National Cancer Drugs Fund List Ver6.0

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Version Control

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Version Control		
Versio	**Date**	**Revision summary**
Ver1.0	19 Mar 2014	Update following Mar-14 NCDF panel meeting
Ver1.1	14 May 2014	Update following licensing of Cabozantinib
Ver2.0	21 August 2014	Update following Jul-14 NCDF panel meeting
Ver2.1	24 October 2014	Minor updates to ABI1_v2.1, BEV1_v3.1, DAB1_v2.1, RADIU1_ver3.1 and ENZ2_v1.1 and addition of IDE1_v1.0
Ver3.0	12 January 2015	Update following Dec-14 NCDF panel meeting
Ver4.0	12 March 2015	Update following removal of drugs as a result of the Dec-14 NCDF panel meetin
Ver4.1	21 May 2015	Update following Mar-15 NCDF panel meeting. Removal of adjuvant Imatinib for the treatment of GIST following NICE approval and NHS England funding from 2 February 2015
Ver4.2	22 May 2015	Re-addition of Cabazitaxel
Ver4.3	05 June 2015	Removal of AXI1_v2.0 following NICE approval and baseline funding from 27th M 2015; Update to BEV3_v2.1 to incorporate ICON 8b trial patients; Update to PEM2_v3.0 as per NHSE SSC 1530 to remove wording around removal in Jul-15
Ver4.4	21 July 2015	Removal of EVE_v2.1 and PEM1_v2.0 following the Mar-15 NCDF panel meeting
Ver5.0	04 September 2015	Update following Jul-15 NCDF panel meeting; expansion of PAN3_ver1.0 and update to PAN1_ver3.1
Ver5.1	11 September 2015	Update to EVE3_v2.1 and creation of new form with addition of "Will apply from 4th November 2015" to new Everolimus form. Creation of new form for ibrutinib with addition of "Will apply from 4th November 2015" to new ibrutinib form. Removal of Cabazitaxel from Confirmation of previously notified drugs and indications delisted March 12th 2015. Update to CET1_v5.0 to remove note limiting use with other oxaliplatin-based regimens or upfront single agent fluoropyrimidine. Update to CET4_v3.0 to state "Given with oxaliplatin-based combination chemotherapy regimens"; to remove note limiting use with other oxaliplatin-based regimens, irinotecan- based combinations or upfront single agent fluoropyrimidine; and to state "1st Line in combination with oxaliplatin-based chemotherapy" Removal of OFA2_v1.0 following NICE approval
Ver6.0	04 November 2015	Update following removal of drugs/indications as a result of the July 2015 NCDF Panel reprioritisation meeting

National Cancer Drugs Fund List – Approved

DRUG	*NCDF APPROVED CRITERIA*
Abiraterone **Form ref: ABI1_v2.1**	*The treatment of metastatic castration resistant prostate cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. *a. Histologically/ cytologically confirmed adenocarcimoma of the prostate* *OR* *b. Clinical suspicion of prostate cancer is high due to high PSA value (>100ng/ml) and evidence of bone metastases (identified by a positive isotope bone scan or sclerotic metastases on plain radiographs)*
	3. Documented metastatic disease
	4. Either PSA progression according to Prostate Cancer Clinical Trials Working Party Group 2 criteria or radiographic progression
	5. Continuing androgen deprivation
	6. Performance status 0 or 1
	7. Asymptomatic (0 or 1) or mildly symptomatic (2-3) as scored on the Brief Pain Inventory Short Form question 3
	8. No visceral disease
	9. No previous chemotherapy
	10. No previous treatment with enzalutamide unless enzalutamide has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression
Bendamustine **Form ref: BEN1_v2.0**	*The first line treatment of low grade lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Low grade non-Hodgkin's lymphoma
	3. Option for 1st-line chemotherapy
	4. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication
	Note: Can be used in combination with Rituximab, which is commissioned by NHS England for this indication.
Bendamustine **Form ref: BEN6_v2.0**	*The treatment of relapsed low grade lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Low grade non-Hodgkin's lymphoma
	3. Relapsed disease
	4. Unable to receive CHOP-R
	5. Unable to receive FCR
	6. Unable to receive high dose-therapy

