



**GIG**  
CYMRU  
**NHS**  
WALES

Pwyllgor Gwasanaethau Iechyd  
Arbenigol Cymru (PGIAC)  
Welsh Health Specialised  
Services Committee (WHSSC)

## **Specialised Services Policy Position Statement PP253**

**Dexrazoxane for preventing cardiotoxicity in  
children (aged under 16 years old) receiving  
high-dose anthracyclines or related drugs for the  
treatment of cancer**

*February 2023*

*Version 1*



## Document information

<b>Document purpose</b>	Policy Position Statement
<b>Document name</b>	Dexrazoxane for preventing cardiotoxicity in children (aged under 16 year old) receiving high-dose anthracyclines or related drugs for the treatment of cancer
<b>Author</b>	Welsh Health Specialised Services Committee
<b>Publication date</b>	February 2023
<b>Commissioning Team</b>	Women & Children
<b>Target audience</b>	Chief Executives, Medical Directors, Directors of Finance, Directors of Planning, Chief Pharmacists, Paediatric Cancer Leads, NHS Providers
<b>Description</b>	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
<b>Document No</b>	PP253
<b>Review Date</b>	2026

## Contents

<b>Policy Statement</b> .....	4
1. Introduction .....	6
1.1 Plain language summary .....	6
1.2 Aims and Objectives .....	6
1.3 Epidemiology .....	7
1.4 Current Treatments for Cancer in Children.....	7
1.5 Proposed Treatment .....	8
1.6 What NHS Wales has decided.....	8
2. Criteria for Commissioning .....	9
2.1 Inclusion Criteria .....	9
2.2 Exclusion Criteria .....	9
2.3 Stopping Criteria .....	9
2.4 Continuation of Treatment.....	9
2.5 Acceptance Criteria.....	10
2.6 Patient Pathway .....	10
2.7 Blueteq and reimbursement.....	10
2.8 Transition Arrangements .....	11
2.9 Exceptions.....	11
2.10 Clinical Outcome and Quality Measures .....	12
2.11 Responsibilities .....	12
3. Documents which have informed this policy .....	13
4. Date of Review .....	13
5. Putting Things Right.....	14
5.1 Raising a Concern.....	14
5.2 Individual Patient Funding Request (IPFR) .....	14
6. Equality Impact and Assessment.....	15
Annex i Abbreviations and Glossary .....	16

## **Policy Statement**

Welsh Health Specialised Services Committee (WHSSC) will commission dexrazoxane for preventing cardiotoxicity in children aged under 16 years old and receiving high-dose anthracyclines or related drugs for the treatment of cancer in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the relevant guidance issued by NHS England<sup>1</sup> and has concluded that dexrazoxane should be made available.

## **Welsh Language**

WHSSC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language Act \(1993\)](#), the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this WHSSC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

## **Decarbonisation**

WHSSC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the WHSSC commitment.

## **Disclaimer**

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

---

<sup>1</sup> <https://www.england.nhs.uk/publication/dexrazoxane-for-preventing-cardiotoxicity-in-children-and-young-people-under-25-years-receiving-high-dose-anthracyclines-or-related-drugs-for-the-treatment-of-cancer/>

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

## **1. Introduction**

This Policy Position Statement has been developed for the planning and delivery of dexrazoxane for children aged under 16 years old and resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

The WHSSC Prioritisation Panel recommended the use of dexrazoxane for children and young people up to the age of 25. WHSSC only has commissioning responsibility for children aged under 16 years of age, therefore it will be for Health Boards to approve the use of dexrazoxane for young people aged between 16 and 25.

### **1.1 Plain language summary**

The types of cancers affecting children and young people are different to those that affect adults; these cancers tend to occur in different parts of the body to adult cancers and respond differently to treatment. The most common cancers affecting children and young people are cancers of the blood, such as leukaemia, and lymphoma.

Treatment for children and young people with cancer depends on the type of cancer. Common treatments include surgery, chemotherapy and radiotherapy, which may be given in combination.

