exclusions

Rituximab	<p>Rituximab is not included on the formulary for non-malignant haematology – autoimmune related conditions including;</p> <ul style="list-style-type: none"> • Immune thrombocytopenic purpura, • Thrombotic thrombocytopenic purpura and • Autoimmune hemolytic anemias. <p>Whilst these are considered suitable clinical uses of rituximab they will not be funded through the cancer LCCB commissioning arrangements, therefore clinicians will either have to fund these through their institute’s haematology contracts with their purchaser PCT’s or through individual patient request (IFR) directly to the patient’s PCT</p>
-----------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Routine use

Unrestricted drugs

The following is the list of drugs that are available for use and where funding is allocated through the chemotherapy activity baseline budget – managed by Acute Trust.

Unrestricted drugs		
Alemtuzumab	Daunorubicin	Mitomycin
Amsacrine	Doxorubicin	Mitoxantrone
Azathioprine	Epirubicin	Pentostatin
Bacillus Calmette-Guérin (BCG)	Estamustine	Procarbazine
Bleomycin	Etoposide	Raltitrexed
Busulfan	Etoposide Phosphate	Strontium 89
Carboplatin	Fludarabine	Thalidomide
Carmustine	Fluorouracil	Thioguanine
Chlorambucil	Hydroxycarbamide (Hydroxyurea)	Thiotepa
Cisplatin	Idarubicin	Treosulfan
Cladribine	Ifosfamide	Tretinon
Crisantaspase (Asparaginase)	Interferon - alfa	Vinblastine
Cyclophosphamide	Lomustine	Vincristine
Cytarabine	Melphalan	Vindesine
Dacarbazine	Mercaptopurine	
Dactinomycin (Actinomycin D)	Methotrexate	
Hormonal chemotherapy*		
Aminoglutethimide	Ethinylestradiol	Leuprorelin
Anastrozole	Exemestane	Medroxy-progesterone
Bicalutamide	Flutamide	Megestrol
Buserelin	Fulvestrant	Norethisterone
Cyproterone	Goserelin	Tamoxifen
Degarelix	Histrelin	Triptorelin
Diethylstilbestrol	Letrozole	Toremifene
This list includes all the depot “multi-month” preparations available		
Somatostatin analogues used in Cancer*		
Lanreotide L.A.	Octreotide Lar	
Lanreotide Autogel	Octreotide	

*Hormonal and somatostatin based chemotherapy appearing in the formulary are considered to be safe and acceptable for monitoring and prescribing by patient's General Practitioners, once initiation and stabilisation under the care of an oncologist has occurred, this will generally be in the order of one to three months.

Drugs approved by the cancer drugs fund

How do you apply to use the fund?

Funding requests can only be made by the patient's Consultant Oncologist or Haematologist. Requests are considered by an independent panel of clinicians, called the Cancer Drug Fund Clinical Panel.

Cohort Policies

The panel have already fast tracked the development of a number of policies for cohorts of patients against which clinicians can apply to on behalf of their patients. Where treatments are included in the Priority Drugs list, there will be an accompanying policy to fund from the CDF.

These applications can be approved without the need to be referred to the PCT. Consultants need to download the application form and complete sections A & B and return to wm.cancerdrugs@nhs.net where it will be fast tracked for a decision.

Individual Drug Funding Requests

If a drug or indication can not be found in the network formulary or the cohort list below, then a clinician should consider making an individual funding request to the interim cancer drugs fund.

See <http://www.westmidlands.nhs.uk/WhatWeDo/WestMidlandsCancerDrugFund.aspx> for full details of how to apply to the cancer drugs fund, or email wm.cancerdrugs@nhs.net

