Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1825		
Policy Title	Dexrazoxane for preventing cardiotoxicity in children and young people (< 25 years) receiving high-dose anthracyclines or related drugs for the treatment of cancer Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Mandy Sanderson	**Clinical Lead**	Amos Burke
Finance Lead	Justine Stalker-Booth	**Analytical Lead**	Not applicable.

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A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
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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.	Children and young people with either acute myeloid leukaemia (AML) or bone sarcomas are most likely to be in the cohort of patients that would receive dexrazoxane. A 2012 National Cancer Intelligence Network (NCIN) report on childhood tumours registered with children's cancer and leukaemia groups between 1977-2011 (for children aged under 15) showed an average (mean) of 88 AMLs a year, and an average (mean) of 20 bone cancers each year. *Source: Policy Proposition, Section 5 Epidemiology and Needs Assessment*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	108 **Note**: This policy proposition for the use of dexrazoxane treatment is not specific to a particular disease or tumour group, therefore actual number of eligible children receiving anthracyclines for all diseases and tumour groups could be higher than the cohort comprised of AML or bone cancer. *Source: Policy Proposition, Section 5 Epidemiology and Needs Assessment*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Other** Children and young people aged under 25 years.

A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	Both AML and bone cancers are more numerous in teenagers and young adults aged 16-24 years than those aged less than 15 years (Office of National Statistics, 2017, as cited by Cancer Research UK). *Source: Policy Proposition, Section 5 Epidemiology and Needs Assessment*
A1.5 How is the population currently distributed geographically?	**Evenly**
A2 Future Patient Population & Demography	
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?	**Constant**
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	**Yes** The population of young people age up to 25 years of age is expected to rise by approximately six per cent by 2029 (Office of National Statistics Population Projections). The rise in population is not expected to materially impact on activity/outcomes. Cancer in children and young people is rare. In the UK, approximately 1,600 children (up to the age of 15 years) and 2,200 teenagers and

<table>
<tr><td></td><td>young adults (aged between 15 – 24 years of age) are diagnosed with cancer every year (Children’s Cancer and Leukaemia Group, 2014) and the incidence of AML/bone cancers are very rare.

Source: Policy Proposition, Section 5 Epidemiology and Needs Assessment
Source: ONS Population Projections</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></td><td>AML/Bone</td></tr><tr><td>Year 2</td><td>1</td></tr><tr><td>Year 5</td><td>3</td></tr><tr><td>Year 10</td><td>6</td></tr></table>
Net changes were calculated using ONS growth assumptions and a starting baseline of 108 patients.

<u>Yes</u></td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u></td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>108

Source: Policy Working Group</td></tr>
</table>

A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	108 *Source: Policy Working Group*
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.	Not applicable. *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 decision to treat a child or young person with anthracycline chemotherapy (or any other cancer treatment) is made by the relevant multi-disciplinary team, as follows: • Children aged between 0 to 16 years – the MDT hosted by the Children's Cancer Principal Treatment Centre (PTC) • Teenagers aged between 16 -18 years – the MDT hosted by the Teenager and Young Adult (TYA) Cancer PTC • Young people over 19 years of age – either an adult site specific MDT or TYA Cancer PTC. In line with the relevant service specifications for C/TYA cancer, anthracycline based chemotherapy treatment can be delivered from: • Children's Cancer PTCs (for patients aged between 0 – 16 years) • Paediatric Oncology Shared Care Units (for patients aged between 0 – 16 years) • TYA Cancer PTCs (for teenagers and young people from 16 years up to their 25th birthday) • TYA Designated Hospitals (for people aged 19 years and over).

