Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1602		
Policy Title	Clofarabine for refractory or relapsed acute myeloid leukaemia (AML) as a bridge to stem cell transplantation Proposal **not for routine commissioning** (ref A3.1)		
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About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	The incidence of AML in Europe is 5-8 cases per 100,000 people. In 2013, there were 2,942 new cases of AML in the UK. Based on current population estimates, the number of new cases in England in a given year will amount to approximately 2,489. However, this treatment is used for a small subset of this population, with CDF usage data resulting in an estimated 56 cases. *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	56 *Source: Policy Proposition section 6*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages**
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	The policy is proposed as an all ages policy. Therefore there is no difference between the age distribution of the patients diagnosed with AML and those impacted by the clinical criteria within the policy proposition. However the incidence of AML increases with age and median age of onset is 67 years. Between 2011 and 2013, about 55% of cases were diagnosed in people aged 70 years and over. *Source: Policy Proposition section 6*
A1.5 How is the population currently distributed geographically?	**Evenly**

<table>
<tr><td></td><td>Source: Policy Proposition section 6

No geographic distribution issues can be found in the UK</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Increasing</u>

Prevalence increasing due to increasing survival

Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>

Source: Policy Proposition section 6/other</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table><tr><td>YR2 +/-</td><td>2</td></tr><tr><td>YR3 +/-</td><td>3</td></tr><tr><td>YR4 +/-</td><td>3</td></tr><tr><td>YR5 +/-</td><td>4</td></tr><tr><td>YR10 +/-</td><td>8</td></tr></table>Source: Policy Proposition section 6

<u>Yes</u></td></tr>
</table>

A3 Activity	
A3.1 What is the purpose of new policy?	**<u>Confirm non-routine commissioning position of an additional new treatment</u>**
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	56 *Source: CDF Usage Data*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	Not applicable, this is a not for routine commissioning policy
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	56 *Source: Policy working group*
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	The aim of treatment for AML is usually to achieve a remission of the disease through suppression of the patient's own haemopoetic cells (in the bone marrow). Once disease remission is achieved, a haemopoetic stem cell transplant (HSCT) can be given, replacing the haemopoetic system, but without the abnormal white blood cell line. A number of chemotherapy medicines are currently available to treat AML and provide a bridge to HSCT; for patients with refractory or relapsed AML, current European guidelines recommend cytarabine (if not used for first induction), with or

	without an anthracycline. *Source: Policy Working Group*
A4.2. What are the current treatment access and stopping criteria?	See section A4.1
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify Click here to enter text. a) 100% b) Not Applicable c) Not Applicable d) Not Applicable e) Not Applicable *Source: Policy Proposition*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**<u>Yes - additional comparator not routinely commissioned</u>** Relapsed/refractory AML may be treated with cytarabine (if not used for first induction), with or without an anthracycline, or Mitoxantrone plus etoposide and cytarabine (MEC). *Source: Policy Working Group*
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment	Total estimated eligible

b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	a) 100% b) 0 c) 100% d) 100% e) 100% *Source: Policy Working Group*
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable, this is a not for routine commissioning policy.
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Not applicable, this is a not for routine commissioning policy.
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	Not applicable, this is a not for routine commissioning policy.
A7.2 What is the current number of contracted providers for the eligible population by region?	Not applicable

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	Not applicable
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	Not applicable, this is a not for routine commissioning policy
A8.2 Specify how the activity related to the new patient pathway will be identified.	Not applicable, this is a not for routine commissioning policy
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**Not applicable**
A8.4 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
A8.5 **Identification Rules for Activity:** How are activity costs captured?	Not applicable, this is a not for routine commissioning policy

A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	**None**
A9.2 **Excluded Drugs and Devices (not covered by the Zero Cost Model)** For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.	Not applicable, this is a not for routine commissioning policy
A9.3 **Business intelligence** Is there potential for duplicate reporting?	Not applicable, this is a not for routine commissioning policy
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	Not applicable, this is a not for routine commissioning policy
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	Not applicable, this is a not for routine commissioning policy
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No**

<table>
<tr><th colspan="2">Section B - Service Impact</th></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England; this includes Cancer Centres, Teaching Hospitals and District General Hospitals</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u></td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u></td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:
<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table>Please specify:
Click here to enter text.</td></tr>
</table>

B2.2 What impact will the new policy have on the sources of referral?	**No impact**
B2.3 Is the new policy likely to improve equity of access?	**No impact** *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4**
B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**

B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region	**No change**
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	*Select all that apply:* Publication and notification of new policy ☐ Market intervention required ☐ Competitive selection process to secure increase or decrease provider configuration ☐ Price-based selection process to maximise cost effectiveness ☐ Any qualified provider ☐ National Commercial Agreements e.g. drugs, devices ☐ Procurement ☐

	Other ☐
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	**No**
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:*

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☐
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☐
	Paid entirely by Local Tariffs	☐

		Partially paid by National Tariffs	☐
		Partially paid by Local Tariffs	☐
		Part/fully paid under a Block arrangement	☐
		Part/fully paid under Pass-Through arrangements	☐
		Part/fully paid under Other arrangements	☐

C1.2 **Drug Costs** Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable, this is a not for routine commissioning policy. Clofarabine (induction phase) is currently available through the Cancer Drugs Fund (CDF). Cytarabine (consolidation phase) is already routinely commissioned by NHS England. Following the removal of Clofarabine from CDF, patients will received Cytarabine for both the induction and consolidation phase. The list price of Cytarabine is £12.73 per gram inclusive of VAT
C1.3 **Device Costs** Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	The chemotherapy delivery costs are already covered by National Tariffs. The number of deliveries will increase by 1 per patient as Clofarabine is delivered as 5 daily infusions and Cytarabine is delivered as 6 injections. The Chemotherapy Delivery HRGs for Cytarabine are: SB13Z x 2 Deliver more Complex Parenteral Chemotherapy, First

	Attendance @ £299 per delivery SB15Z x 5 Deliver Subsequent Elements of a Chemotherapy Cycle @ £299 per delivery
C1.5 **Activity Costs covered by Local Tariff** List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	Not applicable
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**No**
C3 Overall Cost Impact of this Policy to NHS England	
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost pressure** There is a cost pressure resulting from patients transferring to Cytarabine for the consolidation phase who were previously funded via CDF for Clofarabine. Year 1 £32.9k Year 2 £33.4k Year 5 £34.6k
C3.2 If the budget impact on NHS England cannot be identified set	Not Applicable

out the reasons why this cannot be measured.	
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	Not Applicable
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **No impact on CCGs** Budget impact for providers: **No impact on providers**
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Year 1 £32.9k Year 2 £33.4k Year 5 £34.6k
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not Applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No**
C5 Funding	

C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	The cost pressure is a result of clofarabine being removed from CDF and patients transferring to standard treatment. If the drug were to be routinely commissioned the cost pressure would be higher. Based on the current cost of clofarabine, this extra cost pressure would represent £21,253 per patient.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	None
C6.2 How can these risks be mitigated?	Not Applicable
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not Applicable - patients transferring to an existing treatment pathway
C6.4 What scenario has been approved and why?	Not Applicable
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**There is no published evidence of cost-effectiveness**
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	Not Applicable

C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No**
C8.2 If yes, confirm the source of funds to meet these costs.	Not Applicable