Drug	Indication
Abiraterone and cabazitaxel	<p>Prostate cancer</p> <p>Abiraterone and cabazitaxel have been accepted by the West Midlands Cancer Drugs Fund Clinical Panel for funding from the Cancer Drugs Fund as options for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel containing regimen.</p> <p>Sequential use of abiraterone and cabazitaxel, on the basis of affordability, is not routinely funded by the Cancer Drugs Fund.</p> <p>Use of abiraterone or cabazitaxel outside of the stated eligibility criteria will only be considered in clinically exceptional circumstances through the Individual Funding route. The following criteria must be fulfilled for funding:</p> <ul style="list-style-type: none"> • The patient has hormone refractory metastatic prostate cancer which has previously been treated with a docetaxel-containing regimen, AND • Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 <p>Choice of abiraterone or cabazitaxel is based on a discussion between the clinician and patient.</p>
Abraxane (Paclitaxel albumin)	<p>Metastatic breast cancer</p> <p>Paclitaxel albumin has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as treatment for patients with metastatic breast cancer who have failed first-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated.</p>

	<p>Paclitaxel albumin will not be funded by the Interim Cancer Drugs Fund for breast 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 the Individual Funding route. Patients must have the following criteria for funding:</p> <ul style="list-style-type: none"> • patients must be those who would otherwise receive docetaxel or 3-weekly solvent-based paclitaxel as second-line treatment for metastatic breast cancer • Patients must have an Eastern Cooperative Oncology Group performance status ≤ 2
<p>Alemtuzumab</p>	<p>B-cell chronic lymphocytic leukaemia</p> <p>Alemtuzumab has been accepted by the Cancer Drugs Fund Clinical Panel for funding under the cancer drugs fund for treatment of patients with B-cell chronic lymphocytic leukaemia:</p> <ol style="list-style-type: none"> 1. who have the 17p gene deletion, first line or 2. without bulky (>5cm) lymphadenopathy who are refractory to purine containing regimens or who have progressed within 12 months of a purine treatment <p>Alemtuzumab will not be funded by the Cancer Drugs Fund 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 the Individual Funding route.</p> <p>Patients who have the 17p gene deletion must fulfil the following criteria for first line funding:</p> <ul style="list-style-type: none"> • Have chronic lymphocytic leukaemia with 17p gene deletion • Be unsuitable for fludarabine based combination therapy • Have WHO performance status of 0 to 2 • Have Rai stage I-IV disease • Be experiencing progression of their B-CLL according to National Cancer Institute Working Group (NCIWG) 1996 criteria requiring treatment
<p>Bendamustine monotherapy or combined with rituximab</p>	<p>Relapsed chronic lymphocytic leukaemia</p> <p>Bendamustine as monotherapy or combined with rituximab has been accepted, by the Clinical Panel of the Cancer Drugs Fund for funding under the cancer drugs fund only as treatment for patients with relapsed chronic lymphocytic leukaemia requiring treatment in patients who are suitable for a fludarabine containing regimen. Use of the drug or drug combination outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route.</p> <p>Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have Binet stage B or Binet stage C disease. • Be refractory to the prior therapy (relapse within a period < 6 months after last therapy) or have progressive or relapsed disease. • Have received at least one prior therapy that included chlorambucil or fludarabine. • Be bendamustine naïve. • Have a life expectancy of 3 months or greater. • Have an Eastern Cooperative Oncology Group (ECOG) or WHO performance status ≤ 2.

