GIG CYMRU NHS WALES
Cyd-bwyllgor Comisiynu
Joint Commissioning Committee

# Brachytherapy for the treatment of gynaecological malignancies for people aged 18 years and above

## Commissioning Policy: CP75

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# Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission Brachytherapy for people with gynaecological malignancies in accordance with the criteria outlined in this document.

In creating this document NWJCC has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

## Welsh Language

NWJCC 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, NWJCC 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

NWJCC 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 NWJCC commitment

## Disclaimer

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

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.

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

# 1. Introduction

This policy has been developed as a Policy for the planning and delivery of brachytherapy for people with gynaecological malignancies resident in Wales. This service will only be commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

## 1.1 Plain Language Summary

Cancers that start in the female reproductive system are called gynaecological cancers. These cancer types can affect women, some transgender men and non-binary people assigned female at birth.[1] There are five main types of gynaecological cancers: cervical, ovarian, womb (also called uterine or endometrial cancer), vaginal and vulval cancer.

Brachytherapy is mainly used to treat gynaecological cancers of the cervix and womb. It is sometimes used to treat cancer of the vagina and vulva. It may be image guided or non-image guided. The term "image guided" means that images are taken before or during each session of radiotherapy. The images may include ultrasound, CT scan and/or MRI scan. The images show the size, shape and position of the cancer and the brachytherapy applicator to ensure the treatment is delivered precisely.

Brachytherapy is a type of internal radiotherapy. This means that a radioactive material ("the source") is put inside the body to treat cancer. The radioactivity only affects tissue that is very close to the source. This means the tumour is treated, but healthy areas around it get much less radiotherapy. Areas of the body that are further away are not affected at all.[2]

## 1.2 Aims and Objectives

This policy aims to define the commissioning position of NWJCC on the use of brachytherapy for people with gynaecological malignancies.

The objectives of this policy are to:

- ensure commissioning for the use of brachytherapy is evidence based
- ensure equitable access to brachytherapy
- define criteria for people with gynaecological malignancies to access treatment
- improve outcomes for people with gynaecological malignancies

[1] https://www.cancerresearchuk.org/about-cancer/womens-cancer
[2] https://www.macmillan.org.uk/cancer-information-and-support/treatment/types-of-treatment/radiotherapy/internal-radiotherapy

## 1.3 Epidemiology

Cervical cancer is most common in women in their early 30's. Trans men and non-binary people assigned female at birth can also develop cervical cancer. This can happen when there has not been an operation to remove the womb and cervix (total hysterectomy). Around 3,200 women are diagnosed with cervical cancer in the UK each year.[3] In Wales, an average of 147 people were diagnosed with cervical cancer each year between 2018-2020.[4]

Most people who develop womb cancer are older women. It's much less common in those younger than 40.[5] In Wales, an average of 548 people were diagnosed with cancer of the uterus each year between 2018-2020.[3]

Vaginal cancer is very rare with around 250 women being diagnosed in the UK each year[6]. Almost 40% of new cases are in females aged 75 and over. It is very rare in women younger than 40. In Wales, an average of 14 people were diagnosed with vaginal cancer each year between 2018-2020.[3]

Vulval cancer is a rare cancer. Around 1,400 people are diagnosed in the UK each year. The risk of developing vulval cancer increases with age. On average each year more than 40% of new cases are in women aged 75 and over.[7] In Wales, an average of 76 people were diagnosed with vulval cancer each year between 2018-2020.[3]

## 1.4 Treatment options

Treatment depends on several factors including cancer type, stage of disease at diagnosis and patient co-morbidities. For early stage or locally advanced cervical cancer, the main treatment is usually external radiotherapy alongside chemotherapy (chemoradiotherapy). This is usually followed by internal radiotherapy (brachytherapy).

Radiotherapy is the main treatment for most patients with vaginal cancer as surgery would be very extensive. Radiotherapy treatments are individualised depending on the site, stage, size of the tumour and whether the patient has had a prior hysterectomy. Concurrent chemotherapy may also be given.

Treatment of vulva cancer depends on several factors including cancer type, stage of disease, the part of the vulva affected, previous treatment and patient co-morbidities. The main treatment is surgery. Radiotherapy and chemotherapy may also be given.

[3] https://www.cancerresearchuk.org/about-cancer/cervical-cancer/about
[4] https://publichealthwales.shinyapps.io/Cancer_Reporting_Tool_PHW/
[5] https://www.cancerresearchuk.org/about-cancer/womb-cancer/about
[6] https://www.cancerresearchuk.org/about-cancer/vaginal-cancer/about
[7] https://www.cancerresearchuk.org/about-cancer/vulval-cancer/about

## 1.5 What NHS Wales has decided

NWJCC has carefully reviewed the evidence of brachytherapy for gynaecological malignancies. We have concluded that there is enough evidence to fund the use of brachytherapy within the criteria set out in section 2.1.

