

National Optimal Lung Cancer Pathway

For suspected and confirmed lung cancer: Referral to treatment

UPDATE 2020 Version 3.0

Introduction

This optimal pathway is primarily designed to improve outcomes in lung cancer by encouraging best practice, reducing variation, and reducing delays in diagnosis, staging and treatment. It is also designed to meet the waiting time targets as set out in the Independent Cancer Taskforce report. The principles of remote triage, test bundles and efficient use of clinic time also support recommended infection control measures during the coronavirus pandemic set out in “*Urgent Cancer Diagnostic Services during COVID-19*”

Use of guidelines

The diagnosis, staging and fitness assessments in this pathway should be completed with reference to the British Thoracic Society guidelines for the radical management of lung cancer, the NICE guidelines for the investigation and management of suspected lung cancer (NG 122) and with reference to the NICE Quality Standard (QS 17). The NOLCP is also supported by a series of Diagnostic Standards of Care that provide more detail (see Appendix 1).

Maximum waiting times

The times in the pathway are the **maximum** allowed and the aim should be for the majority of patients to be diagnosed treated before the specified maximum. The maximum length of the pathway is 49 days, encouraging earlier treatment, although the national cancer wait times target is unchanged at 62 days. There is randomised controlled trial evidence that faster pathways improve outcomes. The **start point** of the cancer waiting time pathway is the date of referral on the cancer pathway, or date of upgrade to the cancer pathway once the diagnosis of cancer is suspected; this can be based on chest X-ray or CT.

A note for commissioners

The initial identification and referral of patients with suspected lung cancer is dependent on primary care. Prompt recognition, risk assessment and referral is essential to reduce delay in diagnosis and to reduce the high proportion of lung cancer patients who are diagnosed via emergency admissions. Most of the diagnosis, staging and treatment of lung cancer is provided by secondary and tertiary care; primary care may be involved in supportive care throughout. Supportive, palliative and end of life care is provided by both primary and secondary care.

Key features:

- Potential to reduce delay from CXR to CT and triage to less than 24 hours
- Potential avoidance of emergency admission
- Allows triaged patients to be managed by primary or secondary care, often remotely
- Timed treatment pathways supporting rapid progress to treatment

Requirements:

- Turnaround times have to be short, across the whole pathway
- Hot reporting of all CXRs and subsequent CTs
- Daily respiratory medicine cancer clinic optimal
- Well organised scheduling of appointments for therapies
- Team based approach to radiation planning and dedicated peer review / planning meeting
- Local access to advanced radiotherapy planning and treatment

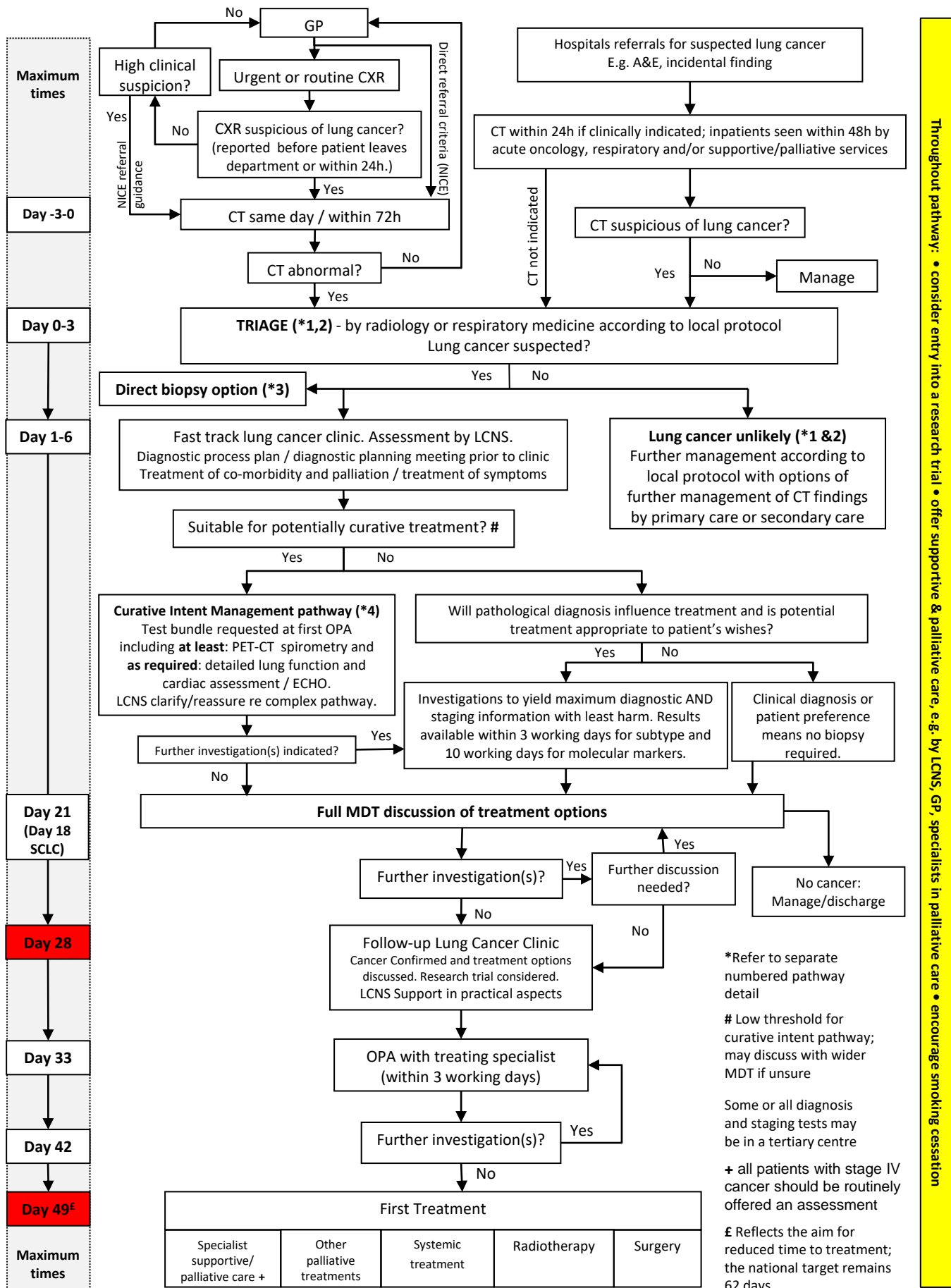
What is new in the update?