	Source: C/TYA Cancer Service Specifications
A4.2. What are the current treatment access and stopping criteria?	Treatment plans for each patient, including chemotherapy and any other drugs, requires a multi-disciplinary team (MDT) discussion. See section A4.1 for further details. *Source: Policy Working Group*
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?	a) 100% b) 0% c) 100% d) 100% e) 100% *Source: Policy Working Group*
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*	**No**

A5.2 What percentage of the total eligible population is estimated 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.
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?	a) 100% b) 0% c) 100% d) 100% e) 100% *Source: Policy Working Group*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**<u>Time limited</u>** Duration of anthracycline infusion: Due to the short half-life of dexrazoxane, the anthracycline must be given alongside dexrazoxane over a period of one hour or less. *Source: Policy Proposition section 7 - Proposed Criteria for Commissioning*

A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?

Emergency/Urgent care attendance	☐
Acute Trust: inpatient	☒
Acute Trust: day patient	☒
Acute Trust: outpatient	☒
Mental Health provider: inpatient	☐
Mental Health provider: outpatient	☐
Community setting	☐
Homecare	☐
Other	☐

A7.2 What is the current number of contracted providers for the eligible population by region?

As outlined in Section A4.1, children and young people with cancer may be treated by any designated children's cancer PTC, POSCU, TYA PTC and TYA designated hospital in line with the relevant service specifications.

Across England, there are currently:

- 13 Children's Cancer PTCs
- 80 POSCUs
- 14 TYA Cancer PTCs
- 80 Designated Hospitals

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Patients will already be receiving anthracyclines. In addition, the patient numbers are small.
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	<table><tr><td>Aggregate Contract Monitoring *</td><td>☐</td></tr><tr><td>Patient level contract monitoring</td><td>☐</td></tr><tr><td>Patient level drugs dataset</td><td>☒</td></tr><tr><td>Patient level devices dataset</td><td>☐</td></tr><tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☐</td></tr><tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☐</td></tr><tr><td>Clinical Database**</td><td>☒</td></tr><tr><td>Other**</td><td>☒</td></tr></table>** High cost drugs list and approved prior approval form
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:* <table><tr><td>OPCS v4.8</td><td>☐</td></tr></table>

<table>
<tr><td></td><td>
<table>
<tr><td>ICD10</td><td>☐</td></tr>
<tr><td>Treatment function code</td><td>☒</td></tr>
<tr><td>Main Speciality code</td><td>☒</td></tr>
<tr><td>HRG</td><td>☐</td></tr>
<tr><td>SNOMED</td><td>☐</td></tr>
<tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Not already specified in current NHS England Drugs List document</u>

This will be added to the NHS England’s Drugs List from April 2019.</td></tr>
<tr><td>A8.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u></td></tr>
<tr><td>A8.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u>

NCBPS01C Chemotherapy</td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u></td></tr>
</table>

<table>
<tr><td>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.</td><td><table>
<tr><td>Drugs or Device MDS</td><td>☐</td></tr>
<tr><td>Blueteq</td><td>☒</td></tr>
<tr><td>Other prior approval</td><td>☐</td></tr>
</table></td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u></td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u></td></tr>
<tr><td>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?</td><td><u>Yes</u>

The MHRA Summary of Product Characteristics (SPC) contains advice on dosing in renal impairment and further information, as outlined in the draft policy proposition.</td></tr>
<tr><td colspan="2">Section B - Service Impact</td></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
</table>

<table>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>Tertiary centres and networked provision.

See Section A4.1.</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></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>

This treatment is not currently commissioned.</td></tr>
</table>

	Source: Policy Proposition.
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** Reduced cardiotoxicity and cardiovascular related morbidity and mortality in childhood survivors of cancer. *Source: Policy Proposition*
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**

<table>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u></td></tr>
<tr><td>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</td><td><u>No change</u></td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:<table>
<tr><td>Publication and notification of new policy</td><td>☒</td></tr>
<tr><td>Market intervention required</td><td>☐</td></tr>
<tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr>
<tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr>
<tr><td>Any qualified provider</td><td>☐</td></tr>
<tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr>
<tr><td>Procurement</td><td>☐</td></tr>
<tr><td>Other</td><td>☐</td></tr>
</table></td></tr>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
</table>

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	☐

	<table><tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr></table>
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.	Dexrazoxane can be considered in all children and young people aged under 25 years receiving anthracyclines with a cumulative dose of doxorubicin 300 mg/m^2 or more or an equivalent dose of another anthracycline for cancer either as a front line-treatment or combined with other treatments. The cumulative dose refers to when the doxorubicin dose will meet or exceed 300 mg/m^2 over the entire lifetime of current or primary treatment regime. Dexrazoxane needs to be handled as a chemotherapy and will be prepared just before each dose due to a short half-life. The maximum dose/cycle proposed for a child or young person of older age or heavier weight is two vials administered across two days up to 6 cycles for osteosarcoma and 2 cycles for AML. In addition, some AML patients may receive an additional cycle of 2 vials across 3 days. The dose for younger children is halved – i.e. 1 vial per day rather than 2. The average NHS Indicative Price (list price) for a 500mg vial is as follows: <table><tr><td>Vial</td><td>Ex-VAT</td><td>Incl VAT</td></tr><tr><td>500mg</td><td>£156.57</td><td>£187.88</td></tr></table> The above is based on the BNF listed prices. The actual price paid will depend on commercial in confidence discounts.

	There will also be costs such as those for dilutents and infusion lines, which are the responsibility of the provider; additional impact is expected to be minimal given the small overall patient numbers. Aseptic preparation costs vary nationally and are funded by locally negotiated agreements; any additional impact is expected to be minimal given small overall patient numbers
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 %)	Aseptic preparation costs are funded by locally negotiated agreements.
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.

<table>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>Yes</u></td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td>YR1</td><td>£3,556</td></tr><tr><td>YR2</td><td>£3,556</td></tr><tr><td>YR3</td><td>£3,556</td></tr><tr><td>YR4</td><td>£3,556</td></tr><tr><td>YR5</td><td>£3,556</td></tr></table>
This is the expected average cost per patient based on 10% of patients only requiring 1 vial per day and 50% of AML patients requiring the additional 3-day cycle. The maximum cost per patient with Osteosarcoma is £4,509 (minimum £2,255) and the maximum cost per patient with AML is £4,133 (minimum £1,503).

No material impact is expected in years 6-10.</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u>
Please specify:

<table><tr><td>YR1</td><td>£384.0k</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td>YR2</td><td>£387.6k</td></tr>
<tr><td>YR3</td><td>£387.6k</td></tr>
<tr><td>YR4</td><td>£391.2k</td></tr>
<tr><td>YR5</td><td>£391.2k</td></tr>
</table>

The above is based on the average cost per patient set out in section C2.1, incorporating changes in activity as estimated in section A2.3.

The actual cost per patient will be lower depending any potential ‘commercial in confidence’ discounts.
</td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Not applicable</td></tr>
<tr><td>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?</td><td>Not applicable</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:

<u>No impact on CCGs</u></td></tr>
</table>

	Budget impact for providers: **Cost neutral**
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** As per Section C3.1
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?	**Unknown**
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.	CPAG prioritisation reserve.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	There are not expected to be any material financial risks associated with implementing this policy.
C6.2 How can these risks be mitigated?	Not applicable.

<table>
<tr><td>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</td><td>PWG estimates around 108 patients could be eligible for treatment. Not every patient with bone cancer or AML will be eligible for treatment so the ‘best case’ cost scenario is a slightly lower number; and the ‘worst case’ cost impact scenario is that patients with other types of tumours or diseases may also receive anthracyclines and be eligible for this treatment, however the overall numbers are expected to be small.</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>The most likely cost scenario has been approved based on PWG estimates of around 108 patients requiring treatment based on available data relating to bone cancer and AML.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>There is no published evidence of cost-effectiveness</u></td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td><table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☒</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
</table></td></tr>
</table>

	The data does not support a high level of certainty about the impact on value ☐
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.