## 1.6 Relationship with other documents

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

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).
  - NHS Wales Gynaecological Guidelines

- **NHS Wales Joint Commissioning Committee policies and service specifications**
  - CP50 Positron Emission Tomography (PET) Commissioning Policy, April 2023

- **Other published documents**
  - Royal College of Radiologists: Radiotherapy Dose Fractionation 4th edition
  - British Gynaecological Cancer Society: Guidelines
  - Recommendations from gynaecological (GYN) GEC-ESTRO working group – ACROP: Target concept for image guided adaptive brachytherapy in primary vaginal cancer, December 2019
  - ESGO/ESTRO/ESP Guidelines for the management of patients with cervical cancer – Update 2023

# 2. Criteria for Commissioning

The NHS Wales Joint Commissioning Committee will approve funding of brachytherapy for gynaecological malignancies in line with the criteria identified in this policy.

## 2.1 Inclusion Criteria – Image-Guided Brachytherapy

**Cervical cancer**[8]

- Inoperable Stage IA1 cervical cancer patients (i.e. those who are unable to have surgery) may be treated definitively with brachytherapy alone.
- Inoperable Stage IA2 – IB2 cervical cancer patients should be treated radically with brachytherapy in conjunction with external beam radiation. Concurrent chemotherapy may be considered at the physician's discretion and based on the presence of high risk features.
- Clinical stage IB3 - IVA cervical cancer should be treated radically with concurrent chemoradiotherapy (or radical radiotherapy alone if unfit for concurrent chemotherapy) followed by brachytherapy.
- Stage IVB cervical cancer where the only site of metastatic disease is within a radical radiotherapy field (e.g. localised metastases in the pelvic region) may also be treated with concurrent chemoradiotherapy (or radiotherapy) followed by brachytherapy.
- Stage IVB cervical cancer where the disease has spread beyond a radical treatment volume may be palliatively treated with brachytherapy with or without external beam to decrease the risk of severe haemorrhage or other life-threatening symptoms.

Patients are treated with brachytherapy regardless of lymph node status, grade, presence of lymphovascular invasion, tumour size, age, or histology.

**Other gynaecological cancers**

- Occasionally, patients with endometrial cancer who are medically unfit for surgery or for whom the MDT recommends brachytherapy.[9]
- Vaginal cancer is rare but brachytherapy may form part of its treatment.[10]
- Vulval cancer is rare and brachytherapy may form part of its treatment.[11]

[8] ESGO/ESTRO/ESP Guidelines for the management of patients with cervical cancer – Update 2023
[9] Nag et al., 2000. The American Brachytherapy Society recommendations for high-dose-rate brachytherapy for carcinoma of the endometrium. Int J Radiat Oncol Biol Phys, 48: 779-90.
[10] Recommendations from gynaecological (GYN) GEC-ESTRO working group – ACROP: Target concept for image guided adaptive brachytherapy in primary vaginal cancer, December 2019
[11] British Gynaecological Cancer Society: Guidelines

## 2.2 Inclusion Criteria – Non-Image-Guided Brachytherapy

- Patients with post-operative cervical and endometrial cancer who require adjuvant treatment to the vaginal vault.

## 2.3 Exclusion Criteria

- Prior pelvic radiotherapy with brachytherapy
- Life expectancy <6 months
- Rarely, medical co-morbidities may prohibit brachytherapy

The use of Intensity Modulated Radiation Therapy (IMRT) or 3D conformal external beam radiation is not a substitute for brachytherapy.

## 2.4 Stopping Criteria

- Treatment should be suspended if the patient stops responding to treatment or there are intractable side effects or through patient choice.
- Treatment may also be suspended if after imaging it is found that the brachytherapy treatment cannot adequately cover the tumour.

## 2.5 Continuation of Treatment

Healthcare professionals are expected to review a patient'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 patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

## 2.6 Acceptance Criteria

The service outlined in this policy is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients 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.

## 2.7 Patient Pathway (Annex i)

Patients are referred from specialist gynaecology MDTs. They are assessed by the brachytherapy team to check suitability for treatment. Patients sign informed consent prior to treatment.

Please refer to National Optimal Pathways (NOPs) for gynaecological cancer which have been developed to support the implementation of the Single Cancer Pathway (SCP) in Wales.

## 2.8 Designated Centres

Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Road
Birkenhead
Wirral
CH63 4JY

Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
B15 2GW

Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
CF14 2TL

## 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, an IPFR should be submitted.

Further information on making IPFR requests can be found at: 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.

Providers are expected to comply, as a minimum, with The Ionising Radiation (Medical Exposure) Regulations 2017 and take part in the annual audit programme conducted by the Gynaecological Site Specific Team.

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.

Quality of life should be monitored during routine follow up. Patients should be followed up to monitor for recurrence and late effects.

Providers should use a validated patient experience tool for monitoring patient experience on, as a minimum, an annual basis.

## 2.11 Responsibilities

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 alternative treatments 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 NWJCC for the treatment.

In all other circumstances an IPFR must be submitted.

# 3. Evidence

NWJCC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

## 3.1 References

Please see section 1.5

## 3.2 Date of Review

This document is scheduled for review before 2027, where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

If an update is carried out the policy will remain extant until the revised policy is published.