Treatment with chemotherapy is intensive and can include multiple medicines. Anthracyclines are a group of chemotherapy medicines that work by stopping cancer cells from replicating. This group of medicines are commonly used to treat children and young people with leukaemia or lymphoma.

Despite these medicines achieving high cure rates (almost 80%) they can cause long-term side effects including damage to the heart, known as cardiotoxicity. This damage means that the heart becomes weaker and is not as efficient at pumping blood around the body. These effects may not be seen for some time after treatment finishes.

This policy outlines the use of dexrazoxane to prevent cardiotoxicity in children aged under 16 years old, where it is planned for them to receive high-dose anthracyclines for cancer.

### **1.2 Aims and Objectives**

This Policy Position Statement aims to define the commissioning position of WHSSC on the use of dexrazoxane for preventing cardiotoxicity in children aged up to 16 years old receiving high-dose anthracyclines or related drugs for the treatment of cancer.

The objectives of this policy are to:

- ensure commissioning for the use of dexrazoxane is evidence based
- ensure equitable access to dexrazoxane
- define criteria for children aged up to 16 years receiving high-dose anthracyclines or related drugs for the treatment of cancer to access treatment
- improve outcomes for children aged up to 16 years receiving high-dose anthracyclines or related drugs for the treatment of cancer.

### **1.3 Epidemiology**

Cancer in children and young people is rare. There are around 1,900 new cases of cancer in children in the UK every year, spread across 76 cancer types. The number of children diagnosed with each of these 76 cancer types varies considerably, and it is worth noting that for most types of children's cancers, the number of new cases diagnosed each year is fewer than 10.

Although there are 76 types of children's cancer, these can be put into 12 main groups, and some groups are more common than others. The most common of these groups are: leukaemias (around 3 in 10 cancer cases diagnosed in UK children each year), brain and spinal, other central nervous system and intracranial tumours (around 2 in 10), and lymphomas (around 1 in 10).

Survival for children's cancers varies considerably. More than 8 in 10 children in England survive their cancer for 5 years or more (all cancers combined); but some cancer groups and cancer types have much lower survival<sup>2</sup>.

### **1.4 Current Treatments for Cancer in Children**

Treatment for children and young people with cancer depends on the type of cancer. Common treatments include surgery, chemotherapy and radiotherapy, which may be given in combination.

Treatment with chemotherapy is intensive and can include multiple medicines. Anthracyclines are a group of chemotherapy medicines that work by stopping cancer cells from replicating. This group of medicines are commonly used to treat children and young people with leukaemia or lymphoma.

Despite these medicines achieving high cure rates (almost 80%) they can cause long-term side effects including damage to the heart, known as cardiotoxicity. This damage means that the heart becomes weaker and is not as efficient at pumping blood around the body. These effects may not be seen for some time after treatment finishes.

---

<sup>2</sup> [Children's Cancer and Leukaemia Group](#)

## **1.5 Proposed Treatment**

This policy outlines the use of dexrazoxane to prevent cardiotoxicity in children and young people aged up to 16 years where it is planned for them to receive high-dose anthracyclines for cancer. Dexrazoxane belongs to a group of medicines which protect the heart from damage. Dexrazoxane is a cytotoxic drug, i.e. it is toxic to living cells and it is unlicensed in the treatment of children and young people receiving anthracycline-based chemotherapy. This policy for the use of dexrazoxane treatment, as outlined above, is not specific to a particular disease or tumour group.

## **1.6 What NHS Wales has decided**

WHSSC has carefully reviewed the relevant guidance issued by NHS England<sup>3</sup> to treat cardiotoxicity in children and young people aged under 16 years old where it is planned for them to receive high-dose anthracyclines or related drugs for the treatment of cancer with dexrazoxane, either as a front-line treatment or combined with other treatments. We have concluded that dexrazoxane should be made available within the criteria set out in section 2.1.

