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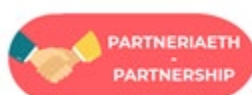
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# **Specialised Services Policy Position Statement PP280 Policy Proposal**

**Stereotactic ablative body radiotherapy (SABR)  
for patients aged 18 years old and above with  
locally advanced, inoperable, non-metastatic  
pancreatic carcinoma (LANPC)**

*August 2023*

*Version 1.0*



## Document information

<b>Document purpose</b>	Policy Position Statement
<b>Document name</b>	Stereotactic ablative body radiotherapy (SABR) for patients aged 18 years old and above with locally advanced, inoperable, non-metastatic pancreatic carcinoma (LANPC)
<b>Author</b>	Welsh Health Specialised Services Committee
<b>Publication date</b>	01 <sup>st</sup> March 2024
<b>Commissioning Team</b>	Cancer & Blood
<b>Target audience</b>	Chief Executives, Medical Directors, Directors of Finance, Wales Cancer Network, Cancer Managers
<b>Description</b>	NHS Wales propose to routinely commission this specialised service in accordance with the criteria described in this policy
<b>Document No</b>	PP280
<b>Review Date</b>	2026

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## **Policy Statement**

Welsh Health Specialised Services Committee (WHSSC) propose to commission Stereotactic ablative body radiotherapy (SABR) for patients aged 18 years old and above with locally advanced, inoperable, non-metastatic pancreatic carcinoma (LANPC) 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 SABR should be made available for this group of patients.

## **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.

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<sup>1</sup> [Clinical Commissioning Policy Statement: Stereotactic ablative body radiotherapy for patients with locally advanced, inoperable, non-metastatic pancreatic carcinoma \(adults\) URN \(2011\) \[210901P\] October 2021](#)

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 Proposal has been developed for the planning and delivery of Stereotactic ablative body radiotherapy (SABR) for patients aged 18 years old and above with locally advanced, inoperable, non-metastatic pancreatic carcinoma (LANPC) and are resident in Wales. This proposed service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

### **1.1 Plain language summary**

Pancreatic cancer is a type of cancer that starts in the pancreas, an organ near the stomach and is relatively rare. Exocrine tumours start in the exocrine cells, where enzymes that help to digest food are made<sup>2</sup>.

Patients with pancreatic cancer normally present as an emergency or via a hospital referral from the GP because of symptoms. Common symptoms include jaundice due to blockage of bile ducts, severe upper abdominal or back pain, loss of appetite and weight loss. As part of the diagnostic process, patients have a computed tomography (CT) scan as one of the first investigations. Endoscopic retrograde cholangio-pancreatography (ERCP) and biliary brushings with or without the insertion of a biliary stent is usually performed in patients with jaundice, where the CT scan indicates likely pancreatic cancer and immediate surgery is not contemplated. In patients without jaundice or where ERCP brushings are not conclusive, an endoscopic ultrasound-guided or CT-guided biopsy is required to confirm histological diagnosis<sup>1</sup>.

SABR is a highly targeted form of radiotherapy which uses multiple radiation beams, given from different angles around the body at the same time. The treatment is delivered in a fewer number of treatments (hypofractionation) than conventional radiotherapy. There are usually five treatments (or fractions) for LANPC. The aim of treatment with SABR is to ensure that the tumour receives a high dose of radiation whilst the tissues close to the tumour receive a lower dose of radiation sparing the surrounding healthy normal tissues and reducing the risk of side effects.

### **1.2 Aims and Objectives**

This Policy Position Statement Proposal aims to define the commissioning position of WHSSC on the use of SABR for patients aged 18 years old and above with LANPC.