	7. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication
	Note: Can be used in combination with Rituximab, which is commissioned by NHS England for this indication.
Bendamustine **Form ref: BEN2_v2.0**	*The first line treatment of mantle cell non-Hodgkin's lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Mantle cell non-Hodgkin's lymphoma
	3. 1st-line treatment in patients unsuitable for standard treatment
	4. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication
	Note: Can be used in combination with Rituximab, which is commissioned by NHS England for this indication.
Bendamustine **Form ref: BEN5_v2.0**	*The treatment of relapsed multiple myeloma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Multiple myeloma
	3. Relapsed disease where other treatments contraindicated or inappropriate
	4. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication
Bevacizumab **Form ref: BEV2_v1.1**	*The first line treatment of recurrent or metastatic cervical cancer in combination with chemotherapy*
	1.Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Histologically confirmed carcinoma of the cervix
	3. Indication for 1st line palliative chemotherapy
	4. Primary stage IVB, recurrent, or persistent disease not amenable to curative treatment with surgery and/or radiotherapy.
	5. Given with Paclitaxel and either Cisplatin or Carboplatin
	6. PS 0 or 1
	7. No previous treatment with bevacizumab or other anti-VEGF therapy
	8. No contra-indication to the use of bevacizumab
	9. Bevacizumab dose to be 15mg/kg every 3 weeks
	Note: Bevacizumab is ONLY approved for use in combination with combination chemotherapy and is not approved for use as a single agent maintenance therapy
	Note: Bevacizumab should be discontinued due to toxicity or disease progression, whichever occurs first.
Bevacizumab **Form ref: BEV8_v1.2**	*The third line treatment of low grade gliomas of childhood where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant paediatric specialist specifically trained and accredited in the use of systemic anti-cancer therapy

	2. Progressive low grade glioma
	3. No previous treatment with either irinotecan or bevacizumab
	4. Irinotecan and bevacizumab to be the 3rd or further line of therapy
	5. A maximum of 12 months duration of treatment to be used with a re-application required at 6 months
	6. Consent with the parent/guardian to specifically document the unknown long term toxicity of this combination, particularly on growth and ovarian function
	8. To be used within the treating Trust's governance framework, as Bevacizumab and Irinotecan are not licensed in this indication in children
	9. The treating Trust has to formally agree to comply with full SACT dataset collection
	10. In the period immediately prior to the application for irinotecan and bevacizumab, the appropriate specialist MDT has considered the use of proton beam radiotherapy.
	NOTE: Bevacizumab is ONLY approved for use in combination with combination chemotherapy and is not approved for use as a single agent maintenance therapy
	NOTE: Additional data on long term toxicity must be collected by the paediatric oncology community
Bevacizumab **Form ref: BEV3_v2.1**	*The first line treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Chemotherapy naïve advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (not licensed at this dosage)
	3. 1st line indication
	4. Patients must satisfy one of the following criteria: *i) FIGO stage III debulked but residual disease more than 1cm OR* *ii) Stage IV disease OR* *iii) Stage III at presentation and requiring neo-adjuvant chemotherapy due to low likelihood of optimal primary surgical cytoreduction*
	5. Given with Carboplatin and Paclitaxel combination chemotherapy
	6. Bevacizumab to start with:
	· 1st or 2nd cycle of chemotherapy following primary debulking surgery, OR
	· 1st or 2nd cycle of chemotherapy following interval debulking surgery performed after 3-4 cycles of neo-adjuvant chemotherapy, OR
	· 1st or 2nd cycles of chemotherapy for those patients with stage IV disease or inoperable disease, OR
	· 1st cycle of neo-adjuvant chemotherapy
	7. Bevacizumab dose to be 7.5mg/kg every 3 weeks
	8. Maximum of 18 cycles of Bevacizumab
	9. As this dosage of Bevacizumab is not licensed in ovarian cancer it must be used within the treating Trust's governance framework