- Timed treatment pathways for thoracic surgery, medical oncology and radiotherapy
- Inclusion of Diagnostic Standards of Care (appendix 1)
- Clarification of the role of the Lung Cancer Nurse Specialist

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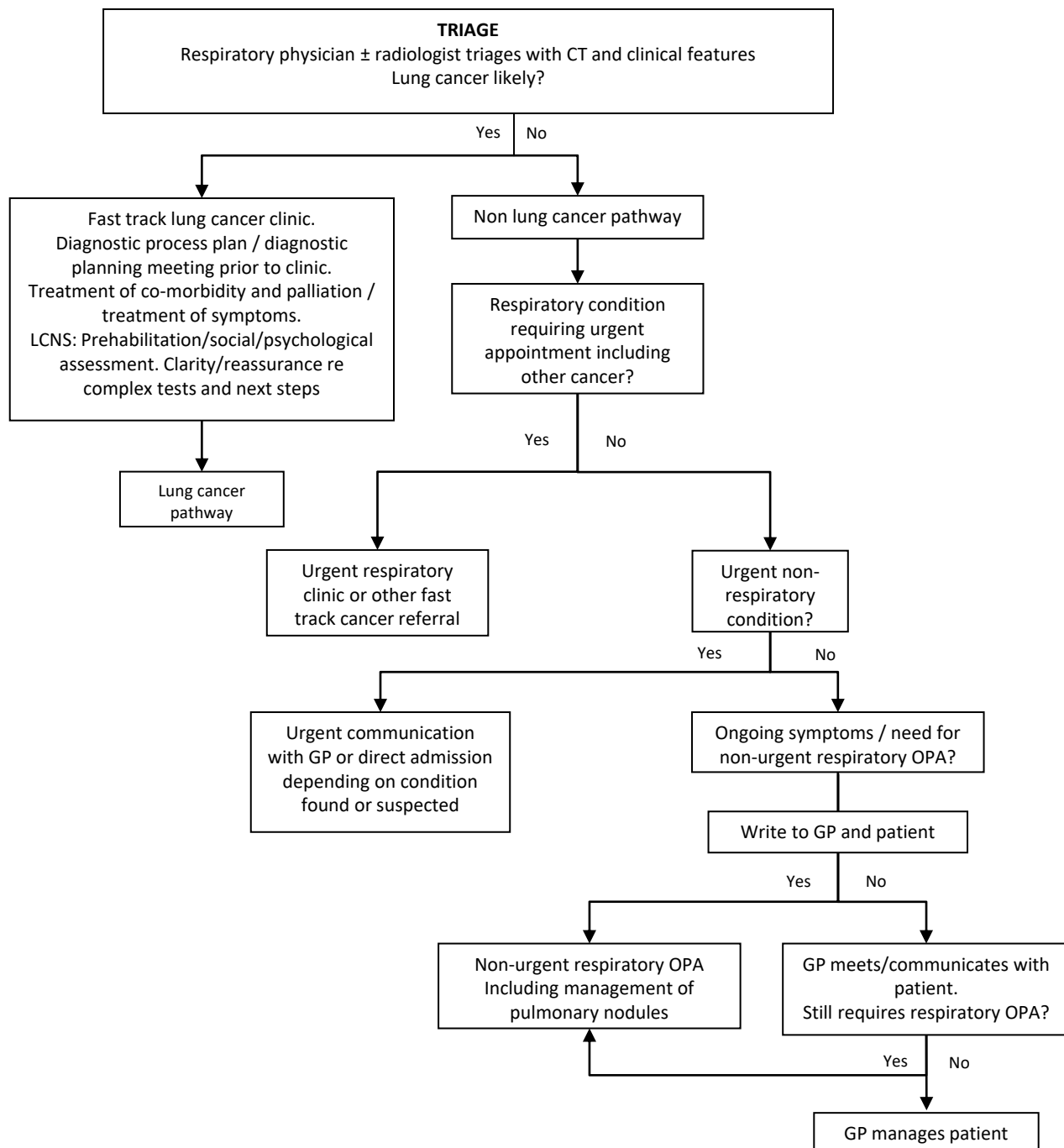


Pathway Detail 1

Triage system for referrals to the lung cancer service: secondary care leads the management process

Triage refers to the process of selecting the appropriate route based on clinical data.

This pathway places the responsibility for managing all patients referred for suspected lung cancer within secondary care. It ensures patients with other conditions that may require secondary care are given appointments and patients not requiring secondary care are directed back to primary care.



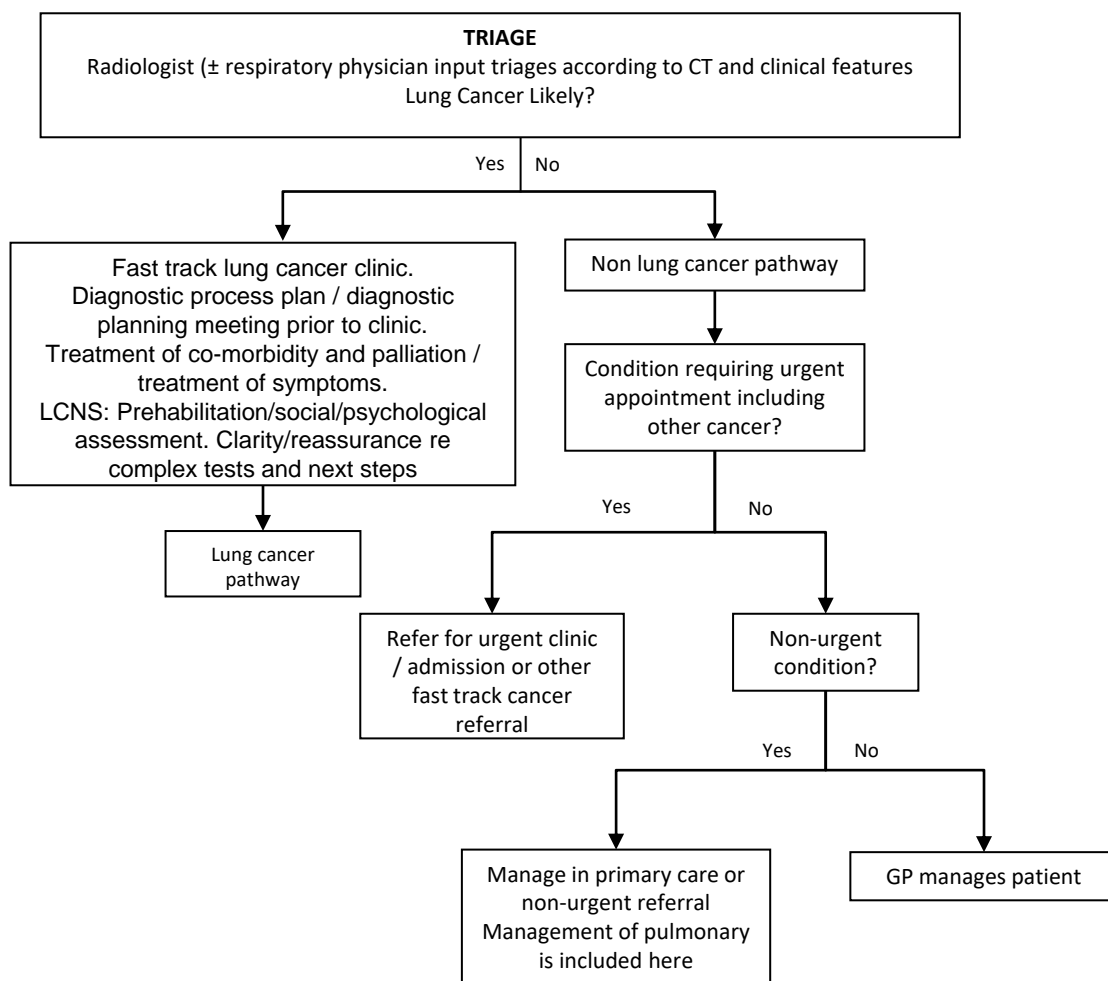
Recommendations for the management of pulmonary nodules can be found in the British Thoracic Society guidelines on the investigation and management of pulmonary nodules.

Pathway Detail 2

Triage system for referrals to the lung cancer service: primary care leads the management process

Triage refers to the process of selecting the appropriate route based on clinical data.

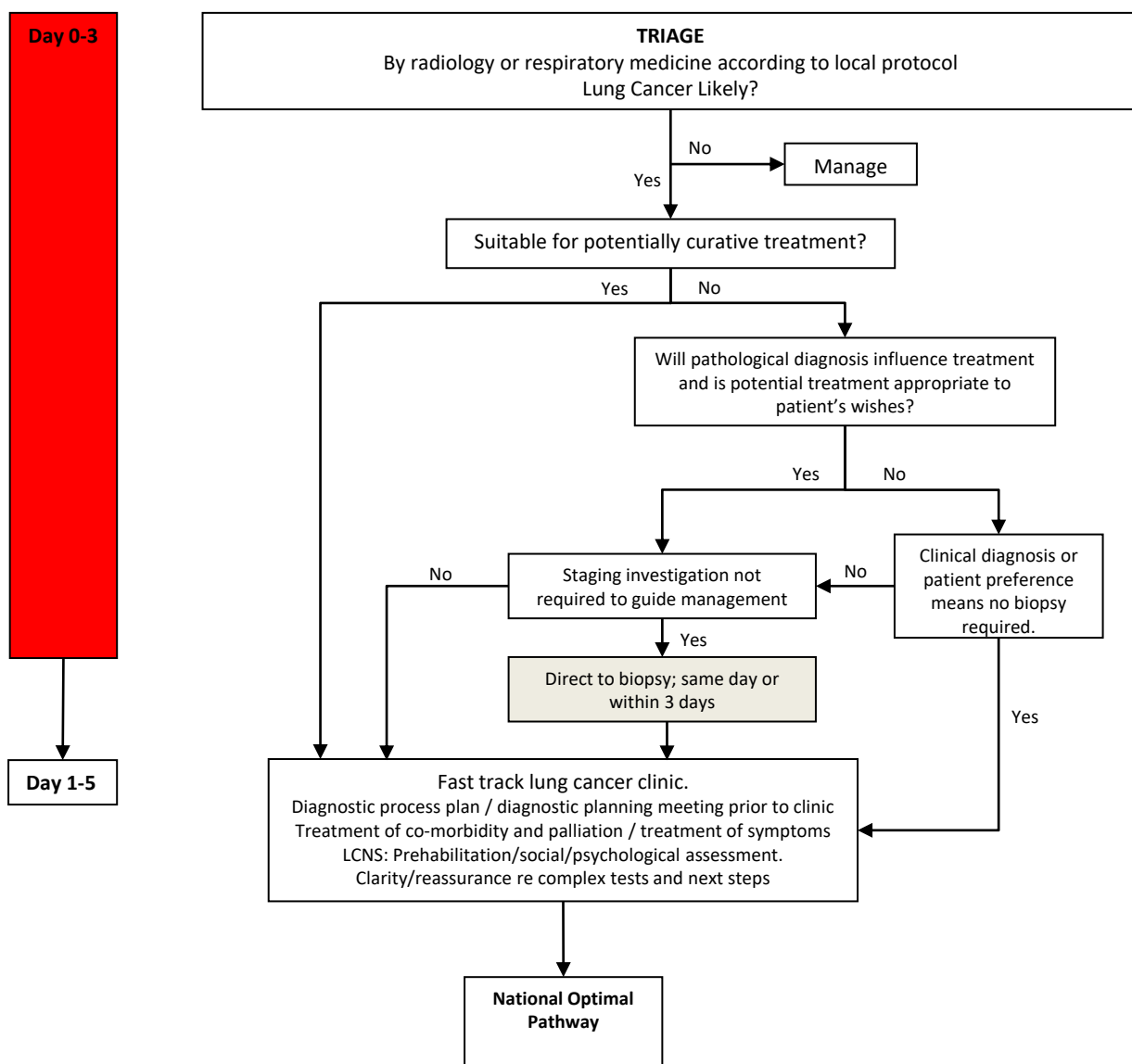
This pathway places the responsibility for managing all patients referred for suspected lung cancer within secondary care. It ensures patients with other conditions that may require secondary care are given appointments and patients not requiring secondary care are directed back to primary care.



Recommendations for the management of pulmonary nodules can be found in the British Thoracic Society guidelines on the investigation and management of pulmonary nodules.

Pathway Detail 3 Direct to biopsy variation

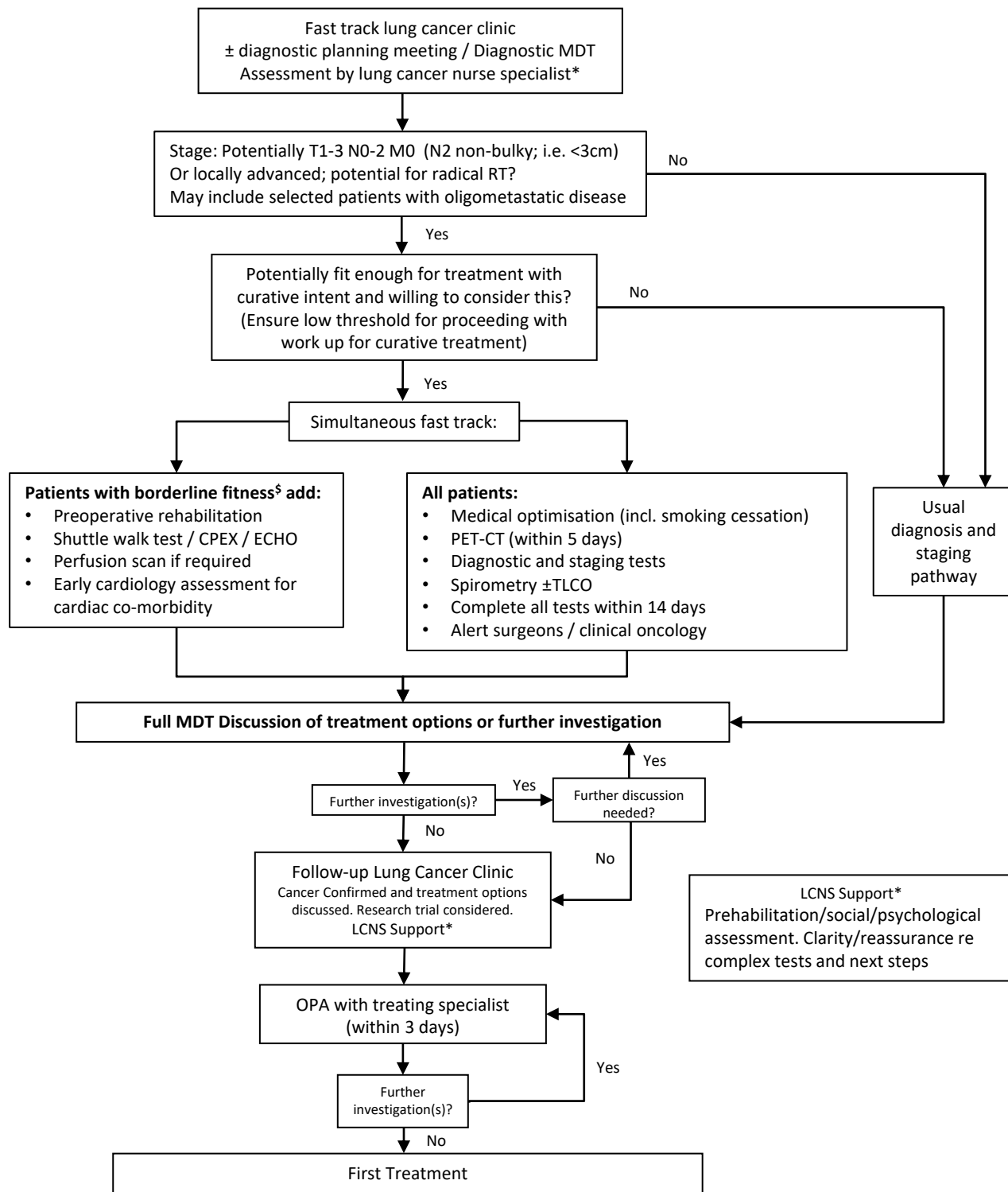
This pathway allows for early diagnostic biopsy where other tests are not required for staging and treatment. Such patients include those that have obvious advanced disease that is not suitable for treatment with curative intent. Patients potentially suitable for curative intent generally require a PET-CT to clarify diagnosis (for small pulmonary nodules) staging and the most appropriate first diagnostic and staging investigation. Direct biopsy investigations include neck ultrasound guided biopsy, percutaneous lung biopsy, endobronchial ultrasound needle biopsy, pleural aspiration and pleural biopsy. The direct biopsy pathway has the potential to provide a rapid diagnosis for some patients where detailed staging and fitness investigations are not needed to guide management.