The objectives of this policy are to:

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<sup>2</sup> [Clinical Commissioning Policy Statement Stereotactic ablative body radiotherapy for patients with locally advanced, inoperable, non-metastatic pancreatic carcinoma \(adults\) URN \(2011\) \[210901P\] October 2021](#)

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

### **1.3 Epidemiology**

Ninety-six percent of all pancreatic cancers are exocrine tumours. The most common type of pancreatic cancer, pancreatic ductal adenocarcinoma (PDAC), is an exocrine tumour. There are approximately 415 people diagnosed with pancreatic cancer each year in Wales<sup>3</sup>. Around 30% of PDAC present as locally advanced, inoperable cancer which has not spread to other parts of the body (known as LANPC). Around 75% of patients with LANPC are fit enough to receive active treatment. Around 65% of patients that receive treatment for LANPC have disease that remains localised following chemotherapy<sup>4</sup>. Therefore, it is estimated that around 35<sup>2</sup> eligible patients per year may choose SABR as an alternative to chemoradiotherapy and will meet the criteria for the intervention described in this policy statement.

### **1.4 Current Treatment**

Patients with LANPC will be discussed at a specialist hepatopancreaticobiliary (HPB) multi-disciplinary team (MDT) meeting, where a decision is made whether the disease is:

- Resectable (where surgery is offered)
- Borderline resectable (where patients either go straight to surgery or receive pre-operative chemotherapy or chemo-radiotherapy prior to surgery)
- LANPC (the tumour is localised, but unlikely to ever be resectable, therefore the recommended treatment is chemotherapy with or without consolidation radiotherapy).

For patients with localised disease on CT who are well enough for treatment, a positron emission tomography (PET)-CT scan is recommended to complete staging.

Patients with LANPC will receive chemotherapy (either combination regimen or gemcitabine monotherapy) for 3 to 6 months depending on the chemotherapy regimen.

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<sup>3</sup> Extrapolated figures given in NHS England SABR for LANPC policy to Welsh population (5%)

<sup>4</sup> Hudson E, Hurt C, Mort D, Brewster AE, Iqbal N, Joseph G, Crosby TDL, Mukherjee S. Induction chemotherapy followed by chemoradiation in locally advanced pancreatic cancer: an effective and well-tolerated treatment. *Clinical Oncology*. 2010;22(1):27-35. Available from [https://www.clinicaloncologyonline.net/article/S0936-6555\(09\)00324-0/fulltext](https://www.clinicaloncologyonline.net/article/S0936-6555(09)00324-0/fulltext)

If the disease remains stable following this treatment, patients may be offered chemoradiotherapy, which involves 28-30 daily radiotherapy treatments alongside daily oral chemotherapy (capecitabine). Following completion of all treatment, patients are generally followed up at 3-monthly intervals with clinical assessment, blood tests and imaging and chemotherapy may be recommenced when the cancer progresses. The average life expectancy of patients who have completed the full course of treatment is 15-18 months from diagnosis.

### **1.5 Proposed Treatment**

The clinical commissioning policy statement recommends the use of SABR as a treatment option for adults with LANPC where the disease remains localised following  $\geq 3$  months of systemic chemotherapy. The use of SABR as an alternative treatment option to chemoradiotherapy means that patients will require fewer daily hospital visits for their radiotherapy and, as concurrent daily oral chemotherapy is not required, are also spared the side effects of the chemotherapy.

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

WHSSC has carefully reviewed the relevant guidance issued by NHS England. We have concluded that SABR should be made available within the criteria set out in section 2.1.

## 2. Criteria for Commissioning

The Welsh Health Specialised Services Committee (WHSSC) propose to approve funding of Stereotactic ablative body radiotherapy (SABR) for patients aged 18 years old and above with locally advanced, inoperable, non-metastatic pancreatic carcinoma (LANPC) in line with the criteria identified in this policy.

### 2.1 Inclusion Criteria

All patients with pancreatic cancer should have their care managed by a variety of different specialists working together as part of a specialist HPB MDT which is responsible for radiotherapy and chemoradiotherapy case selection and should take into consideration patient comorbidities, potential adverse events and likely outcomes of treatment.