<p>Bendamustine combination rituximab</p> <p>in with</p>	<p>First-line treatment of Chronic Lymphocytic Leukaemia</p> <p>Bendamustine in combination with rituximab has been accepted by the West Midlands Cancer Drugs Fund Panel for funding from the Cancer Drugs Fund for the first-line treatment of patients with Chronic Lymphocytic Leukaemia (CLL) who are not suitable for a fludarabine containing regimen.</p> <p>Bendamustine in combination with rituximab will not be funded by the Cancer Drugs Fund for CLL in any other setting (unless covered by a separate policy). Use of this drug combination outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route.</p> <p>The use of bendamustine monotherapy as an option in the treatment of patients with CLL for whom fludarabine combination therapy is not appropriate is supported by NICE Technology Appraisal 216; use in this setting is not covered by this policy.</p> <p>The following criteria must be fulfilled for funding:</p> <ul style="list-style-type: none"> • Have not been previously treated with chemotherapy or chemoimmunotherapy for CLL • Be unsuitable for treatment with a fludarabine containing regimen • Have a life expectancy of 3 months or greater •
<p>Bendamustine</p>	<p>Indolent non-Hodgkin's lymphomas</p> <p>Bendamustine has been accepted by the Cancer Drugs Fund Clinical Panel for funding under the cancer drugs fund as treatment for patients with Indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during/ or within 6 months following treatment with rituximab or a rituximab containing regimen.</p> <p>Bendamustine will not be funded by the Cancer Drugs Fund for non-Hodgkin's lymphomas 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 the Individual Funding route.</p> <p>Patients must have the following criteria for funding:</p> <ul style="list-style-type: none"> • Have a WHO performance status ≤ 2. • Have indolent NHL, being either of follicular NHL, marginal zone lymphoma or small lymphocytic lymphoma. • Have progressed during/ or within 6 months following treatment with rituximab or a rituximab containing regimen. • Had a maximum of 3 prior chemotherapy regimens.
<p>Bevacizumab</p>	<p>Advanced colorectal cancer</p> <p>Bevacizumab has been accepted, within its licensed indication, by the ICDF Clinical Panel for funding under the interim cancer drugs fund as second line systemic treatment for patients with advanced colorectal cancer in combination with oxaliplatin or irinotecan.</p> <p>Bevacizumab may not be used for advanced colorectal cancer in any other setting. Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through the individual funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Should have progressive disease following first line therapy for advanced disease. • Have a life expectancy of 3 months or greater • Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 •

Bevacizumab	<p>Triple negative breast cancer</p> <p>Bevacizumab has been accepted, within its licensed indication, by the ICDF Clinical Panel for funding under the interim cancer drugs fund as first line treatment for patients with advanced “triple negative” breast cancer in combination with paclitaxel or docetaxel.</p> <p>Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have “triple negative” recurrent or metastatic breast cancer i.e. be Human Epidermal Growth Factor 2 (HER2) negative¹, Oestrogen Receptor (ER) negative and Progesterone Receptor (PR) negative. • Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • Patients who had received taxane-based adjuvant therapy were required to have had a disease-free interval of at least 12 months after completion of taxane therapy.
Bortezomib	<p>Multiple myeloma with renal failure</p> <p>Bortezomib been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as treatment for newly diagnosed patients with Multiple Myeloma presenting with acute renal failure.</p> <p>Bortezomib will not be funded by the Interim Cancer Drugs Fund for Multiple Myeloma 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 the individual funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Patients have commenced renal dialysis because of myeloma or have a glomerular filtration rate ≤ 15 ml/min and a renal physician’s opinion that dialysis will be required. • Patients must be started on treatment within 42 days of the onset of renal failure. • Patients should be considered for entry into the Eulite trial (check locally for recruiting centres) - in keeping with the ambition to offer clinical trials to all patients whenever possible.
Cetuximab and panitumumab	<p>Advanced colorectal cancer</p> <p>Cetuximab (as monotherapy or in combination with irinotecan) has been accepted, within its licensed indication, by the ICDF Clinical Panel for funding under the interim cancer drugs fund only as third line systemic treatment for patients with advanced colorectal cancer (i.e. after two previous lines of chemotherapy).</p> <p>Cetuximab may not be used for advanced colorectal cancer in any other setting. Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through the individual funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Should have epidermal growth factor receptor (EGFR) expressing, KRAS wild-type metastatic colorectal cancer • Have a life expectancy of 3 months or greater • Have Karnofsky performance status ≥ 60 • Have Neutrophils $\geq 1.5 \times 10^9/L$, platelets $\geq 100 \times 10^9/L$, and haemoglobin ≥ 9 g/dL; bilirubin level $< 1.5 \times ULN$ (upper limit of normal range), aspartate aminotransferase and alanine aminotransferase $\leq 5 \times ULN$ and serum creatinine $< 1.5 \times ULN$