# 4. 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 NHS Wales Joint Commissioning 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.

# 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 NWJCC.

## 5.2 Individual Patient Funding Request (IPFR)

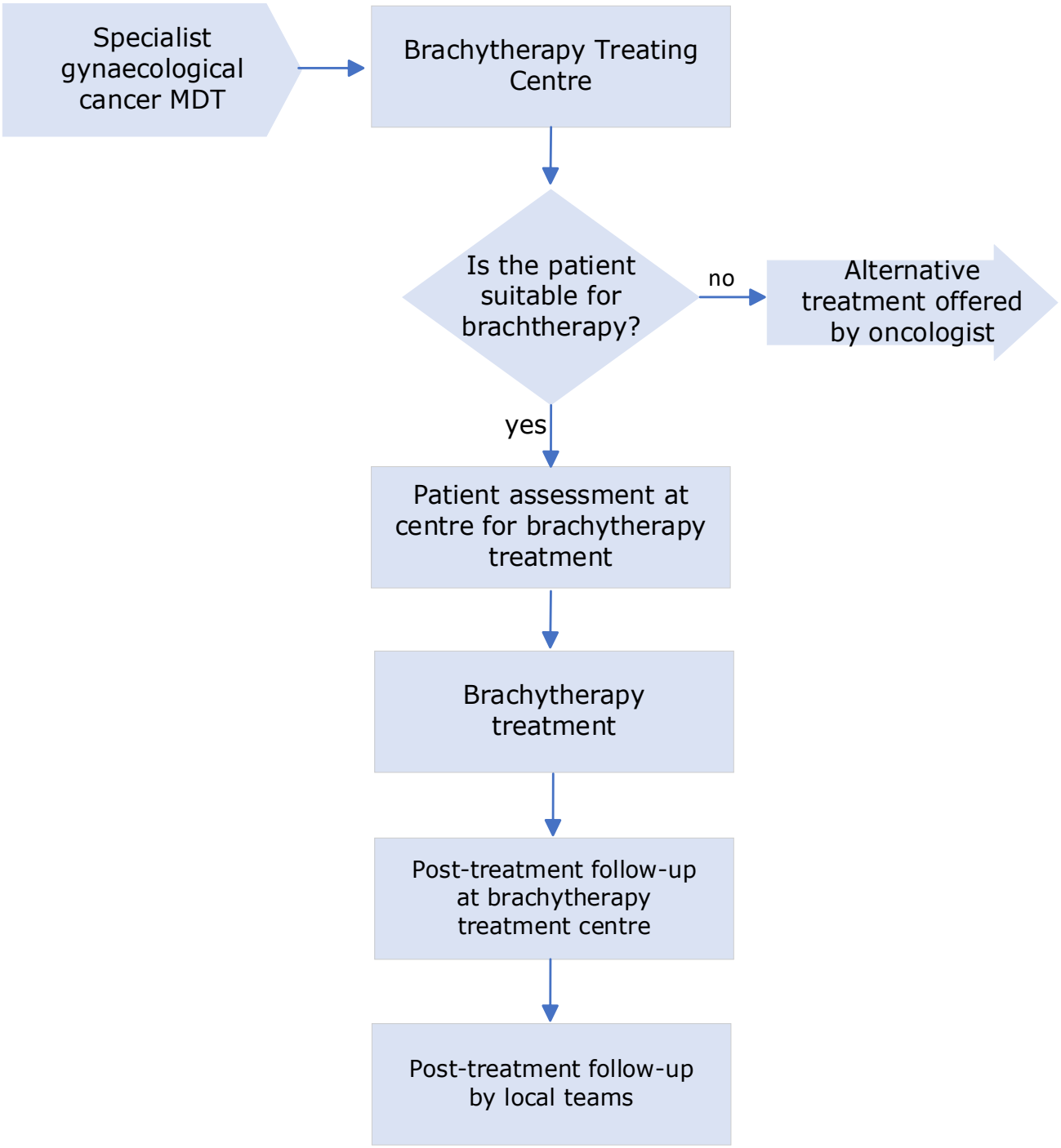
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All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

Further information on making IPFR requests can be found at: Individual Patient Funding Requests

# Annex i Patient Pathway



# Annex ii Codes

| Code Category | Code | Description |
|---|---|---|
| OPCS | X65.2 | Delivery of a fraction of intra-cavitary radiotherapy |
| OPCS | Y35.4 | Introduction of radioactive substance into organ for brachytherapy NOC |
| OPCS | Z45.1 | Cervix uteri |
| ICD-10 | C53 | Malignant neoplasm of cervix uteri |

# Annex iii Abbreviations and Glossary

## Abbreviations

**AWMSG** All Wales Medicines Strategy Group

**IPFR** Individual Patient Funding Request

**NWJCC** – NHS Wales Joint Commissioning Committee

### Glossary

### Individual Patient Funding Request (IPFR)

An IPFR is a request to NHS Wales Joint Commissioning Committee (NWJCC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

### NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio 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.