Patients should meet all the following inclusion criteria:

- $\geq 18$  years; **and**
- Have a diagnosis of non-metastatic LANPC following a specialist HPB MDT<sup>5</sup> and are unsuitable for surgery; **and**
- Histology or cytology confirming adenocarcinoma; OR, if no tissue diagnosis, only where this has been agreed by the HPB MDT as appropriate i.e. radiology and clinical presentation strongly support a diagnosis of malignancy and repeated attempts at obtaining tissue have been unsuccessful; **and**
- Have received at least 3 months of systemic chemotherapy and the disease has remained localised, OR, Patients where systemic therapy has had to be terminated early due to chemotherapy toxicity but where performance status (PS) remains  $\leq 2$  following HPB MDT discussion; **and**
- Locoregional disease where the primary tumour +/- involved nodes are encompassable in a radiation volume; **and**
- Adequate pancreatobiliary drainage (patent stent where present and bilirubin less than 1.5 times the upper limit of normal); **and**
- Patients are suitable for pancreas SABR as determined by SABR and/or specialist HPB MDT; **and**
- WHO PS  $\leq 2$ .

### 2.2 Exclusion Criteria

Treatment with SABR is unsuitable for people who:

- Are not considered candidates for chemotherapy, in whom radiotherapy may be offered up front primarily for symptom management;

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<sup>5</sup> Fluorodeoxyglucose (FDG) positron emission tomography (PET) CT is strongly recommended in the staging of LANPC to exclude metastatic disease (as per [NICE NG85](#))

- Have received prior upper abdominal radiotherapy;
- Have a tumour directly invading the gastrointestinal tract;
- Have evidence of metastatic disease.

### **2.3 Starting Criteria**

Patients that meet all of the inclusion criteria and do not meet any of the exclusion criteria can be considered for treatment with SABR as an alternative to chemo-radiotherapy.

The radiotherapy should not start until at least two weeks after the last dose of systemic chemotherapy and concurrent chemotherapy should not be given.

### **2.4 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.

### **2.5 Acceptance Criteria**

The service outlined in this specification 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.

### **2.6 Patient Pathway (Annex i)**

Radiotherapy is part of an overall cancer management and treatment pathway. Decisions on the overall treatment plan should relate back to a specialist HPB MDT discussion and decision. Patients suitable for radiotherapy are referred to a clinical oncologist for assessment and full explanation of the advantages and side effects of treatment with adequate time for decision making. The clinical oncologist will then arrange treatment planning and delivery of radiation fractions as appropriate. Each fraction of radiation is delivered on one visit, usually on an outpatient basis.

In addition, all providers of treatment with SABR should:

- Ensure all patients treated are subject to an MDT approach to patient selection and treatment including discussion at a specialist HPB MDT and SABR planning group;
- Have an adequate technical multi-professional radiotherapy SABR team present and able to deliver SABR radiotherapy; and
- Have minimum of two subspecialist clinical oncologists with experience in treating SABR patients.

Patients who receive SABR for LANPC should have oncological follow-up as per their organisation's local protocol.

It is recommended that patients who receive SABR should have a restaging CT scan at 6-8 weeks post treatment and be considered for surgery if down staged and considered appropriate at HPB MDT discussion.

## **2.7 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](#)

## **2.8 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.

Radiotherapy providers must submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. Providers will collect the audit clinical outcome data through their own collection process for all SABR.

The [SABR Consortium Guidelines 2019](#) provide detailed information on each indication contained within this policy.

The radiotherapy service should be fully compliant with the [Ionising Radiation \(Medical Exposure\) Regulations \(IR\(ME\)R\) 2017](#).

Clinical governance systems and policies should be in place and integrated into the organisational governance with clear lines of accountability and responsibility for all clinical governance functions. Providers should produce annual clinical governance reports as part of the NHS clinical governance reporting system. Providers must have an externally accredited quality management system (e.g. BSI) in place.