Cetuximab	<p>Advanced squamous cell carcinoma (head and neck)</p> <p>Cetuximab, in combination with platinum based therapy, followed by maintenance monotherapy has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as treatment for patients presenting with advanced squamous cell carcinoma of the head and neck.</p> <p>Cetuximab will not be funded by the Interim Cancer Drugs Fund for head and neck 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 the individual funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have a Karnofsky performance status of 80 or more • Be below 65 years of age • Have adequate haematologic, renal, and hepatic function (serum creatinine 1.5 fold, transaminases 5 fold and bilirubin 1.5 fold the upper limit of normal) • Have not been previously treated with chemotherapy for head and neck cancer
Eribulin	<p>Advanced breast cancer</p> <p>Eribulin has been accepted by the West Midlands Cancer Drugs Fund Clinical Panel for funding from the Cancer Drugs Fund as an option in the treatment of locally advanced or metastatic breast cancer. Use of eribulin outside of the stated eligibility criteria will only be considered in clinically exceptional circumstances through the Individual Funding route. The following criteria must be fulfilled for funding:</p> <ul style="list-style-type: none"> • The patient has previously received the following treatments, in line with NICE Clinical Guideline 81: <ul style="list-style-type: none"> ○ An anthracycline – in the adjuvant or metastatic setting (or a contra-indication to anthracycline treatment) ○ A taxane ○ Vinorelbine ○ Capecitabine, AND • Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
Everolimus	<p>Renal cell cancer</p> <p>Everolimus has been accepted, within its licensed indication, by the Clinical Advisory Panel for Cancer Medicines for funding under the interim cancer drugs fund for patients progressing on first line VEGF-targeted treatments (e.g. sunitinib) being treated for renal cell cancer. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Progressed on first line treatment (e.g. sunitinib) • Have a Karnofsky Performance Status \geq 70% • Must not have severe hepatic impairment (Child-Pugh class C)
FOLFOX (Oxaliplatin)	<p>As part of the FOLFOX regime in pancreatic cancer</p> <p>FOLFOX (a regimen of 5-fluorouracil, folinic acid and oxaliplatin) has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund for the treatment of patients with pancreatic cancer who have progressed after first line chemotherapy.</p> <p>FOLFOX will not be funded by the Interim Cancer Drugs Fund 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 the Individual Funding route.</p> <p>Please note capecitabine may not be substituted for 5FU/folinic acid.</p>

	<p>Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have radiological evidence disease progression following gemcitabine therapy. • Have WHO performance status of 0 to 1 (or Karnofsky performance status of ≥ 70) • They should have adequate renal and hepatic function to tolerate oxaliplatin.
Fulvestrant	<p>Advanced breast cancer</p> <p>Fulvestrant 500mg has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as treatment for women with advanced oestrogen receptor positive advanced breast cancer.</p> <p>Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through the individual funding route. Patients must have the following criteria for funding:</p> <ul style="list-style-type: none"> • Oestrogen receptor positive advanced breast cancer. • Progression after prior endocrine therapy.
Imatinib	<p>Gastrointestinal stromal tumours (GIST).</p> <p>Imatinib has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as adjuvant treatment for patients with gastrointestinal stromal tumours (GIST).</p> <p>Imatinib will not be funded by the Interim Cancer Drugs Fund for GIST 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 the individual funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have a at high risk of relapse following complete resection of Kit (CD117)-positive gastrointestinal stromal tumours • Recurrence risk should be assessed using the Armed Forces Institute of Pathology (AFIP), Miettinen and Lasota risk criteria.
Imatinib	<p>Mucosal melanoma</p> <p>Imatinib has been accepted by the ICDF Clinical Panel for funding under the interim cancer drugs fund as treatment for patients with advanced mucosal melanoma carrying a mutation in "c-kit".</p> <p>Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have advanced mucosal melanoma carrying a mutation in „c-kit“ • Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2.
Imatinib	<p>Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ ALL).</p> <p>Imatinib, has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as treatment for patients with newly diagnosed or relapsed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukaemia (Ph+ ALL).</p> <p>Imatinib will not be funded by the Interim Cancer Drugs Fund for Philadelphia Chromosome-Positive Acute Lymphoblastic Leukaemia 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 the individual funding route. Patients must fulfil the</p>