	Note: This policy is NOT for patients with stage I-III disease who have had optimal debulking
	Note: These criteria also apply to patients entered into the ICON 8b trial. Clinicians should be aware that for patients randomised to the non-bevacizumab arm of ICON 8b, the use of bevacizumab in subsequent lines of treatment is not approved under current CDF criteria.
Bortezomib **Form ref: BOR1_v2.0**	*The treatment of bortezomib naive relapsed multiple myeloma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Relapsed myeloma
	3. No previous Bortezomib as 2nd line (NICE approved) treatment
Bosutinib **Form ref:** **BOS3_v2.1**	*The treatment of chronic phase Chronic Myeloid Leukaemia where there is intolerance of treatment(s) and where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Chronic phase Chronic Myeloid Leukaemia
	3. Significant intolerance to nilotinib (Grade 3 or 4 events)
	4. Significant intolerance to dasatinib (Grade 3 or 4 adverse events) (if Dasatinib accessed via its current approved CDF indication)
Brentuximab **Form ref: BRE1_v2.1**	*The treatment of refractory systemic anaplastic lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Relapsed or refractory systemic anaplastic large cell lymphoma
Brentuximab **Form ref: BRE2_v2.1**	*The treatment of relapsed or refractory CD30+ Hodgkin's lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Relapsed or refractory CD30+ Hodgkin lymphoma
	3. a) Following autologous stem cell transplant (ASCT), OR,
	b) Following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option
	NOTE: If a patient has not achieved a partial or complete response after 6 cycles, then treatment with brentuximab should be discontinued
Cabazitaxel **Form ref: CABA1_v3.0**	*The treatment of castrate-resistant Metastatic Prostate Cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Castrate-resistant Metastatic Prostate Cancer
	3. Previous treatment with docetaxel based regimens
Cabozantinib	*The first line treatment of medullary thyroid cancer where all the following criteria are met:*

Form ref: CABO1_v1.1	*1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy*
	2. Histologically confirmed, unresectable, locally advanced or metastatic medullary thyroid cancer
	3. Progressive and symptomatic disease
	4. No previous tyrosine kinase therapy unless intolerant of vandetanib within 3 months of starting therapy and toxicity which cannot be managed by dose delay or dose modification and in the absence of disease progression on vandetanib
Cetuximab **Form ref: CET7_v2.0**	*The first line treatment of advanced head and neck cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Advanced Head and Neck Cancer
	3. Use with standard 1st line palliative combination chemotherapy
	4. Performance status 0 or 1
	5. No previous treatment with Cetuximab
Cetuximab **Form ref: CET1_v5.1**	*The first line treatment of metastatic colorectal cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Metastatic colorectal cancer
	3. 1st line indication
	4. Patients with wild-type RAS
	5. Given in combination with Irinotecan-based combination chemotherapy
	6. Cetuximab given as a 2-weekly regimen at a dose of 500mg/m^2
	7. a. Not eligible for NICE TA176 approved indications ***OR*** *b. Eligible for treatment under TA176 and no progression after receiving the approved 16 weeks treatment with cetuximab but unsuitable for surgery and meeting criteria 1-6*
	8. No previous treatment with Cetuximab or Panitumumab (unless meeting condition 7b)
	Note: No treatment breaks of more than 4 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or in the case of intercurrent co-morbidities)
	Note: If excessive toxicity with irinotecan, cetuximab can be continued with a fluoropyrimidine alone until disease progression only.
Cetuximab **Form ref: CET4_v3.1**	*The first line treatment of metastatic colorectal cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Metastatic colorectal cancer
	3. 1st line indication
	4. Patients with wild-type RAS
	5. Given in combination with oxaliplatin-based chemotherapy regimens

