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

Specialised Services Clinical Access Policy: Stereotactic Ablative Body Radiotherapy (SABR) for the management of surgically inoperable Non-Small Cell Lung Cancer in Adults

Document Author:	Assistant Director - Evidence, Evaluation and Effectiveness
Clinical Editors	Dr Alison Brewster
Executive Lead:	Medical Director
Lead Planner:	Cancer Specialist Commissioner
CERG:	Cancer
Approved by:	Joint Committee
Issue Date:	19 May 2014
Review Date:	May 2022
Document No:	CP76

Document History

Revision History			
Version No.	Revision date	Summary of Changes	Updated to version no.:
0.1		Formatted to template	0.2
0.2	19/05/2014	Ratified	1.0
1.0		Review date extension	2.0
Date of next revision		**May 2022**	

Consultation		
Name	Date of Issue	Version Number
Dr. Alison Brewster	03.11.13	0.2
Dr. Tom Crosby	04.11.13	0.2
Dr Gareth Collier	09.12.13	0.2

Approvals		
Name	Date of Issue	Version No.
Joint Committee via Chair Action	19.05.2014	1.0

Distribution – *this document has been distributed to*			
Name	By	Date of Issue	Version No.
LHB Medical Directors	Corporate	19.05.2014	1.0
Providers	Planning Directorate	19.05.2014	1.0
WHSSC Internet Site	Corporate	19.05.2014	1.0

Table of Contents

1. POLICY STATEMENT

The Welsh Health Specialised Services Committee (WHSSC) will commission Stereotactic Body Radiotherapy / Stereotactic Ablative Radiotherapy for a small subset of patients with early non small cell lung cancer within defined criteria in accordance with this policy.

In creating this policy the WHSSC has reviewed the evidence for 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. Clinicians are requested to consider this policy when discussing management options with patients.

For the purpose of this policy the SBRT/ SABR refers to hypofractionated treatment of not more than 8 fractions. Arrangements for fractionated treatments utilising a larger number of fractions are beyond the remit of this policy.

2. CLINICAL INDICATIONS

- Patients with surgically inoperable, Non-Small Cell Lung Cancer (NSCLC) in patients Age > 18 years; and
- MDT diagnosis of NSCLC based on findings of positive histology, positive PET scan or growth on serial CT scan

3. CLINICAL ASSESSMENT

3.1 Clinical Staging

- Clinical stages of T1 N0 M0 or T2 (_5cm) N0 M0 or T3 (_5cm) N0 M0 [radiologically N2 (CT or PET), patients only eligible if possible nodal disease is subsequently confirmed as histologically negative with mediastinoscopy or endoscopic bronchial or oesophageal ultra-sound biopsy];
- 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 0-2.

3.2 Anatomical criteria

- Peripheral lesions outside a 2cm radius of main airways and proximal bronchial tree. This is defined as 2cm from the bifurcation of the second order bronchus e.g. where the right upper lobe bronchus splits.

4. TREATMENT

Doses used for peripheral lesions range from 55 Gy in 3 F to 54 Gy in 5 fractions depending upon where the lung lesion is to avoid toxicity to chest wall and subsequent risk of rib fracture.

4.1 Stopping Criteria

For the purpose of this policy the SBRT/ SABR refers to hypofractionated treatment of not more than 8 fractions. Arrangements for fractionated treatments utilising a larger number of fractions are beyond the remit of this policy.

5. RELATIONSHIP WITH OTHER POLICIES AND SERVICE SPECIFICATIONS

This document should be read in conjunction with the following policies and service specifications:

- SABR Service Specification;
- Clinical Access Policy for FDG-PET/CT;
- All Wales Policy: Making Decisions on Individual Patient Funding Requests.

6. DEFINITIONS

Stereotactic body radiotherapy (SBRT) Stereotactic radiation therapy has been used for benign and malignant lesions in the brain for many years. Stereotactic radiosurgery (SRS) is a single fraction of stereotactic directed radiation of a limited volume in the brain or other structure of the skull base, whereas stereotactic radiotherapy (SRT) has been defined as a fractionated stereotactic directed radiation of a limited volume in the brain. Stereotactic body radiotherapy (SBRT / SABR) refers to the use of stereotactically directed radiation therapy to structures outside the brain and skull.

Non Small Cell Lung Cancer (NSCLC) Lung cancer is responsible for 1 in 7 new cases of cancer and is responsible for 22% of all cancer deaths.

Approximately 80% of patients have non-small cell lung cancer (NSCLC), of whom about 20% have early-stage disease (AJCC Stage I, TNM Stage T1-2N0M0) which is associated with the best chance of cure. Lung cancer is more common in elderly patients and smokers, who have a higher incidence of medical co-morbidity. This means that in a proportion of patients with early stage NSCLC, surgery is too risky. Such patients are termed 'medically inoperable'. Some other patients may be inoperable for technical reasons.

World Health Organisation (WHO) performance status. The WHO performance scale is one way of assessing general health. The WHO performance status classification categorises patients as:

- 0: able to carry out all normal activity without restriction;
- 1: restricted in strenuous activity but ambulatory and able to carry out light work;
- 2: ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours;
- 3: symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden;
- 4: completely disabled; cannot carry out any self-care; totally confined to bed or chair.

TNM. The TNM system is one of the most widely used staging systems for cancer. This system has been accepted by the International Union Against Cancer (UICC) and the American Joint Committee on Cancer (AJCC).

The TNM system is based on the extent of the tumour (T), the extent of spread to the lymph nodes (N), and the presence of distant metastasis (M). A number is added to each letter to indicate the size or extent of the primary tumour and the extent of cancer spread.

7. PATIENT PATHWAY

7.1 South Wales

Patients will be discussed at the local lung MDT and considered for surgical resection if possible. If surgery is not considered appropriate then a letter should be faxed to Dr Alison Brewster (02920196870) at Velindre Hospital for an opinion on suitability for SABR. The letter should contain the patient's performance status, full lung function, results of CT thorax, PET and biopsy (if possible) . The CT scan should be forwarded to PACs at Velindre as soon as possible as the patient will be discussed at the next lung planning meeting once the images are available. The

decision regarding likely suitability with be faxed back to the referring consultant and it will be their responsibility to discuss the possible radiotherapy treatment options with the patient. If the patient is willing to attend for treatment in Cardiff then an OP appt will be forwarded. If the patient proves suitable for SABR then they will undergo the treatment at Velindre but would be followed up according to the protocol at the local referring centre.

7.2 North Wales

Patients will be discussed at the local lung MDT and considered for surgical resection if possible. If surgery is not considered appropriate then a letter should be faxed to Clatterbridge Cancer centre for an opinion on suitability for SABR. The letter should contain the patient's performance status, full lung function, results of CT thorax, PET and biopsy (if possible). The CT scan should be forwarded to PACs at Clatterbridge as soon as possible as the patient will be discussed at the next lung planning meeting once the images are available. The decision regarding likely suitability with be faxed back to the referring consultant and it will be their responsibility to discuss the possible radiotherapy treatment options with the patient.

8. EXCLUSIONS

- NSCLC patients with T2 or T3 primary tumours > 5cm;
- T3 primary NSCLC tumours involving the mediastinal structures or central T3 primary tumours;
- Metastatic lung tumours;
- 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;
- Tumours within 2cm radius of main airways and proximal bronchial tree;
- Primary NSCLC tumours with clinical evidence of regional or distant metastasis after appropriate staging studies;
- Previous radiotherapy within the planned treatment volume;
- Presence of pulmonary fibrosis (unless the increased risk of SABR has been fully considered and the patient has been appropriately consented);
- Chemotherapy administered within 6 weeks prior to study entry or planned for < 6 weeks following SABR.
- Advanced interstitial lung disease;
- Pregnant or lactating females; or

- Inability to obtain informed consent or comply with treatment.

9. CLINICAL OUTCOME AND QUALITY MEASURES

9.1 Quality and Patient Safety

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

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.

9.2 Clinical and Quality Criteria

The Provider must work to written quality standards and provide monitoring information to the lead purchaser. Providers are expected to comply with the following clinical and quality measures:

9.3 Patient Experience

Providers should use a validated patient experience tool for monitoring patient experience on, as a minimum, an annual basis (e.g. CAREs tool (http://www.caremeasure.org/)

Patient experience will be included in the departmental audit programme.

9.4 Quality of Life

- EQ-5D;
- Overall survival (1y, 3y and 5y dependent on data maturity and ONS linkage);
- Progression free survival;
- Local tumour control;
- Tissue toxicity;
- Dose reporting:
    - Dose conformity
    - Dose calculation algorhythm

Quality assurance of this technically complex and challenging treatment modality is critical to its success.

10. EQUALITY IMPACT 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.

REFERENCES

National Radiotherapy Implementation Group Report. Stereotactic Body Radiotherapy Guidelines for Commissioners, Providers and Clinicians in England 2011. Available from:

http://www.ncat.nhs.uk/sites/default/files/NRIG%20SBRT%20Final%20June%2011.p df. Accessed September 2012.

National Radiotherapy Implementation Group Report. Stereotactic Body Radiotherapy Clinical review of the evidence for SBRT 2011. Yorkshire and the Humber commissioning policy Stereotactic radiosurgery/radiotherapy.

Baumann, P., J. Nyman, I. Lax, et al., Factors important for efficacy of stereotactic body radiotherapy of medically inoperable stage I lung cancer. A retrospective analysis of patients treated in the Nordic countries. Acta Oncol, 2006. 45(7): p. 787-95.

Bissonnette JP et al, Quality assurance for the geometric accuracy of cone-beam CT guidance in radiation therapy. Int J Radiat Oncol Biol Phys. 2008;71(1 Suppl):S57-6.

Chi A, Liao Z, Hguyen NP, Xu J, Stea B, Komaki R. Systemic review of the patterns of failure following stereotactic body radiation therapy in early-

stage non-small-cell lung cancer: Clinical implications. Radiother Oncol , 2010;94:1-11.

Das IJ, Cheng CW, Watts RJ, Ahnesjö A, Gibbons J, Li XA, Lowenstein J, Mitra RK, Simon WE, Zhu TC; TG-106 of the Therapy Physics Committee of the AAPM. Accelerator beam data commissioning equipment and procedures: report of the TG-106 of the Therapy Physics Committee of the AAPM. Med Phys, 2008;35(9):4186-215.

De Ruysscher D, Faivre-Finn C, Nestle U, Hurkmans CW, Le Pechoux C, Price A, Senan S. European Organisation for Research and Treatment of Cancer recommendations for planning and delivery of high-dose, high precision radiotherapy for lung cancer. JCO Published online Nov 2010.

Galvin JM, Bednarz G. Quality assurance procedures for stereotactic body radiation therapy. Int J Radiat Oncol Biol Phys. 2008;71(1 Suppl):S122-5.
Hurkmans, C. W., et al., Recommendations for implementing Stereotactic radiotherapy in peripheral stage 1A non-small cell lung cancer: report for the Quality Assurance Working Party Party of the randomised phase III ROSEL study, Radiation Oncology, 2009. 4:1.

Kirby, D., S. Ryde, and C. Hall, Report 94: Acceptance Testing and Commissioning of Linear Accelerators. Institute of Physics and Engineering in Medicine (IPEM), 2007 Lagerwaard, F.J., C.J. Haasbeek, and B.J. Slotman, Clinical results and toxicity after 4-D stereotactic radiotherapy for early stage non small cell lung cancer (NSCLC): B5 -04. Thorac Oncol, 2007;2(suppl 4):S348.

Lagerwaard FJ, Haasbeek CJ, Smit EF et al. Outcomes of risk-adapted fractionated stereotactic radiotherapy for stage I non-small cell lung cancer. Int J Radiat Oncol Biol Phys ,2008;71:1118-23.

Lehmann J, Perks J, Semon S, Harse R, Purdy JA. Commissioning experience with cone-beam computed tomography for image-guided radiation therapy. J Appl Clin Med Phys, 2007;8(3):2354.

Mayles, W.P., Physics Aspects of Quality Control in Radiotherapy (Report No. 81). Institute of Physics and Engineering in Medicine (IPEM), 1999 Version 1 - December2010. Page 10.

Mutic, S., J.R. Palta, E.K. Butker, et al., Quality assurance for computed-tomographysimulators and the computed-tomography-simulation process: report of the AAPM Radiation Therapy Committee Task Group No. 66. Med Phys, 2003;30(10):2762-92.

Nagata, Y., K. Takayama, Y. Matsuo, et al., Clinical outcomes of a phase I/II study of 48 Gy of stereotactic body radiotherapy in 4 fractions for

primary lung cancer using a stereotactic body frame. International Journal of Radiation Oncology Biology Physics, 2005;63(5):1427.

Nyman, J., K.A. Johansson, and U. Hulte?n, Stereotactic hypofractionated radiotherapy for stage I non-small cell lung cancer - Mature results for medically inoperable patients. Lung Cancer, 2006;51(1):97.

Onishi, H., H. Shirato, Y. Nagata, et al., Hypofractionated stereotactic radiotherapy (HypoFXSRT) for stage I non-small cell lung cancer: updated results of 257 patients in a Japanese multi-institutional study. J Thorac Oncol, 2007;2(7 Suppl 3):S94-100.

Palta JR, Liu C, Li JG. Current external beam radiation therapy quality assurance guidance: does it meet the challenges of emerging image-guided technologies? Int J Radiat Oncol Biol Phys, 2008;71(1 Suppl):S13-7.

RCR., IPEM., NPSA., and BIR., Towards Safer Radiotherapy. The Royal College of Radiologists, London, 2008.

Solberg TD, Medin PM, Mullins J, Li S. Quality assurance of immobilization and target localization systems for frameless stereotactic cranial and extracranial hypofractionated radiotherapy. Int J Radiat Oncol Biol Phys. 2008;71(1 Suppl):S131-5.

Stereotactic Body Radiation Therapy (SBRT) for Patients with Early Stage Non-small Cell Lung Cancer: A Resource. UK SBRT Consortium, September 2009.

Timmerman, R., R. McGarry, C. Yiannoutsos, et al., Excessive toxicity when treating central tumors in a phase II study of stereotactic body radiation therapy for medically inoperable early-stage lung cancer. J Clin Oncol, 2006;24(30):4833-9.

Trial of Either Surgery or Stereotactic Radiotherapy for Early Stage (IA) Lung Cancer(ROSEL).ClinicalTrials.govIdentifier:NCT00687986. Available from: http://clinicaltrials.gov/ct2/show?term=stereotactic&rank=11.

Wulf, J., U. Hadinger, U. Oppitz, et al., Stereotactic radiotherapy of targets in the lung and liver. Strahlentherapie