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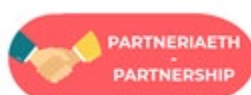
Pwyllgor Gwasanaethau Iechyd
Arbenigol Cymru (PGIAC)
Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Commissioning Policy: CP121

Stereotactic ablative radiotherapy (SABR) for patients with metachronous extracranial oligometastatic cancer (all ages)

October 2021

Version 1.0



Document information

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) commission Stereotactic ablative radiotherapy (SABR) for people with metachronous extracranial oligometastatic cancer 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 SABR 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.

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.

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 SABR for metachronous extracranial oligometastatic cancer for people of all ages resident in Wales.

1.1 Plain Language Summary

Oligometastatic cancer is a form of metastatic cancer. 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. When cancer spreads, the most common sites it spreads to are the lymph nodes, lung, bones, spine and liver. Metastatic cancer is diagnosed in approximately 9,000 patients in Wales per year ([Wales Cancer and Intelligence Surveillance Unit \(WCISU\)](#)).

There is no consensus on the definition of oligometastatic cancer, however, the disease is usually confined to a small number of sites in the body (between one to five sites), as opposed to being widespread across the body¹.

Metastatic cancer can occur at diagnosis or the cancer can come back after previous treatment. If the metastasis develops more than six months after the original (primary) cancer is treated, this is called a metachronous metastasis.

This policy is specifically for people with metachronous oligometastatic disease who present with up to three sites of metastases, confined to the following organs: (i) bone; (ii) spine; (iii) lymph nodes; (iv) liver; (v) adrenal gland; and/or (vi) lung.

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.

SABR, limited to up to three sites of oligometastatic disease, may prolong disease-free survival and overall survival, delaying the use of systemic treatment in people with metachronous oligometastatic disease.

¹ Guckenberger M, Lievens Y, Bouma AB, et al. [Characterisation and classification of oligometastatic disease: a European Society for Radiotherapy and Oncology and European Organisation for Research and Treatment of Cancer consensus recommendation](#). The Lancet Oncology 2020; 21(1): Pe18-e28.

1.2 Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of SABR for people with metachronous extracranial oligometastatic cancer.

The objectives of this policy are to:

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

1.3 Epidemiology

Metastatic cancer is diagnosed in approximately 9,000 patients in Wales per year ([WCISU](#)). All patients presenting with a maximum of three sites of extracranial, metachronous oligometastatic disease from any primary site and confined to the bone, spine, lymph nodes, liver, adrenal gland and/or lung would be eligible for treatment with SABR.

The SABR Commissioning through Evaluation (CtE) programme treated 1,500 patients over a three-year period. As a result, the Policy Working Group estimate that approximately 2,200 patients per year would be suitable for SABR treatment in line with the criteria set out in this policy.

1.4 Current Treatment

Current treatment options for metachronous oligometastatic cancer depend on location of the metastases but can include:

- (i) surgical excision
- (ii) RFA
- (iii) systemic treatment (chemotherapy, hormonal therapy or immunotherapy)
- (iv) radiotherapy.

The aim of treatment is usually to control symptoms and extend life expectancy.

1.5 Proposed Treatment

SABR, a form of hypofractionated radiotherapy, should be routinely offered for the treatment of metachronous extracranial oligometastatic cancer. The use of SABR in this indication is thought to: (i) prolong disease free survival; (ii) delay the use of systemic treatment; (iii) improve quality of life; and (iv) improve overall survival in this indication.

1.6 What NHS Wales has decided

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

1.7 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).
- **WHSSC policies and service specifications**
 - [CP76 Stereotactic Ablative Body Radiotherapy \(SABR\) for the management of surgically inoperable Non-Small Cell Lung Cancer in Adults May 2014](#)
 - CP124 Commissioning Policy. Stereotactic Ablative Body Radiotherapy (SABR) for hepatocellular carcinoma (HCC). In Development
- **Relevant NHS England policies**
 - [Clinical Commissioning Policy: Stereotactic ablative radiotherapy \(SABR\) for patients with metachronous extracranial oligometastatic cancer \(all ages\) \(URN: 1908\) \[200205P\] March 2020](#)
 - [Service Specification: Radiotherapy \(all ages\) B01/S/a 2013](#)
- **Other published documents**
 - [Stereotactic Ablative Body Radiation Therapy \(SABR\): A Resource, SABR UK Consortium Version 6.1 January 2019](#)

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of SABR for people of all ages with metachronous extracranial oligometastatic cancer in-line with the criteria identified in this policy.

2.1 Inclusion Criteria

To receive treatment with SABR patients will need to meet **all** of the following criteria:

- A confirmed histological diagnosis of metastatic cancer originating from any primary cancer in the body, including carcinoma, sarcoma, melanoma or a Prostate Specific Antigen (PSA) level of >50 and clinical evidence of prostate cancer. .
- A disease-free interval between primary treatment and manifestation of metastases of at least six months.
- At the time of disease presentation, have extracranial metastatic disease of only one to three sites, which is confined to one or two of the following organs (defined after appropriate imaging²):
 - Bone
 - Spine
 - Lymph node
 - Liver
 - Adrenal gland, and/or
 - Lung.
- A maximum size of 5 cm for any single metastasis.
- A life expectancy of at least 6 months
- A World Health Organisation (WHO) performance status of ≤ 2 .

Patients may only receive treatment with SABR for a maximum of three sites of metastases in line with the criteria described above. Should further metastases develop, alternative treatment options should be sought.

For patients being treated for spinal metastases, a maximum of 2 sites in the spine can be treated with SABR.

2.2 Exclusion Criteria

SABR is only commissioned for people who meet the criteria in section 2.1. Treatment with SABR is unsuitable in people with:

- Haematological malignancies (e.g. lymphoma, myeloma).
- Evidence of active intracranial disease that is unsuitable for surgical resection or stereotactic radio surgery.
- Evidence of spinal cord compression or spinal instability.

² See [WHSSC Positron Emission Tomography \(PET\) Policy CP50a](#)

- Evidence of severe interstitial lung disease (for lung metastases).
- Poor liver function and a Child-Pugh score of B (for liver metastases).
- More than three sites of metastatic disease or development of new metastases post treatment of a maximum of three lesions.
- A disease-free interval between primary treatment and manifestation of metastases of less than six months.
- A life expectancy of less than six months.
- Severe co-morbidities.
- A WHO performance status >2.

In addition, SABR is not suitable in people who:

- Require irradiation of whole nodal field (e.g. supra-clavicular recurrence for breast cancer), or
- Have had previous treatment with SABR to the same site of the metastases in line with the criteria set out in this policy.

2.3 Dose and fractionation

The dose and fractionation are dependent on the site of the oligometastatic disease and clinical scenario. However, it is expected that one, three, five or eight fractions of SABR are used in the treatment of oligometastases.

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 an MDT discussion and decision. Patients requiring radiotherapy are referred to a clinical oncologist for assessment, treatment planning and delivery of radiation fractions. Each fraction of radiation is delivered on one visit, usually on an outpatient basis.

2.7 Designated Centres

- Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
CF14 2TL
- Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Road
Birkenhead
Wirral
CH63 4JY
- Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston, Birmingham
B15 2GW

2.8 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](#)

2.9 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.

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 should:

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

2.10 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 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. 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.

The two main sources of evidence that describe the use of SABR in people with metachronous extracranial oligometastatic cancer (all ages) are provided by NHS England (KiTEC 2019 NHS England 2020) and an evaluation report of the SABR Commissioning through Evaluation (CtE) programme (KiTEC, 2019).

Overall survival

The highest quality evidence on median overall survival (OS) is provided by the randomised controlled trial (RCT) by Palma et al. (2020) (the SABR-COMET trial), which compared SABR to standard care. All patients had a controlled primary malignancy and 1-5 metastatic lesions, with all metastases amenable to SABR. Median OS was 28 months in the control arm (95% CI, 18 to 39 months) v 50 months in the SABR arm (95% CI, 29 to 83 months; stratified log-rank test $p=0.006$; HR, 0.47; 95% CI, 0.27 to 0.81). Five-year OS rates were 17.7% (95% CI, 6% to 34%) in the standard of care arm compared to 42.3% (95% CI, 28% to 56%) in the SABR arm.

The SABR-COMET RCT (Palma et al 2020) was adequately powered to detect a difference in OS between SABR and standard care, however, it was designed as a phase II RCT and will require a confirmatory phase III study to demonstrate if the OS advantage is true. However the findings of SABR-COMET, is corroborated by a prospective cohort study (Sutera et al. 2019) with a median overall survival of 42.3 months. Both studies recruited a contemporary cohort, and had comparable populations and interventions.

There is good evidence to confirm the superiority of SABR against standard care (Palma et al. 2020), albeit to the expense of a higher rate of toxicity with the intervention, and more importantly grade 5 (G5) adverse events (i.e. deaths). There is weaker evidence that SABR is non-inferior to surgery in the case of pulmonary metastases, and to radiofrequency ablation (RFA) for liver metastases. However, this evidence provided should be interpreted with caution given that these were retrospective and underpowered studies (KiTEC 2109; NHS England 2020).

Progression free survival

The strongest evidence for this outcome is provided by SABR-COMET (Palma et al. 2020). The authors concluded that use of SABR more than doubles the median progression free survival from 5.4 months in the control arm (95% CI, 3.2 to 6.8 months) to 11.6 months in the SABR arm (95%

CI, 6.1 to 23.4 months; stratified log-rank test $p=0.001$; HR, 0.48; 95% CI, 0.31 to 0.76).

Local control (LC)

The best evidence on local control is provided by three retrospective case-control studies comparing SABR with surgery for lung oligometastatic disease or RFA for liver lesions (KiTEC 2019). In all three studies, LC with SABR was not statistically significantly different to either of the comparators. The clinical benefit to the patient group is that a less invasive treatment such as SABR can provide equivalent results. The evidence provided should be interpreted with caution given that these were retrospective and underpowered studies with often not well-matched populations between the two treatment arms.

Quality of life (QoL)

The best evidence is provided by two RCTs. Ost et al. (2018) reported similar QoL outcomes between SABR and active surveillance in patients with prostate cancer at 3 months and 2 years follow-up using the EORTC score. Palma et al (2020) also reported equivalent FACTG scores between SABR and standard care at 6-month follow-up.

The evidence is considered medium quality for this outcome due to potential serious risks of bias. Most studies had a very short follow-up for QoL outcomes, which could mean they failed to capture the effect of late toxicity on QoL. Prostate cancer patients in particular have relatively good prognoses and QoL is an important factor in treatment decisions for these patients.

Commissioning through evaluation report

Between 2015 and 2018, the Commissioning through Evaluation (CtE) registry collected data on a number of outcomes, including survival (KiTEC 2019). Data were collected on 1422 patients from 17 different centres across the UK. The median age of patients was 69 years, and most (66.6%) were men and had good performance status. The cohort was mainly comprised of prostate (28.6%) and colorectal patients (27.9%) and most of the patients had a solitary lesion of either nodal metastasis (31.3%) or lung metastasis (29.3%).

Survival rates were high in the CtE analysis with 1-year survival of 92.3% and 2-year survival of 79.2% (due to the length of follow-up it was not possible to calculate median overall survival but it was estimated as higher than 24 months). However, the results varied considerably depending on the location of the primary tumour – for example, 2-year survival rates ranged from 33.5% for oesophageal cancer to 94.6% for prostate cancer.

Results showed slightly lower levels of local control compared to the published literature with 1-year local control rates of 86.9% and 2-year local control rates of 72.3%. However, the CtE used a different definition of local control to the published studies so the results are not easily comparable. The CtE report did not include progression free survival as one of its outcomes.

The CtE did not report outcomes for QoL as seen in the published literature, but it did report on 'patient experience' with 93% (1136 out of 1227 patients) saying they were 'likely' or 'extremely likely' to recommend SABR to family or friends.

The analysis of CTCAE adverse events showed 5.8% (95% CI 4.7-7.2%) of patients suffered grade 3 events, while 1.8% (95% CI 1.2-2.7%) suffered grade 4 events. No patient suffered grade 5 toxicity. These results are consistent with most of the published literature. The exception being the high incidence of grade 5 toxicity reported by the SABR-COMET RCT (4.5%) (Palma 2020) as a secondary outcome measure. Finally, the analysis of the CtE data showed absence of severe toxicity with SABR confirming the results in the literature.

3.1 References

[NHS England \(2020\). Stereotactic ablative radiotherapy \(SABR\) for patients with metachronous extracranial oligometastatic cancer \(all ages\).](#)

KiTEC. (2019). Commissioning through Evaluation: Stereotactic ablative radiotherapy (SABR). King's College Technology Evaluation Centre, London.

KiTEC. (2019). Evidence Review: Efficacy, toxicity and cost-effectiveness of stereotactic ablative radiotherapy (SABR) in patients with metachronous extracranial oligometastatic cancer. King's College Technology Evaluation Centre, London.

Ost et al (2018). Surveillance or Metastasis-Directed Therapy for Oligometastatic Prostate Cancer Recurrence: A Prospective, Randomized, Multicenter Phase II Trial. *Journal of Clinical Oncology*, 36, 446-453.

[Palma et al. \(2020\). Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of Oligometastatic Cancers: Long-Term Results of the SABR-COMET Phase II Randomized Trial. *J Clin Oncol* 38.](#)

Sutera et al (2019). Initial Results of a Multicenter Phase 2 Trial of Stereotactic Ablative Radiation Therapy for Oligometastatic Cancer. *International Journal of Radiation Oncology, Biology, Physics*, 103, 116-122.

3.2 Date of Review

This document is scheduled for review before 2024, 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 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 WHSSC.

5.2 Individual Patient Funding Request (IPFR)

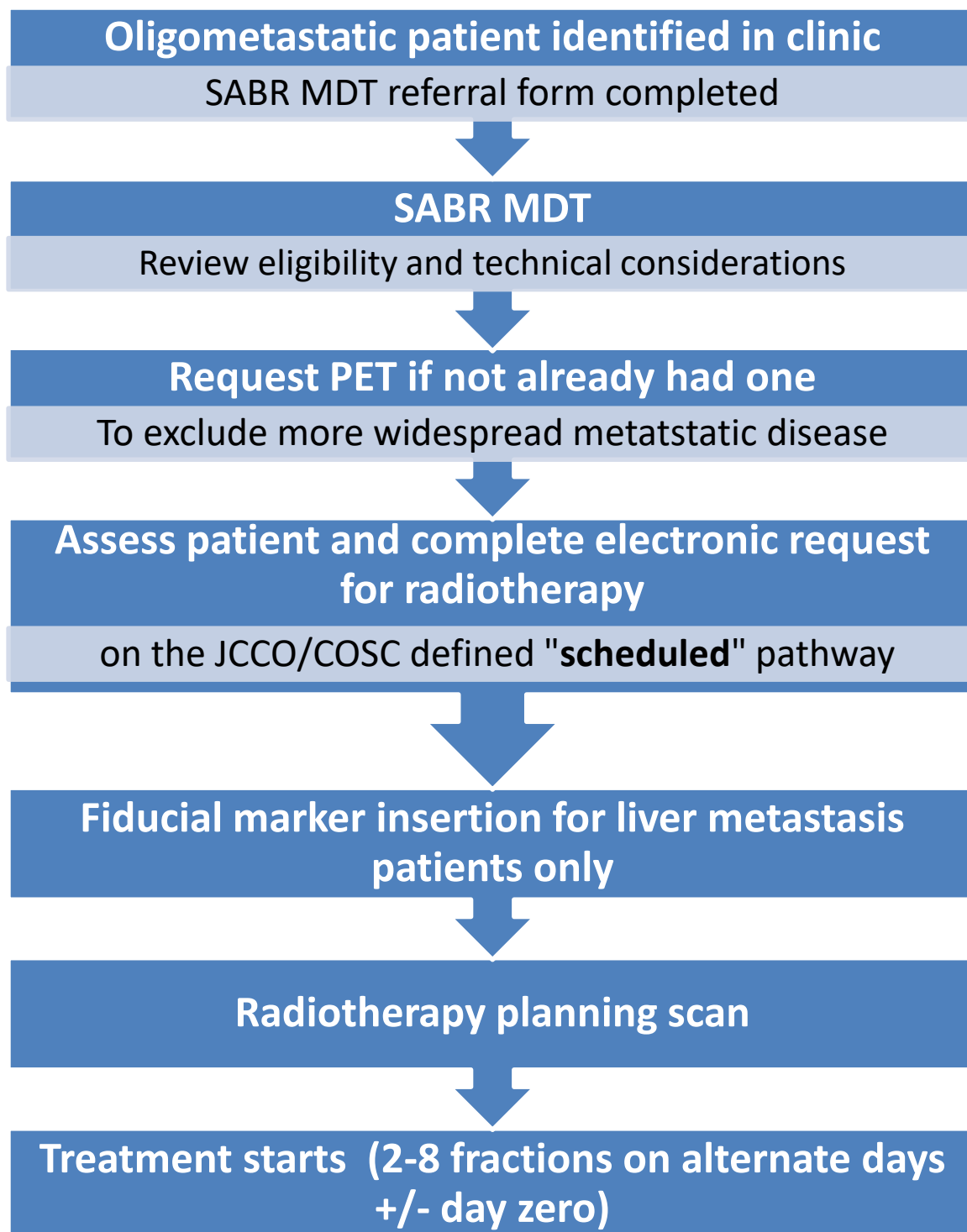
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All 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: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

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

CRUK	Cancer Research United Kingdom
CtE	Commissioning through Evaluation
EBRT	External beam radiotherapy
IOG	Improving Outcomes Guidance
IPFR	Individual Patient Funding Request
MDT	Multi-disciplinary Team
OS	Overall survival
PFS	Progression Free Survival
PROM	Patient Recorded Outcome Measure
RFA	Radiofrequency Ablation
SABR	Stereotactic Ablative Body Radiotherapy
WHO	World Health Organisation
WHSSC	Welsh Health Specialised Services

Glossary

Child-Pugh score

A scoring system used to assess liver disease.

External beam radiotherapy (EBRT)

A form of radiotherapy delivered by a linear accelerator, which focuses high-energy radiation beams onto the area requiring treatment.

Extracranial

This means the disease is outside of the cranium, the bony dome that houses and protects the brain.

Fractionation

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

Hypofractionation

This describes a treatment regimen that delivers high doses of radiation using a smaller 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.

Metachronous Disease

Refers to development of metastases at least six months after treatment of the primary cancer.

Oligometastatic disease

A type of metastatic cancer, defined by the presence of a limited number of clinically detectable lesions, usually between one to five metastases across the body.

Overall Survival (OS)

The length of time from either diagnosis or start of treatment that the patient is still alive

Performance Status

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

Primary cancer or tumour

The term used for where in the body that a cancer starts.

Progression free survival (PFS)

The length of time from start of treatment to when the disease gets worse or death.

Radiofrequency ablation (RFA)

A cancer treatment that uses heat to destroy cancer cells.

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 an image defined extra cranial lesion and is associated with the use of 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 healthy normal tissues.

Synchronous disease

Development of metastases at the time of diagnosis of the primary tumour.

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.