---

<sup>3</sup> [NHS England » Dexrazoxane for preventing cardiotoxicity in children and young people \(under 25 years\) receiving high-dose anthracyclines or related drugs for the treatment of cancer](#)



## **2. Criteria for Commissioning**

The Welsh Health Specialised Services Committee have approved funding of dexrazoxane for preventing cardiotoxicity in children aged up to 16 years old and receiving high-dose anthracyclines or related drugs for the treatment of cancer in line with the criteria identified in the policy.

### **2.1 Inclusion Criteria**

Dexrazoxane to prevent cardiotoxicity must be considered in all children aged up to 16 years old where it is planned for them to receive doxorubicin with a cumulative dose 300 mg/m<sup>2</sup> or more (or the equivalent cumulative dose of another anthracycline or related medicine) for the treatment of cancer over the entire lifetime of treatment, either as a first line treatment or combined with other treatments. The use of dexrazoxane is not specific to a particular disease or tumour group.

### **2.2 Exclusion Criteria**

Use of dexrazoxane is contraindicated in children (please refer to the MHRA SmPC<sup>4</sup> for latest guidance):

- Where it is planned for them to receive a cumulative dose of doxorubicin < 300 mg/m<sup>2</sup> or an equivalent dose of another anthracycline or related drugs.
- With hypersensitivity to dexrazoxane.
- Where the child or young person is breastfeeding their own child.
- Receiving concomitant vaccination with yellow fever vaccine.
- Who require continuous infusion of anthracyclines over a period of longer than one hour.

### **2.3 Stopping Criteria**

There are no specific criteria relating to treatment cessation for dexrazoxane in this population group.

### **2.4 Continuation of Treatment**

Healthcare professionals are expected to review a child's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a child's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

---

<sup>4</sup> [CARDIOXANE 500mg powder for solution for infusion - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

## **2.5 Acceptance Criteria**

The service outlined in this specification is for children aged up to 16 years old ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes children who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

## **2.6 Patient Pathway**

### **For patients accessing treatment in NHS Wales**

Children with cancer accessing their treatment in NHS Wales, may be treated in either a Children's Cancer Principal Treatment Centre, a Teenage Cancer Unit or some patients may access treatment at their local District General Hospital through a shared care arrangement with a Children's Cancer Principal Treatment Centre.

### **For patients accessing treatment in NHS England**

Children and young people with cancer accessing their treatment in NHS England, may be treated in either a Children's Cancer Principal Treatment Centre, a Paediatric Oncology Shared Care Unit (POSCU), a Teenage and Young Adult (TYA) Principal Treatment Centre and/or a TYA Designated Hospital, using pathways outlined in the service specification(s) for children and young people with cancer<sup>5</sup>.

All treatment must be delivered in accordance with local Children's Cancer Network and/or local TYA Cancer Network protocols.

## **2.7 Blueteq and reimbursement**

Dexrazoxane for preventing cardiotoxicity in children aged up to 16 years old receiving high-dose anthracyclines or related drugs for the treatment of cancer will only be funded for patients registered via the Blueteq system and where an appropriately constructed paediatric cancer MDT has approved its use.

Where the patient meets the criteria in this policy and the referral is received by an agreed centre, a Blueteq form should be completed for approval. For further information on accessing and completing the Blueteq form please contact WHSSC using the following e-mail address: [WHSSC.blueteq@wales.nhs.uk](mailto:WHSSC.blueteq@wales.nhs.uk)

If a non-contracted provider wishes to treat a patient that meets the criteria, they should contact WHSSC (e-mail: [WHSSC.IPC@Wales.nhs.uk](mailto:WHSSC.IPC@Wales.nhs.uk)),

---

<sup>5</sup> <https://whssc.nhs.wales/commissioning/whssc-policies/cancer/cp86-services-for-children-with-cancer-pdf/>

and they will be asked to demonstrate they have an appropriate MDT in place.

Funding is approved on the basis that dexrazoxane is prescribed and administered in accordance with local Children's Cancer Network and/or local TYA Cancer Network protocols.