	6. Cetuximab given as a 2-weekly regimen at a dose of 500mg/m^2
	7. a. Not eligible for NICE TA176 approved indications ***OR*** *b. Eligible for treatment under TA176 and no progression after receiving the approved 16 weeks treatment with cetuximab but unsuitable for surgery and meeting criteria 1-6*
	8. No previous treatment with Cetuximab or Panitumumab (unless meeting condition 7b)
	Note: No treatment breaks of more than 4 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or in the case of intercurrent co-morbidities)
	Note: If excessive toxicity with oxaliplatin, cetuximab can be continued with a fluoropyrimidine alone until disease progression only.
Clofarabine **Form ref: CLO1_v2.0**	*The treatment of relapsed/refractory acute lymphoblastic leukaemia where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Acute lymphoblastic leukaemia
	3. Relapsed/ refractory disease with intent to use treatment to bridge to bone marrow transplant
Clofarabine **Form ref: CLO2_v2.0**	*The treatment of relapsed/refractory acute myeloblastic leukaemia where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Acute myeloblastic leukaemia (not licensed for this indication)
	3. Relapsed/ refractory disease with intent to use treatment to bridge to bone marrow transplant
	4. To be used within the treating Trust's governance framework, as Clofarabine is not licensed for this indication
Crizotinib **Form ref: CRI1_v2.0**	*The treatment of ALK +ve advanced or metastatic non-small cell lung cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. ALK +ve advanced or metastatic non-small cell lung cancer
	3. 2nd or subsequent line treatment post 1st line combination chemotherapy
Dasatinib **Form ref: DAS3_v3.0**	*The treatment of chronic phase chronic myeloid leukaemia where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Chronic phase chronic myeloid leukaemia
	3. Refractory or significant intolerance to imatinib (Grade 3 or 4 adverse events)
	4. Significant intolerance to nilotinib (Grade 3 or 4 adverse events)
Dasatinib	*The treatment of accelerated phase chronic myeloid leukaemia where all the following criteria are met:*

Form ref: DAS1_v3.0	*1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy*
	2. Accelerated phase chronic myeloid leukaemia
	3. Refractory or significant intolerance to imatinib (Grade 3 or 4 adverse events)
	4. Significant intolerance to nilotinib (Grade 3 or 4 adverse events)
Enzalutamide **Form ref: ENZ2_v1.1**	*The treatment of chemotherapy naïve castrate-resistant Metastatic Prostate Cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. *a. Histologically/ cytologically confirmed adenocarcimoma of the prostate* *OR* *b. Clinical suspicion of prostate cancer is high due to high PSA value (>100ng/ml) and evidence of bone metastases (identified by a positive isotope bone scan or sclerotic metastases on plain radiographs)*
	3. Documented metastatic disease
	4. Progressive disease despite the continued use of LHRH analogues or a previous bilateral orchidectomy
	5. No previous chemotherapy for metastatic disease
	6. Performance status 0 or 1
	7. Asymptomatic (0 or 1) or mildly symptomatic (2-3) as scored on the Brief Pain Inventory Short Form question 3
	8. No previous treatment with abiraterone unless abiraterone has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression
Eribulin **Form ref: ERI1_v2.0**	*The treatment of advanced breast cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Advanced breast cancer
	3. At least 2 prior chemotherapy regimens for advanced disease
Everolimus **Form ref: EVE1_v2.0**	*The treatment of advanced breast cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. ER +ve, HER2 –ve metastatic breast cancer
	3. No symptomatic visceral disease
	4. In combination with exemestane
	5. Previous treatment with a non-steroidal aromatase inhibitor
	6. No previous treatment with exemestane for metastatic breast cancer
	7. No more than one line of chemotherapy for the treatment of advanced breast cancer
Everolimus **Formref:**	*The treatment of metastatic renal cell carcinoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically

EVE3_v2.2	*trained and accredited in the use of systemic anti-cancer therapy*
	2. Biopsy proven renal cell carcinoma
	3. Use in patients who have had prior treatment with only one previous TKI
	4. Contraindication to 2nd line axitinib therapy OR excessive toxicity to axitinib necessitating discontinuation of axitinib within 3 months of starting therapy and at which time there is no evidence of disease progression
Ibrutinib **Form ref: IBR1_v1.2**	*The treatment of relapsed/ refractory Chronic Lymphocytic Leukaemia where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Confirmed CLL
	3. Must have received at least one prior anti-CD20 - containing chemo-immunotherapy for CLL
	4. Considered not appropriate for treatment or retreatment with purine analogue based therapy due to:
	a. Failure to respond to chemo-immunotherapy OR
	b. A progression-free interval of less than 3 years OR
	c. Age of 70yrs or more OR
	d. Age of 65yrs or more plus the presence of comorbidities OR
	e. A 17p or TP53 deletion
	5. A performance status of ECOG 0-2
	6. A neutrophil count of $\geq 0.75 \times 10^9$/l
	7. A platelet count of $\geq 30 \times 10^9$/l
	8. Patient not on warfarin or CYP3A4/5 inhibitors
	9. No prior treatment with idelalisib unless idelalisib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.
	Note: Patients receiving Ibrutinib via the compassionate use programme should not be switched to CDF funding. Free of charge supplies from the manufacturer should continue to be used in these patients until NICE approval and as per the terms of the compassionate use programme
Ibrutinib **Form ref: IBR2_v1.1**	*The treatment of relapsed/ refractory Mantle Cell Lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Confirmed Mantle Cell Lymphoma with cyclin D1 overexpression or translocation breakpoints at t(11;14)
	3. Failure to achieve at least partial response (PR) with, or documented disease progression disease after, the most recent treatment regimen
	4. An ECOG performance status of PS 0-2
	5. At least one but no more than five previous lines of treatment
	Note: Patients receiving Ibrutinib via the compassionate use programme should not be switched to CDF funding. Free of charge supplies from the manufacturer should continue to be used in these patients until NICE approval and as per the terms of the compassionate use programme

Idelalisib **Form ref: IDE1_v1.2**	*The treatment of relapsed/ refractory Chronic Lymphocytic Leukaemia where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Confirmed CLL
	3. Disease progression within 24 months of last systemic therapy
	4. At least one previous anti-CD 20 antibody-based treatment or 2 previous chemotherapy regimens
	5. Contraindications to cytotoxic chemotherapy (severe neutropenia or thrombocytopenia as a consequence of previous treatments) or an estimated creatinine clearance <60 mls/min or comorbidities as measured by a score of >6 on the Cumulative Illness Rating Scale
	6. Given in combination with Rituximab at a dose of 375 mg/m2, followed by 500 mg per square meter every 2 weeks for 4 doses and then every 4 weeks for 3 doses, for a total of 8 infusions. Idelalisib should be continued to progression.
	7. No prior treatment with ibrutinib unless ibrutinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.
	NOTE: Rituximab in this indication is funded via baseline commissioning
Lenalidomide **Form ref: LEN1_v2.1**	*The treatment of myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Low or intermediate risk MDS
	3. Associated with an isolated deletion 5q cytogenetic abnormality PLUS one additional cytogenetic abnormality
	4. Transfusion dependent anaemia (< 8 consecutive weeks without RBC transfusions within 16 weeks prior to commencing treatment)
	5. Other therapeutic options insufficient OR inadequate
	6. To be used within the treating Trust's governance framework, as Lenalidomide is not licensed for this indication
	Note: Lenalidomide is in baseline commissioning for low and intermediate risk MDS when associated with an isolated deletion 5q cytogenetic abnormality
Nelarabine **Form ref: NEL1_v2.0**	*The treatment of refractory T-cell acute lymphoblastic leukaemia or refractory T-cell lymphoblastic non-Hodgkin's lymphoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. a) Refractory T-cell acute lymphoblastic leukaemia, OR
	b) Refractory T-cell lymphoblastic non-Hodgkin's lymphoma
	3. Treatment intent is to proceed to bone marrow transplantation
Panitumumab **Form ref: PAN3_v1.0**	*The first line treatment of metastatic colorectal cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Metastatic colorectal cancer