All providers must be compliant with radiotherapy quality assurance for contouring and outlining. A national approach to regular peer review of patient eligibility and treatment plans will be required.

In addition, all providers of treatment with SABR must:

- ensure all patients treated are subject to an MDT approach to patient selection and treatment including discussion at the HPB MDT and SABR planning group;
- have an adequate technical multi-professional radiotherapy SABR team present and able to deliver SABR radiotherapy; and
- have minimum of two subspecialist clinical oncologists with experience in treating SABR patients.

## **2.9 Responsibilities**

Health Boards and WHSSC are to circulate this Policy Position Statement to all Hospitals/MDTs to inform them of the conditions under which the treatment will be commissioned.

Referrers should:

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

Clinician 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.

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

The following documents have been used to inform this policy:

- **WHSSC policies and service specifications**
  - [CP219 Stereotactic Ablative Body Radiotherapy \(SABR\) Service Specification June 2019](#)
  - [CP50a Positron Emission Tomography \(PET\) Commissioning Policy April 2023](#)
- **National Institute of Health and Care Excellence (NICE) guidance**
  - [NG85 Pancreatic cancer in adults: diagnosis and management NICE guideline February 2018](#)
- **NHS England policies**
  - [Clinical Commissioning Policy Statement: Stereotactic ablative body radiotherapy for patients with locally advanced, inoperable, non-metastatic pancreatic carcinoma \(adults\) URN \(2011\) \[210901P\] October 2021](#)
- **Other published documents**
  - [Stereotactic Ablative Body Radiation Therapy \(SABR\): A Resource, SABR UK Consortium Version 6.1 January 2019](#)

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](#)

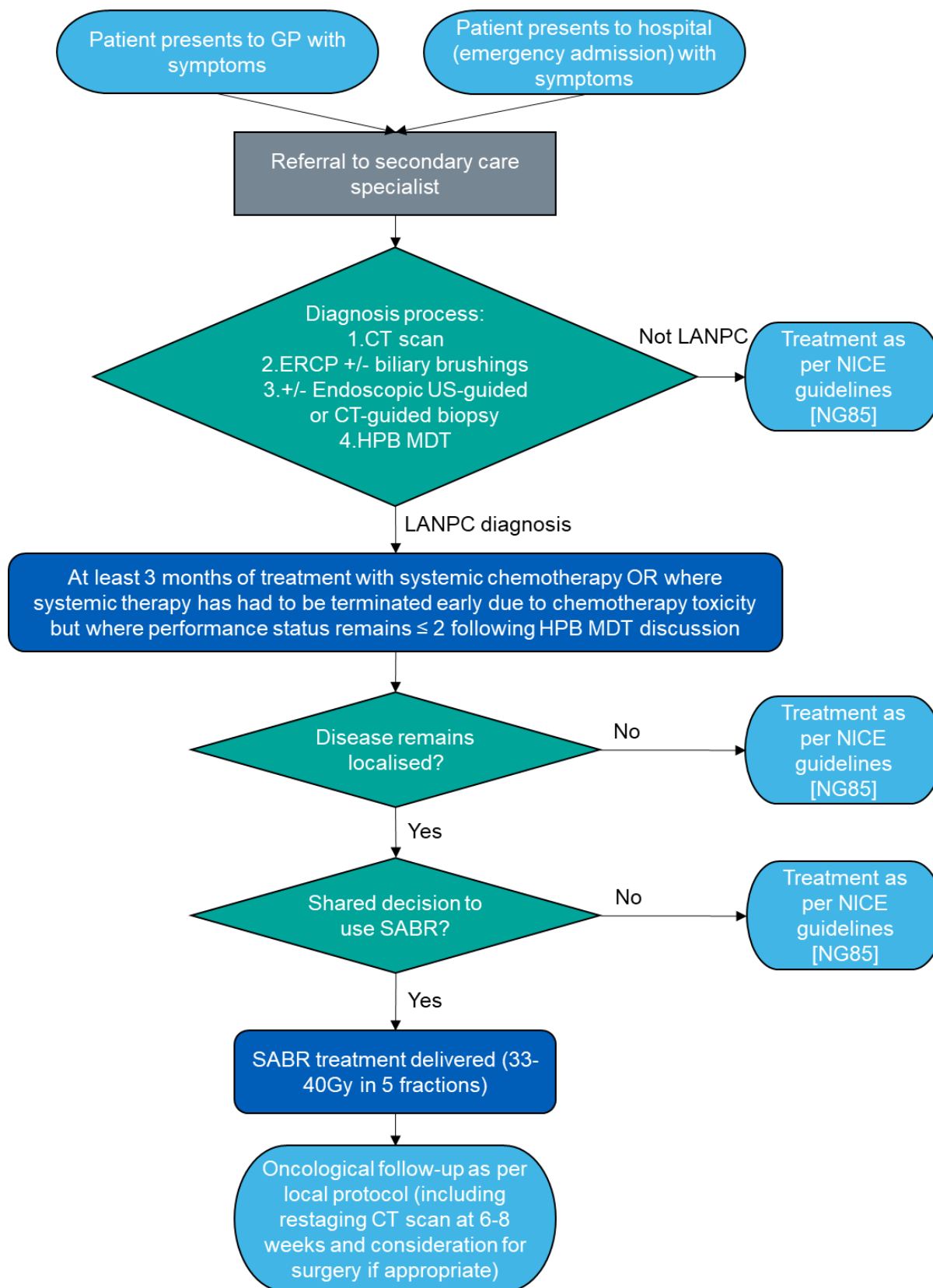
## **6. Equality Impact and Assessment**

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 Patient Pathway



## Annex ii Codes

<b>Code Category</b>	<b>Code</b>	<b>Description</b>
OPCS	Y91.5	Megavoltage treatment for hypofractionated stereotactic radiotherapy

## **Annex iii Abbreviations and Glossary**

### **Abbreviations**

<b>HPB</b>	Hepato-pancreato-biliary
<b>IPFR</b>	Individual Patient Funding Request
<b>LANPC</b>	locally advanced, inoperable, non-metastatic pancreatic carcinoma
<b>MDT</b>	Multi-disciplinary Team
<b>PROM</b>	Patient Recorded Outcome Measure
<b>PS</b>	Performance Status
<b>SABR</b>	Stereotactic Ablative Body Radiotherapy
<b>WHO</b>	World Health Organisation
<b>WHSSC</b>	Welsh Health Specialised Services Committee

### **Glossary**

#### **Chemotherapy**

The use of a drug to kill or damage cells, most commonly used in cancer treatment.

#### **Fraction**

The term that describes how the full dose of radiation is divided into a number of small doses (called fractions). The fractions are given as a series of treatment sessions which make up a radiotherapy course.

#### **Hypofractionation**

Describes a treatment regimen that delivers high doses of radiation using a shorter number of treatments as compared to conventional treatment regimens.

#### **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.

#### **Metastatic cancer/metastases**

Metastatic cancer is a cancer that has spread from the part of the body where it started (the primary site) to other parts of the body. Metastases is the plural form of metastasis and indicates that the cancer spread to more than one other site in the body.

#### **Performance Status (PS)**

A recognised system developed by the World Health Organisation and other bodies to describe the general health and daily activity of patients.

### **Radiotherapy**

The safe use of ionising radiation to destroy cancer cells with the aim of cure or effective palliation.

### **Stereotactic Ablative Radiotherapy (SABR)**

Refers to the irradiation of a lesion and is associated with the use of high radiation dose delivered in a small number of fractions. The technique requires specialist positioning of equipment and imaging to confirm correct targeting. It allows sparing of the healthy normal tissues.

### **Systemic treatment**

Treatment, usually involving chemotherapy or hormone treatment, which aims to treat the whole body.

### **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.