In treatment is discontinued, it is the responsibility of the prescribing team to discontinue the Blueteq form.

## **2.8 Transition Arrangements**

Transition arrangements should be in line with [Transition from children's to adults' services for young people using health or social care services NICE guidance NG43 and the Welsh Government Transition and Handover Guidance](#).

Transition involves a process of preparation for young people and their families for their transition to adulthood and their transition to adult services. This preparation should start from early adolescence 12-13 year olds. The exact timing of this will ideally be dependent on the wishes of the young person but will need to comply with local resources and arrangements.

The transition process should be a flexible and collaborative process involving the young person and their family as appropriate and the service.

The manner in which this process is managed will vary on an individual case basis with multidisciplinary input often required and patient and family choice taken into account together with individual health board and environmental circumstances factored in.

## **2.9 Exceptions**

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

## **2.10 Clinical Outcome and Quality Measures**

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

## **2.11 Responsibilities**

Services should be delivered in accordance with the relevant service specification(s) for children and teenage and young adults with cancer<sup>6</sup>.

The use of dexrazoxane in children is unlicensed. Each provider organisation treating children with a medicine approved under this policy will be required to assure itself that the internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the Trust's Drugs and Therapeutics Committee (or similar) and WHSSC can ask for documented evidence that these processes are in place. Further details on the use of dexrazoxane can be found within the MHRA SmPC<sup>7</sup>.

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

---

<sup>6</sup> <https://whssc.nhs.wales/commissioning/whssc-policies/cancer/cp86-services-for-children-with-cancer-pdf/>

<sup>7</sup> [CARDIOXANE 500mg powder for solution for infusion - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](https://www.medicines.org.uk/emc/products/1248/1/1)

### **3. Documents which have informed this policy**

The following documents have been used to inform this policy:

- **NHS England policies**

- [Clinical Commissioning Policy: Dexrazoxane for preventing cardiotoxicity in children and young people \(under 25 years\) receiving high-dose anthracyclines or related drugs for the treatment of cancer 200204 February 2020](#)

This document should be read in conjunction with the following documents:

- **NHS Wales**

- All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).

### **4. Date of Review**

This document will be reviewed when information is received which indicates that the policy requires revision.

## **5. Putting Things Right**

### **5.1 Raising a Concern**

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

### **5.2 Individual Patient Funding Request (IPFR)**

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

## **6. Equality Impact and Assessment**

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

## **Annex i Abbreviations and Glossary**

### **Abbreviations**

<b>IPFR</b>	Individual Patient Funding Request
<b>WHSSC</b>	Welsh Health Specialised Services

### **Glossary**

#### **Anthracycline**

A type of chemotherapy used to treat cancer. These medicines are derived from antibiotics and work by preventing cell replication. The medicines classified as anthracyclines are:

- (i) doxorubicin
- (ii) epirubicin
- (iii) daunorubicin
- (iv) idarubicin
- (v) estramustine and
- (vi) vairubicin.

#### **Anthracycline related drugs**

These drugs are not classified in the anthracycline drug family, however, have the potential to cause significant cardiotoxicity. These medicines are:

- (i) mitoxantrone and
- (ii) pixantrone.

#### **Cardiotoxicity**

Damage to the heart.

#### **Individual Patient Funding Request (IPFR)**

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

#### **Second malignant neoplasm**

A histologically distinct second cancer that develops after the first.



### **Sub-clinical cardiotoxicity**

Asymptomatic changes in echocardiographic measures beyond specified thresholds (for example, a decline in ejection fraction to <50% shortening fraction to <28%, or a decrease of  $\geq 10\%$  from baseline)<sup>8</sup>.

### **Troponin-T**

A protein released when cardiac muscle is damaged which is a marker of cardiac damage.

### **Welsh Health Specialised Services Committee (WHSSC)**

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

---

<sup>8</sup> definition used in [Shaikh et al. 2016](#)