	3. 1st line indication
	4. Patients with wild-type RAS
	5. Given in combination with Irinotecan-based combination chemotherapy
	6. No previous treatment with Cetuximab or Panitumumab
	Note: No treatment breaks of more than 4 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or in the case of intercurrent co-morbidities)
	Note: If excessive toxicity with irinotecan, panitumumab can be continued with a fluoropyrimidine alone until disease progression only.
Panitumumab **Form ref: PAN1_v3.1**	*The first line treatment of metastatic colorectal cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Metastatic colorectal cancer
	3. 1st line indication
	4. Patients with wild-type RAS
	5. Given with oxaliplatin-based combination chemotherapy regimens
	6. No previous treatment with Panitumumab or Cetuximab
	Note: No treatment breaks of more than 4 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or in the case of intercurrent co-morbidities)
	Note: If excessive toxicity with oxaliplatin, panitumumab can be continued with a fluoropyrimidine alone until disease progression only.
Pegylated Liposomal Doxorubicin **Form ref: PLD1_v2.2**	*The treatment of named sarcomas where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. a) Sarcoma in patients with cardiac impairment requiring an anthracycline, 1st line indication, OR
	b) Sarcoma in patients with cardiac impairment requiring an anthracycline, 2nd line indication, OR
	3. To be used within the treating Trust's governance framework, as Pegylated Liposomal Doxorubicin is not licensed in these indications
Pemetrexed **Form ref: PEM2_v3.0**	*The maintenance treatment of advanced non-squamous non-small cell lung cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Non-squamous non-small cell lung cancer
	3. As maintenance therapy following 1st line chemotherapy with Cisplatin and Pemetrexed not progressing after 4 cycles of such chemotherapy
	4. PS 0 or 1 at time to commence maintenance pemetrexed
	Note: the evidence for the use of maintenance pemetrexed following induction chemotherapy with the combination of pemetrexed and carboplatin has not been established and is therefore not approved

Pertuzumab **Form ref: PER1_v3.1**	*The first line treatment of locally advanced or metastatic breast cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Locally advanced or metastatic breast cancer
	3. HER2 3+ or FISH positive
	4. PS 0 or 1
	5. Any adjuvant HER2 therapy should have been completed more than 12 months prior to metastatic diagnosis
	6. No prior treatment with chemotherapy or HER2 therapy for metastatic disease
	7. To be given as first line treatment in combination with docetaxel and trastuzumab
	NOTE: not to be used beyond first disease progression outside the CNS. Do not discontinue if disease progression is within the CNS alone
Ponatinib **Form ref: PON2_v2.0**	*The treatment of Chronic Myeloid Leukaemia with T315I Mutation where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Chronic Myeloid Leukaemia
	3. a) Chronic Phase OR *b) Accelerated Phase OR* *c) Blast Phase*
	4. Documented T315I mutation
Ponatinib **Form ref: PON1_v2.0**	*The treatment of Ph+ Acute Lymphoblastic Leukaemia with T315I Mutation where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Philadelphia chromosome positive ALL
	3. Documented T315I mutation
Radium-223 Dichloride **Form ref:** **RADIU1_v3.1**	***To be removed from the CDF List subject to Appeal outcome*** *The treatment of castration-resistant prostate cancer patients with bone metastases where the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. *a. Histologically/ cytologically confirmed adenocarcimoma of the prostate with two or more bone metastases detected on skeletal scintigraphy* *OR* *b. Clinical suspicion of prostate cancer is high due to high PSA value (>100ng/ml) with two or more bone metastases detected on skeletal scintigraphy*
	3. PS 0-2
	4. Absence of visceral metastases on recent scanning and no

	previous history of visceral spread
	5. Received prior docetaxel, were not healthy enough or declined to receive it
	6. Symptomatic disease with regular use of analgesic medication or treatment with external-beam radiation therapy required for cancer related bone pain within the previous 12 weeks
	7. No previous hemibody external radiotherapy, systematic radiotherapy with radioisotopes within the previous 24 weeks
	8. No malignant lymphadenopathy that is more than 3cm in diameter
	9. No imminent or established spinal cord compression
	10. If receiving treatment with abiraterone or enzalutamide, a sufficient trial of treatment with the abiraterone or enzalutamide has been given to relieve bone symptoms before consideration of radium-223
Regorafenib **Form ref: REG1_v2.0**	*Treatment of adult patients with advanced gastro-intestinal stromal tumours (GIST) after failure of at least previous imatinib and sunitinib where the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Histologically confirmed, metastatic or unresectable GIST
	3. PS 0-1
	4. Disease progression on or intolerance to previous imatinib
	5. Disease progression on previous sunitinib
Ruxolitinib **Form ref: RUX1_v2.0**	*The treatment of symptomatic splenomegaly in primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. a) Intermediate / high risk primary myelofibrosis, OR
	b) Post polycythaemia myelofibrosis, OR
	c) Post essential thrombocytosis myelofibrosis
	3. a) 1st line indication, OR
	b) 2nd line indication
	4. Symptomatic splenomegaly and/or constitutional symptoms
	5. Unsuitable for a stem cell transplant
Sorafenib **Form ref: SOR1_v2.0**	*The first line treatment of advanced hepatocellular carcinoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Hepatocellular carcinoma
	3. a) Child-Pugh grade A liver impairment OR
	b) Child-Pugh grade B liver impairment with low disease burden