	<p>following criteria for funding:</p> <ul style="list-style-type: none"> • Have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia or relapsed <i>or</i> • Have refractory Philadelphia chromosome positive acute lymphoblastic leukaemia.
Ipilimumab	<p>Melanoma</p> <p>Ipilimumab has been accepted by the West Midlands Cancer Drugs Fund Panel for funding from the Cancer Drugs Fund as a first- or second-line therapy for the palliative treatment of patients of good performance status with unresectable stage 3 or stage 4 malignant melanoma. Ipilimumab will not be routinely funded by the Cancer Drugs Fund for melanoma in any other setting, including relapse after initial response to ipilimumab. Use of ipilimumab outside of the stated eligibility criteria will only be considered in clinically exceptional circumstances through the Individual Funding route. The following criteria must be fulfilled for funding:</p> <ul style="list-style-type: none"> • Ipilimumab, as monotherapy or in combination with dacarbazine, will be funded as a first-line therapy for the treatment of patients with unresectable stage 3 or stage 4 malignant melanoma, OR • Ipilimumab, as monotherapy, will be funded as a second-line therapy for the treatment of unresectable stage 3 or stage 4 malignant melanoma, AND • Patients must have an Eastern Cooperative Oncology Group (ECOG) • performance status of 0 or 1
Lapatinib	<p>Advanced breast cancer</p> <p>Lapatinib has been accepted, within its licensed indication, by the ICDF Clinical Panel for funding under the interim cancer drugs fund as second line systemic treatment for patients with previously treated advanced breast cancer whose tumours express ErbB2 (HER2).</p> <p>Lapatinib may not be used for advanced breast cancer in any other setting. Use of the drug outside of the stated eligibility criteria will only be considered in exceptional circumstances through the individual funding route. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Should have progressive disease following prior therapy which must include anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. Funding is approved for advanced disease in patients at first relapse. • Have a life expectancy of 12 weeks or greater • Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Have histologically confirmed invasive breast cancer with stage IIIb or stage IIIc with T4 lesion, or stage IV disease
Lenalidomide	<p>Myelodysplasia</p> <p>Lenalidomide has been accepted by the Cancer Drugs Fund Clinical Panel for funding under the cancer drugs fund as treatment for patients with myelodysplasia with „5q- syndrome“.</p> <p>Lenalidomide may not be used for myelodysplasia in any other setting. Funding of the drug by the Cancer Drugs Fund outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route.</p> <p>Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have 5q- syndrome • a confirmed histological diagnosis of primary myelodysplasia with typical dysmegakaryopoiesis • Have a chromosome 5q31 deletion not accompanied by additional cytogenetic abnormalities

	<ul style="list-style-type: none"> • Have a disease of low or intermediate-1 risk, according to the International Prognostic Scoring System (IPSS) • Be blood transfusion dependant (defined for the purpose of this policy as requiring more than 2 units of blood each month)
Pazopanib	<p>Renal cancer</p> <p>Pazopanib has been accepted by the Cancer Drugs Fund Clinical Panel for funding under the interim cancer drugs fund as treatment for patients with renal cancer who are unable to tolerate sunitinib.</p> <p>Pazopanib will not be funded by the Cancer Drugs Fund for renal 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 the Individual Funding route.</p> <p>Patients must have the following criteria for funding:</p> <ul style="list-style-type: none"> • Been initiated on sunitinib, as described in NICE Technology Appraisal 169 • Have not received prior cytokine therapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
Rituximab combination chemotherapy	<p>in with</p> <p>First-line treatment of Mantle Cell Lymphoma (MCL)</p> <p>Rituximab in combination with chemotherapy has been accepted by the West Midlands Cancer Drugs Fund Panel for funding from the Cancer Drugs Fund for the first-line treatment of Mantle Cell Lymphoma (MCL). The chemotherapy regimen used should be based on the level of fitness of the individual.</p> <p>Use of the 2nd Nordic MCL protocol (rituximab with alternating maxi-CHOP and high dose cytarabine) has been accepted for funding from the Cancer Drugs Fund in patients with MCL who are fit enough for autologous stem cell transplantation.</p> <p>Rituximab in combination with chemotherapy will not be funded by the Cancer Drugs Fund for mantle cell lymphoma in any other setting (unless covered by a separate policy). Use of the drug combination outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route.</p> <p>The following criteria must be fulfilled for funding:</p> <ul style="list-style-type: none"> • Have not received previous systemic treatment for mantle cell lymphoma • For treatment with the 2nd Nordic MCL protocol: <ol style="list-style-type: none"> 1. Have a performance status of 0 – 2 2. Planned to undergo autologous stem cell transplantation
Sorafenib	<p>Hepatocellular cancer</p> <p>Sorafenib has been accepted, within its licensed indication, by the Clinical Advisory Panel for Cancer Medicines for funding under the interim cancer drugs fund as first line systemic treatment for patients with hepatocellular cancer. Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have a predicted to have a life expectancy of at least 12 weeks • Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0–2 • Have histologically or cytologically documented hepatocellular carcinoma • Have at least one measurable tumour not previously treated with local therapy • Have a Child–Pugh liver function status of grade A or B • Have platelet count, $\geq 60 \times 10^9$ /L; haemoglobin, ≥ 8.5 g/dL; and prothrombin time international normalized ratio, ≤ 2.3; or prothrombin time ≤ 6 seconds above control • Have serum albumin greater than 28 g/L , bilirubin less than 51.3 $\mu\text{mol/L}$, alanine aminotransferase and aspartate aminotransferase ≤ 5 times the upper limit of the

	<p>normal range</p> <ul style="list-style-type: none"> • Have adequate renal function (serum creatinine, ≤ 1.5 times the upper limit of the normal range).
Sunitinib and Everolimus	<p>Pancreatic neuroendocrine tumours</p> <p>Sunitinib and Everolimus have been accepted by the Cancer Drugs Fund Clinical Panel for funding under the cancer drugs fund as treatment for patients with pancreatic neuroendocrine tumours. Insulinomas are excluded from this policy.</p> <p>Funding of the drugs by the Cancer Drugs Fund outside of the stated eligibility criteria will only be considered in exceptional circumstances through the Individual Funding route.</p> <p>Patients must fulfil the following criteria for funding:</p> <ul style="list-style-type: none"> • Have a well differentiated tumour with evidence of progressive disease, • Have relapsed after ocreotide or sandostatin analogues
Temsirolimus	<p>Renal cancer</p> <p>Temsirolimus has been accepted by the Interim Cancer Drugs Fund Clinical Panel for funding under the Interim Cancer Drugs Fund as treatment for patients with renal cancer with a poor prognosis for whom sunitinib is unsuitable.</p> <p>Temsirolimus will not be funded by the Interim Cancer Drugs Fund for renal 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 the Individual Funding route. Patients must have three of the following criteria for funding:</p> <ul style="list-style-type: none"> • less than 1 year from time of initial Renal Cell Carcinoma (RCC) diagnosis to initiation of treatment • Karnofsky performance status of 60–70 • haemoglobin less than the lower limit of normal • corrected calcium greater than 10 mg/100 ml (or 2.5 mmol/litre) • serum lactate dehydrogenase more than 1.5 times the upper limit of normal • more than one metastatic organ site.
Trastuzumab	<p>Metastatic IHC2-positive gastric cancer</p> <p>Trastuzumab, in combination with cisplatin and 5FU or capecitabine, has been accepted by the West Midlands Cancer Drugs Fund Panel for funding from the Cancer Drugs Fund for the treatment of patients with metastatic adenocarcinoma of the stomach or gastro-oesophageal junction whose tumours have HER2 overexpression as defined by IHC2-positive and a confirmatory SISH or FISH result who have not received prior anti-cancer treatment for their metastatic disease.</p> <p>Trastuzumab will not be funded by the Cancer Drugs Fund for metastatic gastric 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 the Individual Funding route.</p> <p>The following criteria must be fulfilled for funding:</p> <ul style="list-style-type: none"> • Have not been previously treated with chemotherapy for metastatic • gastric cancer • Have HER2 overexpression as defined by Immunohistochemistry (IHC)2-positive and a confirmatory fluorescence in situ hybridisation (FISH) or silver in situ hybridisation (SISH) positive result. Accurate and validated assay methods should be used.