Pathway detail 4

National Optimum Curative Intent Management Pathway

Patients who are potentially suitable for curative treatment usually require multiple investigations to accurately assess their diagnosis, stage and fitness. The capacity to provide rapid access to these investigations may be limited and so the logistics of scheduling needs to be optimised to prevent long waiting times. This pathway fast tracks these patients by requesting tests concurrently, supported by pre-planned availability of urgent test appointments e.g. lung biopsy, bronchoscopy, endobronchial ultrasound, mediastinoscopy, ECHO and complex lung function. Reference should be made to the British Thoracic Society guidelines for the radical management of lung cancer and the NICE guidelines for the investigation and management of suspected lung cancer. To prevent delays in treatment, consider early notification of thoracic surgeons or clinical oncology to help with scheduling.

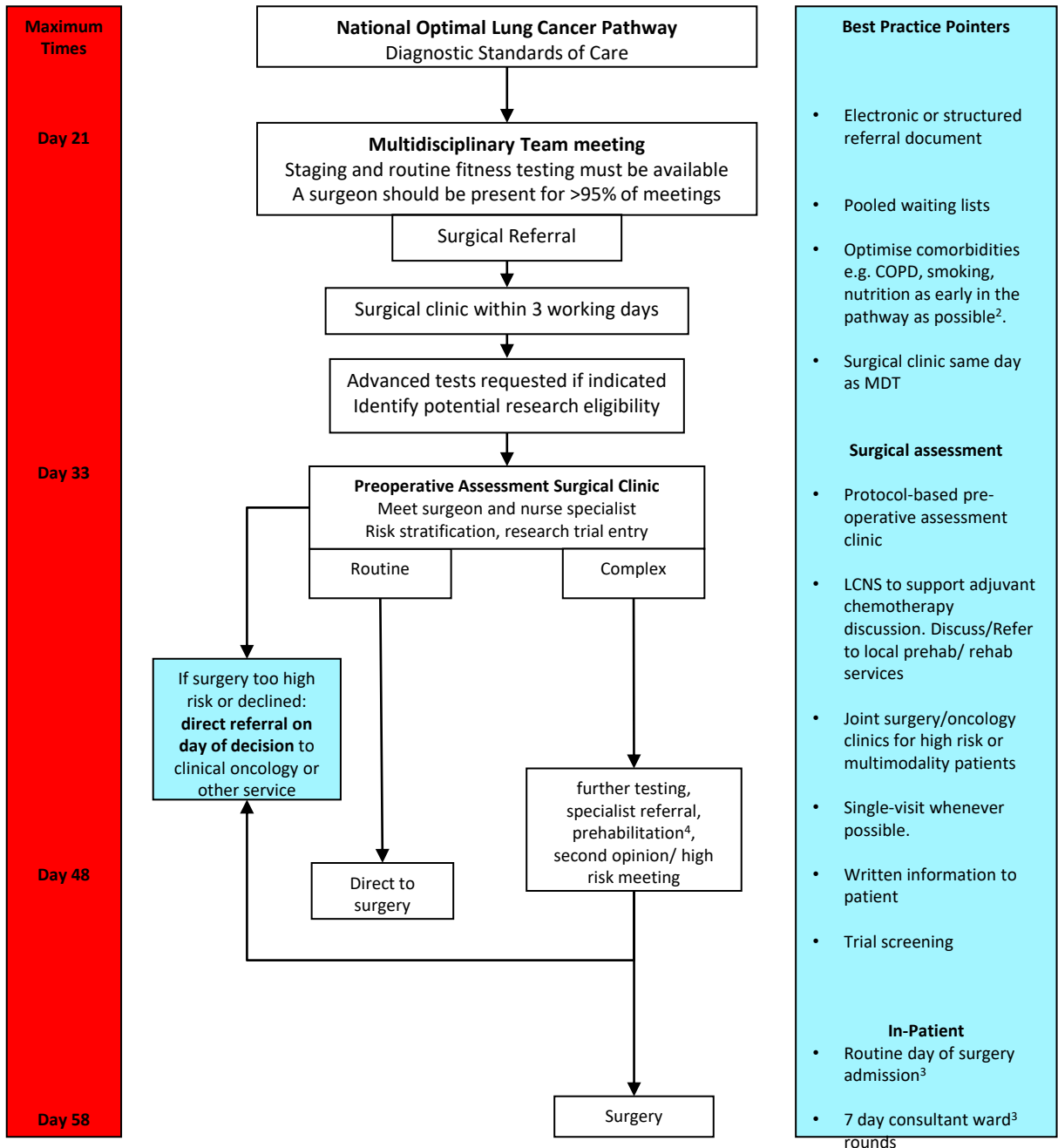


[§]There is no agreed definition of borderline fitness. NICE QS 17 (Lung Cancer) defines this as a level of fitness that could lead to a greater than average morbidity or mortality from surgery. However, modern radiotherapy techniques mean that assessment for curative treatment can be applied at lower levels of fitness than defined in QS17.



Timed Treatment Pathway 1: Thoracic Surgery

This pathway was developed by members of the CEG for Lung Cancer and Mesothelioma, NHSE and the Thoracic Surgery section of the Society of Cardiothoracic Surgeons. It was led by D West and S Barnard.



(1) Thoracic Surgery Service Specification 170016/S . NHS England
<https://www.england.nhs.uk/wp-content/uploads/2017/07/thoracic-surgery-service-specification.pdf>
 (2) NICE Lung Cancer Guideline CG122 updated 2019
<https://www.nice.org.uk/guidance/ng122>
 (3) Cardiothoracic Surgery GIRFT Programme National Specialty Report 2018 David Richens
<https://gettingitrightfirsttime.co.uk/wp-content/uploads/2018/04/GIRFT-Cardiothoracic-Report-1.pdf>
 (4) Preoperative exercise training for patients with non-small cell lung cancer
 Cavalheri V, Granger C Cochrane Database Syst Rev 2017 Jun 7;6: CD012020

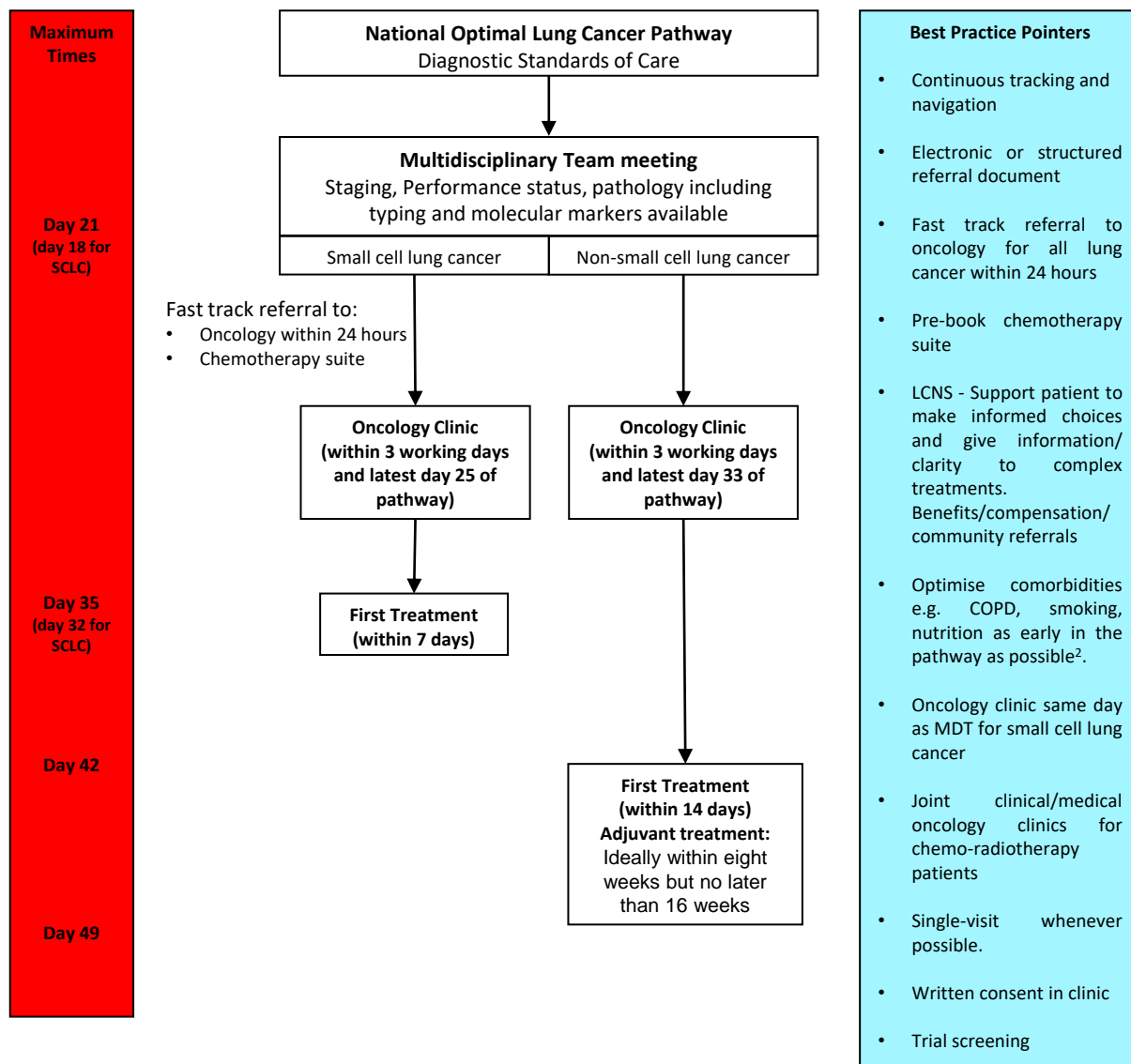
Enhanced recovery perioperative care

Definition of routine and advanced fitness testing

Routine fitness testing includes spirometry, transfer factor, and transthoracic echocardiography, and six-minute walk testing when indicated. Tests beyond these, for example cardiopulmonary exercise testing, split function tests or cardiology investigations including perfusion scanning or angiography are defined as “advanced” for the purpose of the pathway

Timed Treatment Pathway 2: Systemic Therapies

This pathway was developed by members of the CEG for Lung Cancer and Mesothelioma, NHSE and led by D Talbot, Y Summers, M Hatton, L Toy and S Popat.



Notes: Time Treatment Pathway 2: Systemic Therapies

Goals

The purpose of this document is to provide, from current best practice in the UK, suggestions on how the delivery of systemic therapy for people with lung cancer might be coordinated within provider centres to achieve the objective of the National Optimal Lung Cancer Pathway (NOLCP) and compliance with NICE Guidance (Currently NG122, June 2019). The goal is to enable safe, timely systemic treatment for patients with lung cancer that is coordinated efficiently by MDTs and communicated effectively with the patient, their carers' and community. With Quality Assured treatment and audit, demonstrable delivery of the Long-Term Plan of the NHS will ensure "every patient has access to optimal, personalised treatment and care and effective follow-up".

Scope

This document relates to the planning and provision of systemic therapies for non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC) given with curative or palliative intent by MDTs in England. This guidance is summarised in the companion Flow Chart "Timed Treatment Pathway 2: Systemic Therapy".

Systemic Therapy with Curative Intent

Following potentially curative surgery for NSCLC for patients of good performance status (PS), cisplatin-based adjuvant chemotherapy improves survival for Stages T1a-4, N1-2, M0 disease and can be considered also for Stages T2b-4, N0, M0 disease with tumours >4cm in diameter. Available evidence supports guidance recommending the use of adjuvant treatment within 60 days of surgery. Combined modality therapy of concurrent chemo-radiotherapy with surgery, ideally within a six-week window, is indicated for patients with operable Stage IIIA N2 NSCLC with suitable lung function and performance status.

- For locally advanced unresectable NSCLC, concurrent chemo-radiotherapy followed by durvalumab maintenance therapy, funded by the Cancer Drugs Fund (CDF), is the preferred standard of care for suitable patients (TA578). Whilst less effective, sequential chemo-radiotherapy can be considered for those for whom concurrent therapy is contra-indicated.
- For Stage I-III (Limited) SCLC, concurrent chemo-radiotherapy is the standard of care. Sequential chemo-radiotherapy is less effective but may be considered for those for whom concurrent therapy is contra-indicated. Early stage SCLC is rarely managed initially by surgical resection. In such cases adjuvant combination chemotherapy with platinum and etoposide should be considered.
- As treatment with curative intent is invariably multi-modality in nature, it is important that care is coordinated and planned early by the MDT with information provided to patients at the appropriate time.

Systemic Therapy with Palliative Intent

- People with stage IIIB or IV NSCLC having eligible PS should be offered systemic therapy (first-line, maintenance, second-line treatments and therapies available through the CDF) in accordance with NG122. Treatment should be tailored to the pathological sub-type of the tumour, relevant somatic mutations, individual predictive factors and co-morbidities.
- People with Stage IIIB/IV (Extensive Stage) SCLC should have treatment (typically combination chemotherapy with etoposide and a platinum) initiated within two weeks of the histological/cytological diagnosis.

Co-ordination of the Pathway

Following early diagnosis, staging and assessment of lung cancer, it is the responsibility of MDTs to have in place a robust, integrated pathway designed to deliver appropriate and prompt systemic therapy. It is essential, early in the pathway, to have sufficient diagnostic material for the identification of the cell type, somatic mutations, chromosome re-arrangements and immunological markers. This is a component of the "diagnostic and staging bundle" which, together with radiology and clinical information, enables the team to recommend the most appropriate therapy at the earliest opportunity.

- Patients for whom systemic therapy is recommended as first line therapy should be seen by the oncologist within two weeks of the MDT decision, preferably within one week. Appropriate investigations (haematological indices, liver function, renal function, molecular markers, completion of imaging) should have been completed by this time. The lung cancer specialist nurse (LCNS) has a key role in communication, coordination and as a point of contact throughout the patient journey. Whilst respecting patients' need for adequate time to consider treatment and giving informed consent, it is desirable for the patient to meet the LCNS, or cancer pharmacist, before treatment commences and advanced booking of treatment in the chemotherapy suite.
- Treatment of SCLC should be initiated within two weeks of the diagnosis (NICE QS17). Some providers operate a "small cell lung cancer alert" initiated by pulmonary pathologists on suspicion of a diagnosis of SCLC. Email notification of the MDT, and others, by the thoracic pathologist within 24hrs of the diagnosis enables prompt communication with the patient, completion of investigations, advanced booking of appointments and chemotherapy scheduling before the target date.

Follow up and Continuity of Care

Timely review and assessment of patients undergoing systemic therapy is necessary during each cycle of therapy and following its completion. Pro-active assessment of anticipated adverse events is essential including those that may occur late (following immunotherapy, for example). Telephone follow-up may be considered for some patients. A patient-focused approach is paramount throughout the pathway with expedient intervention of symptom management, multi-disciplinary approach including palliative care input, and community support.

Related Documents

Optimal Lung Cancer Pathway Version 3.0; Lung Cancer Clinical Expert Group, 2020

NICE Guidance: www.nice.org.uk/guidance/ng122

NICE Quality Standards: www.nice.org.uk/guidance/qs17

<https://pathways.nice.org.uk/pathways/lung-cancer>

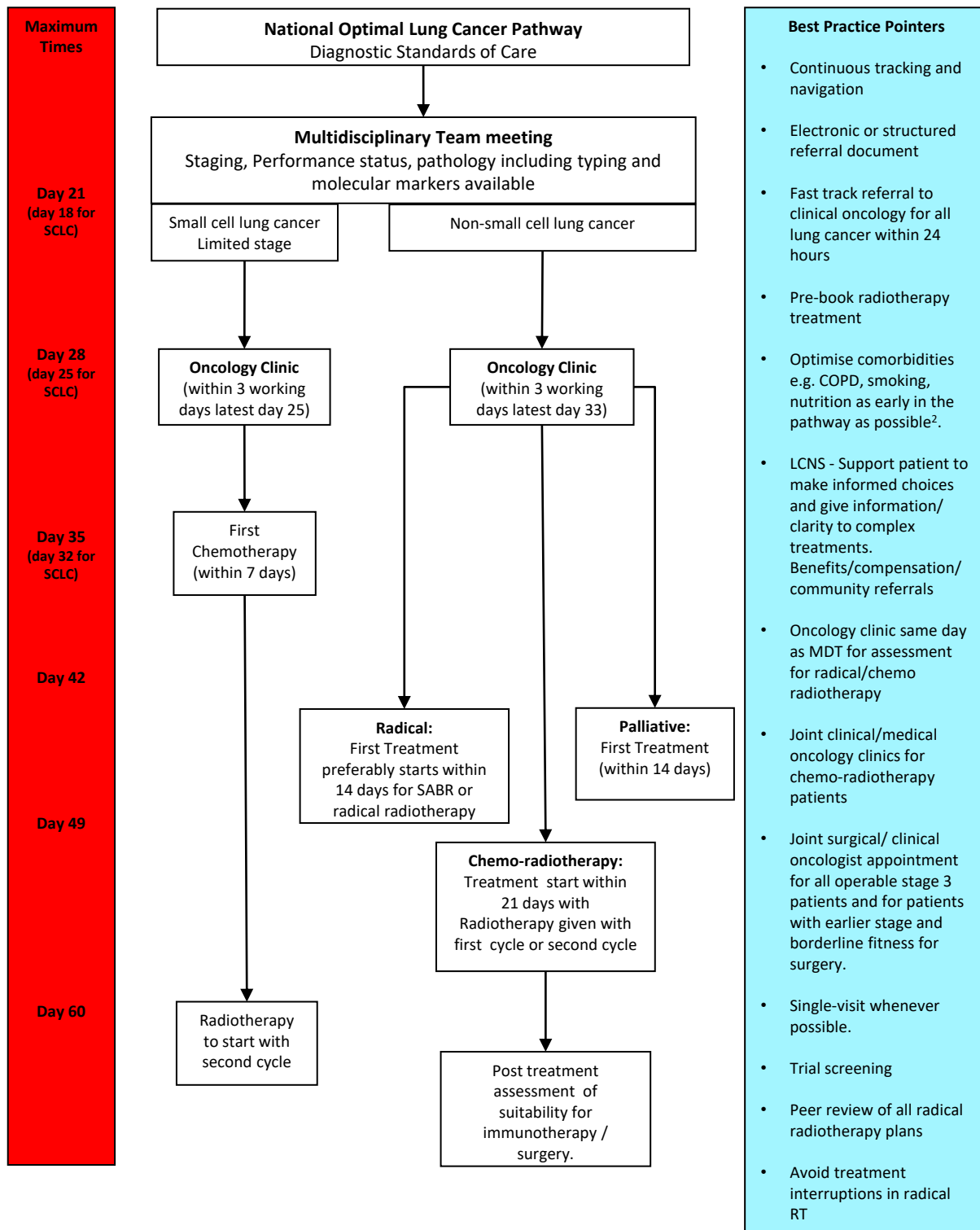
NHS Long Term Plan: www.england.nhs.uk/long-term-plan/

Commissioning Document CEG 2017/18 NHS Standard Contract for Acute, Ambulance Community and Mental Health and Learning Disability Services (Multilateral) Section B Part 1: Commissioning Guidance for the Whole Lung Cancer Pathway.

Companion document on radiation therapy for lung cancer.

Timed Treatment Pathway 3: Radiotherapy

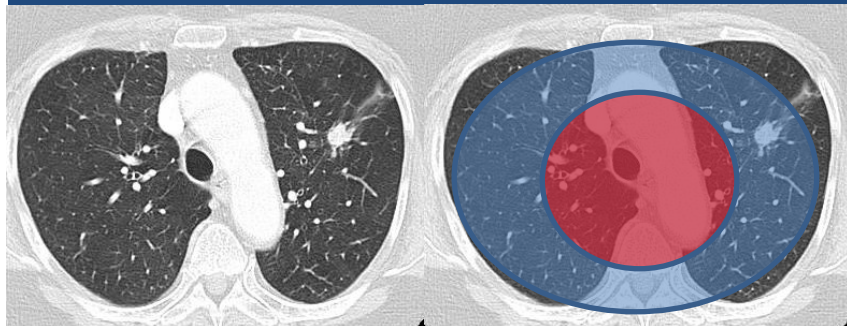
This pathway was developed by members of the CEG for Lung Cancer and Mesothelioma, NHSE and led by D Gilligan, M Hatton, and L Toy



Appendix 1: Diagnostic Standards of Care for suspected lung cancer

Assess contrast-enhanced CT of lower neck, thorax and upper abdomen

Broadly assess for fitness for treatment



Proceed with this standard of care where patients are thought to be fit enough for, and willing to undergo, investigations and treatment. Patients who are unfit for, or unwilling to undergo investigations and treatment, should be discussed at the MDT meeting to explore further options including supportive care.

'Peripheral lesion' = positioned in the outer 2/3 of the thorax based on axial CT image (blue area); not involving central structures (red area)

Notes and guidance

Percutaneous image-guided biopsy is the preferred method of suspected primary tumour biopsy after PET where possible given the higher sensitivity. Bronchoscopic guided biopsy is considered where percutaneous is high risk and /or where CT shows a bronchus leading directly into the tumour (bronchus sign).

This DSOC includes solid pulmonary nodules $\geq 8\text{mm}$ diameter / $\geq 300\text{mm}^3$ volume with a Brock risk of malignancy $\geq 10\%$ or persistent sub-solid nodules for ≥ 3 months with a solid component $\geq 5\text{mm}$. Smaller nodules are excluded from this DSOC. Pure ground glass nodules usually do not require further diagnostics and should continue under surveillance. Further invasive investigations or intervention may be indicated if a solid component develops.

A specialist supportive/palliative care review can be considered for patients for whom the MDT treatment decision is 'best supportive care' and/or with uncontrolled symptoms.

Commence prehabilitation / optimisation at first assessment – Ensure the pillars of prehabilitation are covered:

Offer smoking cessation

Encourage physical activity

Prevent and manage malnutrition

Refer to Lung Cancer Nurse Specialist

Consider participation in research

Diagnostic and staging tests

Physiology tests (request simultaneously)

Request Diagnostic and Staging Bundle:

Request Fitness assessment:

- **PET-CT** (complete within 5 days); pre-book primary tumour biopsy. Review PET-CT **avoiding full MDT discussion** and if clear of nodal or distant metastases, proceed with biopsy. Where PET-CT upstages the tumour, to: N1-3 M0 see DSOC 2; N0-3 M1 see DSOC 4
- **Percutaneous image-guided biopsy** OR bronchoscopic guided biopsy (Fluoroscopy, radial EBUS, navigational bronchoscopy)
- Some MDTs may consider it appropriate to offer treatment without a biopsy if there is no upstaging on PET and the probability of malignancy is sufficiently high
- Consider alerting surgical or radiotherapy service early.

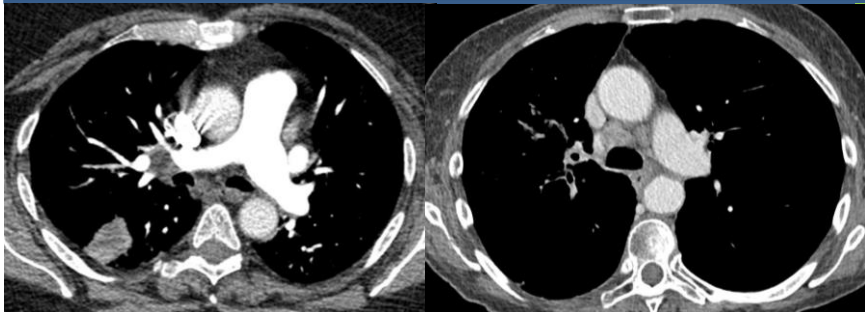
- Spirometry and transfer factor
 - Consider one or more of: Shuttle walk*, or CPEX*
 - ECG
 - Consider perfusion scan if pneumonectomy
- Request echocardiogram if*:**
- Heart murmur
 - Abnormal ECG
 - Known ischaemic heart disease / valvular disease
 - Possibility of pneumonectomy
- Assessment by a cardiologist may be required
*May be omitted if surgery not an option

Dataset for MDT discussion:

- PET-CT results
- Diagnostic and staging test; usually percutaneous lung biopsy if done; may be other.
- Performance status, FEV₁ and DLCO
- Additional fitness tests as necessary

Assess contrast-enhanced CT of lower neck, thorax and upper abdomen

Broadly assess for fitness for treatment



Proceed with this standard of care where patients are thought to be fit enough for, and willing to undergo, investigations and treatment. Patients who are unfit for, or unwilling to undergo investigations and treatment, should be discussed at the MDT meeting to explore further options including supportive care.

Notes and guidance

Staging EBUS ± EUS should be performed where there are enlarged nodes, including isolated N1 hilar nodes and where there is FDG avidity in normal sized nodes. PET-CT has a significant false negative rate, so sampling of normal sized, PET negative nodes is recommended when nodal appearances are not typically benign on CT or endosonography.

Where staging EBUS ± EUS is performed there should be a systematic examination of mediastinal and hilar lymph nodes beginning with N3 stations, followed by N2 and finally N1. Any accessible lymph node based on CT (≥10mm), PET-CT (FDG avidity above the mediastinal blood pool) or sonographic assessment, is sampled.

A specialist supportive/palliative care review should be routinely offered to all patients for whom the MDT treatment decision is 'best supportive care' and/or uncontrolled symptoms.

Commence prehabilitation / optimisation at first assessment – Ensure the pillars of prehabilitation are covered:

Offer smoking cessation

Encourage physical activity

Prevent and manage malnutrition

Refer to Lung Cancer Nurse Specialist

Consider participation in research

Diagnostic and staging tests

Physiology tests (request simultaneously)

Request Diagnostic and Staging Bundle:

- **PET-CT** (complete within 5 days); **pre-book** staging EBUS ± EUS . Review PET-CT **avoiding full MDT discussion** and proceed as below. Where PET-CT upstages the tumour to M1 see DSOC 4
- Proceed with staging **EBUS ± EUS** where no SCN seen.
- **US guided nodal biopsy** where CT or PET-CT show enlarged or FDG avid supraclavicular nodes (SCN)
- **Biopsy of the primary lesion** where nodes negative on EBUS ± EUS
- Reflex predictive biomarker testing is preferred
- Contrast-enhanced CT brain for suspected stage II (or if known small cell).
- Contrast-enhanced MR brain for suspected stage III

Request Fitness assessment:

- Spirometry and transfer factor
- Consider one or more of: Shuttle walk*, or CPEX*
- ECG
- Consider perfusion scan if pneumonectomy

Request echocardiogram if*:

- Heart murmur
 - Abnormal ECG
 - Known ischaemic heart disease / valvular disease
 - Possibility of pneumonectomy
- Assessment by a cardiologist may be required

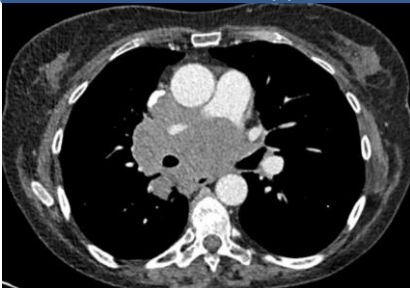
*May be omitted if surgery not an option

Dataset for MDT discussion:

- PET-CT and CT or MR brain results
- Bronchoscopy / EBUS ± EUS / other pathology
- Performance status, FEV₁ and DLCO
- Additional fitness tests as required

Assess contrast-enhanced CT of lower neck, thorax and upper abdomen

Broadly assess for fitness for treatment



Proceed with this standard of care where patients are thought to be fit enough for, and willing to undergo, investigations and treatment. Patients who are unfit for, or unwilling to undergo investigations and treatment, should be discussed at the MDT meeting to explore further options including supportive care.

Notes and guidance

This category of patients may be suitable for treatment with curative intent using radiotherapy or chemoradiotherapy. Mediastinal nodes contiguous with the primary tumour or conglomerate are almost always involved and sampling may proceed to confirm diagnosis. There is a high chance of metastatic disease.

Diagnostic EBUS refers to the targeted sampling of nodal disease for pathological confirmation, tumour sub-typing and molecular pathology.

“Invasive mediastinal lymphadenopathy” has poorly defined borders and cannot be easily measured. It forms conglomerate disease with other nodal stations.

A specialist supportive/palliative care review should be routinely offered to all patients for whom the MDT treatment decision is ‘best supportive care’ and/or uncontrolled symptoms.

Commence prehabilitation / optimisation at first assessment – Ensure the pillars of prehabilitation are covered:

Offer smoking cessation

Encourage physical activity

Prevent and manage malnutrition

Refer to Lung Cancer Nurse Specialist

Consider participation in research

Diagnostic and staging tests

Physiology tests (request simultaneously)

Request Diagnostic and Staging Bundle:

- **PET-CT** (complete within 5 days); **pre-book** Bronchoscopy / EBUS ± EUS / SCN node biopsy. Review PET-CT; where no upstaging patient is potentially appropriate for curative treatment. Where PET-CT upstages the tumour: to N0-3 M1 see DSOC 4
- Proceed with **EBUS ± EUS** or where no SCN or US negative (staging EBUS may be required to define tumour extent)
- **US guided nodal biopsy** where CT or PET-CT show enlarged or FDG avid supraclavicular nodes (SCN)
- Contrast-enhanced MR brain. (CT if known small cell)
- Reflex predictive biomarker testing is preferred

Request Fitness assessment:

- Spirometry and transfer factor†
- Renal function

† transfer factor may be omitted if does not influence treatment

Dataset for MDT discussion:

- PET-CT and MR brain results
- Bronchoscopic / EBUS / other pathology
- Performance status, FEV₁ and DLCO
- Renal function

Assess contrast-enhanced CT of lower neck, thorax and upper abdomen

Broadly assess for fitness for treatment



Proceed with this standard of care where patients are thought to be fit enough for, and willing to undergo, investigations and treatment. Patients who are unfit for, or unwilling to undergo investigations and treatment, should be discussed at the MDT meeting to explore further options including supportive care.

Notes and guidance

Follow this algorithm in cases where there is clear evidence of distant metastases on CT. Sometimes this may need to be clarified with additional tests e.g. liver US/MR/CT or PET-CT.

A specialist Supportive/Palliative care review should be routinely offered to all patients, irrespective of any other treatment offered and/or uncontrolled symptoms.

Diagnostic EBUS refers to the targeted sampling of nodal disease for pathological confirmation. It is essential that pathological samples are adequate to guide targeted treatment. Staging EBUS may be required to clarify tumour volume.

Synchronous brain metastases may be suitable for stereotactic radiosurgery or surgery and should be discussed at the brain metastases MDT. See separate notes for metachronous oligometastatic disease.

Commence prehabilitation / optimisation at first assessment – Ensure the pillars of prehabilitation are covered:

- Offer smoking cessation
- Encourage physical activity
- Prevent and manage malnutrition

Refer to Lung Cancer Nurse Specialist

Consider participation in research

Diagnostic and staging tests

Physiology tests (request simultaneously)

Request Diagnostic and Staging Bundle:

Request Fitness assessment:

Choose the least invasive and safest sampling technique to yield adequate pathology for tumour sub-typing and targeted therapy assessment. Optimal tests include:

- Diagnostic bronchoscopy (±TBNA)
- Diagnostic EBUS
- US or CT guided biopsy of any target area
- Pleural aspiration ± medical thoracoscopy if pleural effusion.
- Predictive biomarker result within 10 working days (facilitated by re-testing)
- Bone biopsy should be avoided where there is no significant soft tissue component because of decalcification time and inability to do molecular pathology
- Consider PET-CT and contrast enhanced CT brain for oligometastatic disease

- Spirometry optional
- Renal function

Dataset for MDT discussion:

- Bronchoscopic / EBUS / other pathology
- Performance status,
- Renal function

Notes for all Lung Cancer SOCs

EBUS ± EUS: The majority of assessments will involve EBUS only but EUS or EUSB may be added where indicated.

Staging EBUS ± EUS: Patients may need to be referred to a specialist centre for this. There should be a mechanism for rapid e-referral and prompt testing in line with the National Optimal Lung Cancer Pathway and the NHSE EBUS service specification.

Reflex testing: refers to the block testing of pathological samples to assess for suitability for targeted therapy. The specific tests depend on the drugs available so will change as new drugs are approved for use.

Oligometastatic Disease

Synchronous brain metastases may be treated by surgery or stereotactic radiosurgery. MDTs may also elect to treat other synchronous oligometastatic sites by surgery on an individual basis (no current guidance).

Oligometastatic disease and the Commissioning through Evaluation (CtE)*.

Patients are eligible if:

- 1-3 sites of metastatic disease (defined after appropriate imaging) which can be treated with stereotactic radiotherapy to a radical radiation dose.
- A maximum of two sites of spinal metastatic disease
- Maximum size of any single metastasis 6cm (5 cm for lung or liver metastases)
- **Disease free interval > 6 months;** (exception: synchronous liver metastases from colorectal primary).
- Not more than three oligometastatic sites treated in total per patient
- Expected life expectancy > 6 months
- Performance status ≤ 2
- All patients to be discussed at stereotactic MDT with presence of, or prior discussion with a disease site specific oncologist
- All patients willing to attend follow up and have details collected on prospective database for a minimum of two years

Abbreviations

CT: computed tomography

PET-CT: Positron emission tomography and computed tomography

US: Ultrasound

MRI: Magnetic resonance imaging

EBUS: Endobronchial ultrasound with needle sampling. Here refers to linear EBUS unless radial US specified

EUS / EUSB: Endoscopic ultrasound / Endoscopic ultrasound with EBUS scope

CPEX: Cardiopulmonary exercise test

ECG: Electrocardiogram

* Pending NHS commissioning guidelines