	4. No previous systemic therapy
	5. No role for surgery or after failure of surgery or after failure of locoregional therapy
Sorafenib **Form ref: SOR2_v2.0**	*The treatment of papillary or follicular thyroid cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Papillary or follicular thyroid cancer (not licensed for this indication)
	3. Inoperable or metastatic disease
	4. Refractory to radioiodine
	5. To be used within the treating Trust's governance framework, as Sorafenib is not licensed in this indication
Sunitinib **Form ref: SUN1_v2.0**	*The treatment of pancreatic neuroendocrine carcinomas where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Biopsy proven well differentiated pancreatic neuroendocrine tumour
	3. a) 1st line indication, OR,
	b) 2nd line indication, OR,
	c) 3rd line indication
	4. No previous VEGF targeted therapy
Temsirolimus **Form ref: TEM1_v2.0**	*The treatment of advanced renal cell carcinoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Renal cell carcinoma
	3. 1st line indication
	4. Poor risk patients (at least 3 of 6 prognostic risk factors)
Trastuzumab Emtansine (Kadcyla) **Form ref: TRA1_v2.1**	*The treatment of HER2-positive locally advanced/ unresectable or metastatic (Stage IV) breast cancer*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Progression of her-2 positive locally advanced or metastatic breast cancer
	3. Progression during or after the most recent treatment for advanced stage disease or within 6 months of completing treatment for early stage disease
	4. Previous treatment with a taxane
	5. Previous treatment with trastuzumab
	6. PS 0 or 1
	7. Left ventricular ejection fraction of 50% or more
	To minimise the risk of errors due to the similarity of the product name Trastuzumab Emtansine (Kadcyla) with that of Trastuzumab (Herceptin) the recommendations in the Risk Minimisation Plan educational material from the manufacturer should be followed when prescribing, dispensing and administering the product
	NOTE: not to be used beyond first disease progression outside the CNS. Do not discontinue if disease progression is within the CNS

	alone
Vandetinib **Form ref: VAN1_v2.1**	*The treatment of medullary thyroid cancer where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Histologically confirmed, locally advanced and unresectable or metastatic medullary thyroid cancer
	3. Progressive and symptomatic disease
	4. No previous tyrosine kinase therapy unless intolerant of cabozantinib within 3 months of starting therapy and toxicity which cannot be managed by dose delay or dose modification and in the absence of disease progression on cabozantinib
Vismodegib **Form ref:** **VIS1_v2.0**	*The treatment of locally advanced or metastatic Basal Cell Carcinoma where all the following criteria are met:*
	1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy
	2. Application approved by relevant specialist skin cancer MDT
	3. Locally advanced or metastatic basal cell carcinoma
	4. Curative resection not possible as assessed by a specialist in dermatological surgery, head and neck surgeon or plastic surgeon
	5. Previous radiotherapy unless contraindicated or inappropriate
	6. PS 0-2
	7. Fit for Vismodegib therapy

National Cancer Drugs Fund – Confirmation of previously notified drugs and indications delisted March 12th 2015

