

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

Specialised Services Commissioning Policy: CP76

Stereotactic Ablative Body Radiotherapy (SABR) for the management of Non-Small Cell Lung Cancer in people aged 18 years and above

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Stereotactic Ablative Body Radiotherapy (SABR) for the management of Non-Small Cell Lung Cancer in people aged 18 years and above in accordance with the criteria outlined in this document.

In creating this document WHSSC 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

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 <u>Welsh Language Act (1993)</u>, the <u>Welsh Language (Wales) Measure</u> 2011 and the <u>Welsh Language Standards (No.7) Regulations</u> 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.

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.

1. Introduction

This policy has been developed for the planning and delivery of Stereotactic Ablative Body Radiotherapy (SABR) for the management of Non-Small Cell Lung Cancer in people aged 18 years and above 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.

1.1 Plain Language Summary

Lung cancer is cancer that starts in the windpipe (trachea), the main airway (bronchus) or the lung tissue.

Around 80 to 85 out of 100 lung cancers (around 80 - 85%) in the UK are **non-small cell lung cancer (NSCLC)**. The three main types are adenocarcinoma, squamous cell carcinoma and large cell carcinoma¹.

They are grouped together because they behave in a similar way and respond to treatment in a similar way. **Adenocarcinoma** is the most common type and starts in the mucus making gland cells in the lining of the airways. **Squamous cell cancer** develops in the flat cells that cover the surface of the airways. It tends to grow near the centre of the lung. In **large cell carcinoma**, the cancer cells appear large and round under the microscope¹.

SABR is a highly targeted form of radiotherapy which targets a tumour with radiation beams from different angles at the same time. The treatment is delivered in a smaller number of treatments (hypofractionation) than conventional radiotherapy using one, three, five or eight fractions. 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.

1.2 Aims and Objectives

The policy aims to define the commissioning position of WHSSC on the use SABR for the management of Non-Small Cell Lung Cancer in people aged 18 years and above.

The objectives of this policy are to:

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

¹ <u>Cancer Research UK: Lung Cancer</u>

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1.3 Epidemiology

Lung cancer is the third most common cancer in the UK. Around 48,500 people are diagnosed in the UK each year. Lung cancer is more common as you get older. Around 45% of people diagnosed with lung cancer in the UK are aged 75 and older.

In the UK each year:

- around 25,300 men are diagnosed
- around 23,300 women are diagnosed

More than 70 out of 100 (more than 70%) of lung cancer cases in the UK are caused by smoking².

Lung cancer has the widest absolute inequality in incidence of any cancer in Wales. The most deprived fifth of the population has more than two and a half times the incidence compared to the least deprived. Geographical differences in incidence of lung cancer across Wales are primarily due to historic trends in smoking and exposure to tobacco smoke, especially in areas of high deprivation³.

During 2019-20 approximately 90 patients in Wales with medically inoperable non-small cell lung cancer were treated with SABR.

1.4 Treatment options

The main curative treatment options for NSCLC are surgery and radiotherapy.

1.5 SABR

SABR is precise irradiation of an image defined extra cranial lesion and is associated with the use of a high radiation dose delivered in a small number of fractions. The technique requires specialist positioning equipment and imaging to confirm correct targeting. It allows sparing of the surrounding healthy normal tissues. For the purpose of this policy SABR refers to hypofractionated treatment of not more than 8 fractions. Commissioning arrangements for fractionated treatments utilising a larger number of fractions are beyond the remit of this policy⁴.

1.6 What NHS Wales has decided

WHSSC has carefully reviewed the evidence of SABR for NSCLC. We have concluded that there is enough evidence to fund the use of SABR, within the criteria set out in section 2.1.

² Cancer Research UK: Lung Cancer

³ <u>http://www.wcisu.wales.nhs.uk/cancer-incidence-in-wales</u>

⁴ <u>https://www.england.nhs.uk/wp-content/uploads/2018/07/Stereotactic-ablative-body-</u> radiotherapy-for-non-small-cell-lung-cancer-adults.pdf

1.7 Relationship with other documents

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

- NHS Wales
 - All Wales Policy: <u>Making Decisions in Individual Patient Funding</u> <u>requests</u> (IPFR).
- WHSSC policies and service specifications
 - Stereotactic Ablative Body Radiotherapy (SABR) Service
 Specification CP219 June 2021
- National Institute of Health and Care Excellence (NICE) guidance

o Lung cancer: diagnosis and management NG122 March 2023

- Relevant NHS England policies
 - <u>Clinical Commissioning Policy: Stereotactic Ablative Body</u> <u>Radiotherapy for Non-Small Cell Lung Cancer (Adult) April 2013</u>
- Other published documents
 - o SABR UK Consortium Guidelines 2019
 - <u>Radiotherapy for lung cancer: RCR consensus statements, June</u> 2020

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee will approve funding of SABR for people aged 18 years and above with NSCLC, in line with the criteria identified in this policy.

2.1 Inclusion Criteria

- Age 18 years and above
- MDT diagnosis of NSCLC based on findings of positive histology, positive PET scan or growth on serial CT scan
- MDT confirmed clinical stages of T1 N0 M0 or T2 (${\leq}5{\rm cm}$) N0 M0 or T3 (${\leq}5{\rm cm}$) N0 M0
- Not suitable for surgery because of medical co-morbidity, lesion is technically inoperable or patient declines surgery after surgical assessment (or option of assessment)
- WHO performance status (PS) 0-2. Patients who are WHO PS3 due to pre-existing co-morbidities may be eligible if agreed by the MDT.

The dose/fractionation will be delivered as set out in the UK SABR Consortium Guidelines⁵.

2.2 Exclusion Criteria

- Ultra-centrally located tumours as defined by SABR Consortium Guidelines³.
- Any tumour that is not clinically definable on the treatment planning CT scan e.g. surrounded by consolidation or atelectasis.
- If tumour has respiratory motion > 1cm despite using techniques to reduce tumour motion, only proceed with treatment if target delineation is reliable and suggested normal tissue and tumour planning constraints can be achieved.
- Presence of pulmonary fibrosis/advanced interstitial lung disease; (unless the increased risk of SABR has been fully considered and the patient has been appropriately consented).
- Inability to obtain informed consent or comply with treatment.

2.3 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.

⁵ SABR Consortium Guidelines 2019

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2.4 Patient Pathway (Annex i)

South Wales

People are referred by their local lung cancer MDT to the Network SABR MDT if they are suitable for SABR. If the Network SABR MDT agrees that SABR should be provided, they will be treated at their regional cancer centre.

For people from South East Wales, this will usually be at Velindre Cancer Centre, Cardiff.

For people from South West Wales, this will usually be at South West Wales Cancer Centre, Singleton Hospital, Swansea.

Follow up will take place at the referring hospital.

North Wales

People are referred by their local lung cancer MDT to Clatterbridge Cancer Centre. If they are suitable for SABR, treatment will take place at Clatterbridge Cancer Centre and follow up will take place at the referring hospital.

Mid Wales

People resident in Powys diagnosed and treated via cancer pathways within South Wales will be referred for SABR as per the pathways outlined above.

Patients resident in Powys diagnosed and treated via cancer pathways to Trusts in England (Wye Valley or Shrewsbury & Telford) will be referred for SABR to the Royal Shrewsbury Hospital.

2.5 Designated Centres

- Clatterbridge Cancer Centre NHS Foundation Trust Clatterbridge Road Birkenhead Wirral CH63 4JY
- The Lingen Davies Oncology Centre Royal Shrewsbury Hospital Mytton Oak Rd Shrewsbury Shropshire SY3 8XQ

- South West Wales Cancer Centre Singleton Hospital, Sketty Lane, Sketty, Swansea SA2 8QA
- Velindre Cancer Centre Velindre Road Whitchurch Cardiff CF14 2TL

2.6 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: <u>Welsh Health</u> <u>Specialised Services Committee (WHSSC) | Individual Patient Funding</u> <u>Requests</u>

2.7 Clinical Outcome and Quality Measures

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

Quality indicators, national standards, key performance indicators and other quality requirements are listed in the WHSSC SABR Service Specification.

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.

2.8 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 WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Evidence

WHSSC 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

- o SABR UK Consortium Guidelines 2019
- <u>Radiotherapy for lung cancer: RCR consensus statements, June</u> 2020

3.2 Date of Review

This document is scheduled for review before 2026, 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 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 reassignment, 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 <u>NHS Putting Things Right</u>. For services provided outside NHS Wales the patient or their representative should be guided to the <u>NHS Trust</u> <u>Concerns Procedure</u>, with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

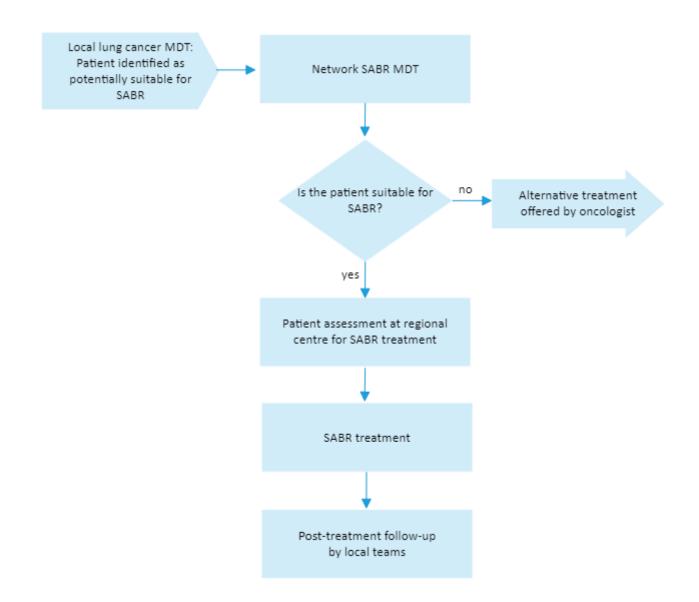
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All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

Further information on making IPFR requests can be found at: <u>Welsh Health</u> <u>Specialised Services Committee (WHSSC) | Individual Patient Funding</u> <u>Requests</u>

Annex i Patient Pathway



Annex ii Codes

Code Category	Code	Description
OPCS	Y91.5	Megavoltage treatment for hypofractionated stereotactic radiotherapy

Annex iii Abbreviations and Glossary

Abbreviations

AWMSG	All Wales Medicines Strategy Group
IPFR	Individual Patient Funding Request
NSCLC	Non-Small Cell Lung Cancer
SABR	Stereotactic Ablative Body Radiotherapy
WHSSC	Welsh Health Specialised Services

Glossary

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.

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