DRUG	*INDICATION REMOVED*
Aflibercept	*2nd line in combination with irinotecan-based combination chemotherapy for metastatic colorectal cancer*
Bendamustine	*Treatment of patients with indolent non-Hodgkin's lymphoma who are refractory to rituximab*
Bevacizumab	*1st line in combination with oxaliplatin–based combination chemotherapy for metastatic colorectal cancer*
Bevacizumab	*1st line in combination with irinotecan–based combination chemotherapy for metastatic colorectal cancer*
Bevacizumab	*1st line in combination with single agent fluoropyrimidine–based chemotherapy for metastatic colorectal cancer.*
Bevacizumab	*In combination with carboplatin and gemcitabine chemotherapy for recurrent platinum sensitive ovarian cancer*
Bortezomib	*Re-treatment in patients with relapsed myeloma*
Bortezomib	*Treatment of patients with relapsed Waldenstrom's macroglobulinaemia*
Bortezomib	*Treatment of patients with relapsed mantle cell lymphoma*
Bosutinib	*Treatment of blast phase chronic myeloid leukaemia*
Cetuximab	*2nd line in combination with irinotecan chemotherapy for metastatic colorectal cancer in patients with RAS wild type (non-mutated) tumours*
Dasatinib	*Treatment of the lymphoid blast phase of chronic myeloid leukaemia*
Everolimus	*Treatment of progressive unresectable or metastatic well differentiated neuroendocrine tumour of the pancreas*
Lapatinib	*In combination with capecitabine chemotherapy for HER-2 receptor positive locally advanced or metastatic breast cancer*
Ofatumumab	*Treatment of relapsed or refractory chronic lymphatic leukaemia*
Pazopanib	*Treatment of previously treated metastatic non-adipocytic soft tissue sarcomas*

Pegylated liposomal doxorubicin	*1st or 2nd line chemotherapy of angiosarcoma*
Pegylated liposomal doxorubicin	*Chemotherapy of primary malignant sarcomas of the heart and great vessels*

Confirmation of previously notified drugs and indications delisted 4th November 2015

DRUG	*INDICATION REMOVED*
Albumin bound Paclitaxel	*First line treatment of advanced adenocarcinoma of the pancreas in combination with Gemcitabine*
Bendamustine	*2nd or subsequent line treatment of chronic lymphatic leukaemia for patients whom fludarabine combination therapy is not a therapeutic option*
Bendamustine	*2nd and subsequent line of treatment of mantle cell lymphoma in patients who have not received previous Bendamustine*
Bevacizumab	*Treatment of patients with triple negative metastatic breast cancer and/or prior Taxane therapy*
Bevacizumab	*2nd or 3rd line treatment of metastatic colorectal cancer in combination with standard chemotherapy in patients who have not previously received Bevacizumab*
Bosutinib	*Treatment of chronic phase CML refractory to Nilotinib or Dasatinib*
Bosutinib	*Treatment of accelerated phase CML refractory to Nilotinib or Dasatinib*
Bosutinib	*Treatment of accelerated phase CML where there is significant intolerance to Dasatinib and Nilotinib.*
Cetuximab	*3rd and subsequent line treatment of metastatic colorectal cancer as a single agent*
Cetuximab	*3rd and subsequent line treatment of metastatic colorectal cancer as a single agent in patients not treated to progression under NICE TA176*
Dasatinib	*Treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) with resistance or intolerance to prior therapy including Imatinib*
Everolimus	*2nd or 3rd line treatment of metastatic renal cell carcinoma where disease has progressed on or after treatment with VEGF-targeted therapy*
Lenalidomide	*2nd line treatment of multiple myeloma in patients who have contraindications to the use of Bortezomib*

Panitumumab	*3rd and subsequent line treatment of metastatic colorectal cancer as a single agent*
Panitumumab	*3rd and subsequent line treatment of metastatic colorectal cancer as a single agent in patients not treated to progression under NICE TA176*
Pegylated Liposomal Doxorubicin	*2nd line treatment of Fibromatosis*
Peptide Receptor Radionucleotide Therapy (Lutetium177 Octreotate or Yttrium90 Octreotide/Octreotate)	*Treatment of advanced neuro-endocrine tumours i.e. for pNETS after Sunitinib/chemotherapy, for mid-gut carcinoid, after octreotide/somatostatin therapies.*
Pomalidomide	*Treatment of relapsed and refractory multiple myeloma in patients who have received at least 2 prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy*