

Lung cancer (update)

Consultation on draft scope Stakeholder comments table

29/06/17 to 13/07/17

ID	Type	Organisation name	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
1	SH	AbbVie Ltd	General	General	Rovalpituzumab tesirine in treating small-cell lung cancer after 2 therapies has been passed to the NICE scoping team to prepare for a consultation exercise (NICE Topic Selection ID 9158).	Thank you for your comment. We have added this guidance to the 'related NICE guidance' section of the scope. Relevant related guidance will be inserted into the NICE pathway for lung cancer.
2	SH	British HIV Association (BHIVA)	General	General	All patients with lung cancer should undergo routine HIV testing prior to initiation of systemic anti-cancer therapy or radiotherapy, as per BHIVA guidelines.	Thank you for your comment. This guideline focuses on diagnosis and management of people with lung cancer. NICE has guidance on increasing uptake of HIV testing in people who may have undiagnosed HIV (NG60).
3	SH	British HIV Association (BHIVA)	General	General	Lung cancer patients with HIV should not be excluded from treatment on the basis of their HIV status alone.	Thank you for your comment. Equality of treatment is covered by the NHS constitution for England, which should be followed by all healthcare providers and commissioners alongside NICE guidance.
4	SH	British HIV Association (BHIVA)	General	General	Lung cancer patients with HIV should not be excluded from clinical trials because of their HIV status alone.	Thank you for your comment. It is not within NICE's remit to state the inclusion and exclusion criteria of primary research.
5	SH	British Thoracic Society	General	General	<p>The current guideline does not mention occupational risk factors at all in the introduction despite ~15% of lung cancer in men and 5% in women being attributable to occupational exposures. This seems odd, as other risk factors are covered. This is fairly prominent in ERS documents eg ERS White Book.</p> <p>It is important in terms of patient risk factors ie not just smoking, but most importantly to increase awareness that patients might be eligible for Industrial Injuries Disablement Benefit - extra financial support that may help families cope.</p> <p>In addition, lung cancer screening with low dose CT is being looked at in some countries for high risk patients based on</p>	<p>Thank you for your comment. In the section of the scope 'key facts and figures' it states that 'An estimated 89% of lung cancers are preventable, with 86% of these linked to smoking, 13% to occupational exposure, 9% to dietary factors and 7.8% to air pollution. Lung cancer can be linked to more than one cause.' We feel that this is sufficient as the purpose of this section is to provide a brief overview of the topic under consideration for update. Figures will be updated in the evidence reviews for each section of the guideline that is being updated.</p> <p>We agree that it is important to raise awareness of the risk factors of smoking, which is undertaken by Public Health England. However, it is not the remit of NICE guidelines to provide advice on financial support.</p> <p>NICE guidelines do not cover screening as this work is undertaken by the UK National Screening Committee (UKNSC). UKNSC review the evidence for screening of certain conditions at</p>

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					smoking history and asbestos exposure - NICE should refer to asbestos in the updated document.	regular intervals. We are aware that people who have been exposed to asbestos have an increased risk of non-mesothelioma lung cancer, however they would not be treated any differently to a person with lung cancer who had not been exposed to asbestos, and therefore are included in the population of the guideline. Adults with mesothelioma are not covered by the scope of this guideline as the management is different to that of SCLC and NSCLC.
6	SH	Society for Cardiothoracic Surgery	General	General	The draft scope is comprehensive and proposes to look at all the relevant areas of practice for which the guidelines may need an update. There are no additional areas required	Thank you for your comment.
7	SH	Department of Health	General	General	Thank you for the opportunity to comment on the draft scope for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
8	SH	Royal College of Nursing	General	General	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the above draft scope consultation at this time. Thank you for the opportunity and we look forward to participating in the next stage of consultations.	Thank you for your comment.
9	SH	The Society and College of Radiographers	General	Line 14 Table:1.5 Treatment	The Society and College of Radiographers would like to highlight the role of Therapeutic Radiographers as key members of the MDT. For example: Line 14 Table:1.5 Treatment This indicates there will be no evidence review and to retain recommendations from existing guideline. Therapeutic Radiographers are key members of the MDT. The document does indicate that in areas that are being retained from the existing guideline this may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context – Therapeutic Radiographers and AHP's being integral to this in the Cancer Plan.	Thank you for your comment. You are correct that we are not updating the section on multi-disciplinary team (MDT), as no evidence was identified during the surveillance review or scoping process that would impact on current recommendations. The guideline does not provide a complete list of members of the MDT as this is an issue for local decision making. We will review current definitions during guideline development and update these to ensure that current editorial standards are met.
10	SH	Pfizer UK Ltd	2	17-23	The draft scope is not explicit about the importance of tumour	Thank you for your comment. We are aware that there are

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					subtype on treatment decision making. "Lung cancer has 2 main types....Treatment depends on the type, size, position and stage of the cancer, and the person's health." The differential in clinical subtype at a level beyond just the distinction between SCLC and NSCLC is important for determining whether targeted therapies or immunotherapy are relevant options for management.	different tumour subtypes, the 'current practice' section is designed to give a very brief overview of the topic. As there are a large number of targeted therapies for different tumour subtypes and we have not listed them in this brief overview. We will refer to different tumour subtypes, where relevant, during development; in the sections 'targeted therapies for NSCLC' and 'testing to inform treatment decisions.'
11	SH	Pfizer UK Ltd	2	25-27	"The 2016 national lung cancer audit identified that only 72% of people have pathological confirmation of their lung cancer." This statement does not qualify that this does not relate to the % patients who have undergone molecular diagnostics to determine molecular subtype. This is not currently a metric assessed by the National Lung Cancer Audit	Thank you for your comment. You are correct that in this instance, pathological confirmation is defined as when cancer cells are examined under a microscope. This statement is not particular to molecular diagnostics, because as you state this is not currently assessed by the National Lung Cancer Audit. This information is presented in the scope of the guideline update to convey the overall picture of how often pathological diagnosis is currently undertaken in clinical practice via EBUS, EUS or FNA procedures.
12	SH	NHS England	2	26	The draft states that only 72% of people have pathological confirmation of their lung cancer. Consideration could be made to clarifying recommendations as to whether pathological diagnosis is recommended or relevant in different settings i.e. T1a nodule to be resected, palliative care etc.	Thank you for your comment. No new evidence was identified in the surveillance review or scoping searches about when to use pathological diagnosis. Therefore this section will not be updated at this time.
13	SH	Medtronic UK	3	12-13	Focus on earlier diagnosis _ consider Electromagnetic navigation bronchoscopy (ENB) as an alternative facilitation of bronchoscopic sampling of peripheral pulmonary nodules (< 20cm) in addition to mediastinal adenopathy. Due to it's relatively poor diagnostic yield, for small peripheral nodules, the ACCP guidelines do not recommend conventional bronchoscopy for the evaluation of small pulmonary nodules unless bronchus sign is clearly present.	Thank you for your comment. No new evidence on the use of Electromagnetic Navigation Bronchoscopy (ENB) that would impact on current recommendations was identified in the surveillance review or the scoping searches. One stakeholder did identify a study on ENB, https://bmcpulmed.biomedcentral.com/articles/10.1186/s12890-017-0403-9 that was published after the surveillance review was published. We note that the results from this study are the results from only 1 month after enrolment (focussing on adverse events only), and that the planned study duration is 24 months, when true negative rate and diagnostic yield will be reported. Given the available evidence on ENB, at this time there is not sufficient new evidence to include this area in the update. We will pass the details of this study onto the surveillance team for review in future surveillance reviews.
14	SH	Pfizer UK Ltd	3	9	Policy, legislation, regulation and commissioning	Thank you for your comment. We are including a section on

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					<p>The draft scope does not currently include the commitment to delivery of molecular diagnostics in the UK, which is particularly poignant now with the announcement from the Chief Medical Officer around the 100,000 genome project and a commitment of the Cancer Taskforce</p>	<p>'testing to inform treatment decisions' which will incorporate NICE technology appraisal guidance on phenotypic and genotypic testing for lung cancer treatment.</p> <p>We are aware of the Chief Medical Officer's announcement and the importance of molecular diagnostics in medicine. NHS England have an ongoing strategy to support a model for molecular diagnostics and to establish which tests will form part of a molecular diagnostics portfolio. Therefore the delivery of molecular diagnostics will not be covered by this update.</p>
15	SH	Pfizer UK Ltd	4	Section 3.1	<p>The draft scope suggests that no specific subgroup should be targeted for NSCLC, however by default those patients with a molecular subtype of advanced NSCLC may be eligible for a specific targeted therapy. This depends on access to upfront molecular testing.</p> <p>The draft scope excludes rare subtypes of lung cancer. Molecular subtypes of lung cancer such as ALK+, ROS1+, BRAF+ NSCLC however are rare diseases based on prevalence. The clinical pathway for patients with ALK+ NSCLC is distinct to that of other advanced NSCLC</p> <p>We feel it is important to highlight the distinction in subgroups, aligned to the acknowledgement that phenotypic and molecular testing is one of the key points being focussed on in the scope</p>	<p>Thank you for your comment.</p> <p>Both NSCLC and SLCLC are included in the scope of the guideline update, along with the different molecular subtypes of these two main types of lung cancer. The groups that will not be covered by the scope of the guideline update are those rare cancers other than NSCLC and SCLC. We will specify in the 'testing to inform treatment' section, which molecular subtypes are being incorporated.</p> <p>In terms of defining subgroups in the scope, subgroups identified here would be for particular consideration throughout the whole guideline update, that is, they would require special consideration for all sections of the updated guideline. To this end, after stakeholder feedback, we have added 'multifocal/ synchronous adenocarcinoma' as a subgroup.</p> <p>We understand that different molecular subtypes should be considered for different targeted therapies, however, much of the other diagnosis and treatment of different molecular subtypes of NSCLC have common diagnosis pathways and would not require specific consideration. Therefore, relevant subgroups (for example, different molecular subtypes) can be identified for individual review questions, but they will not be listed as a specific subgroup in the scope. Subgroups will be discussed with the committee when the review protocols are developed, and we will consider this information during the development of the review protocols.</p>

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						As outlined in the scope, we will incorporate (either unchanged or subject to approval following a review proposal) relevant technology appraisal guidance on 'testing to inform treatment decisions' and 'targeted therapy for NSCLC'; these will take into account the different molecular subtypes of NSCLC as these relate to the most appropriate targeted therapy.
16	SH	Clinical Expert Group for Lung Cancer, NHSE	4	16	We note that that the spectrum of carcinoid through to atypical carcinoid, neuroendocrine tumours is not included in the scope. These tumours are not that rare and are all classified as malignant. It may be that the evidence base is poor here but this should be included.	Thank you for your comment. Carcinoid is a type of neuroendocrine cancer; although carcinoid tumours can be found in the lung, they are quite distinct from NSCLC and SCLC and have different management. Therefore carcinoid tumours are not included in the scope of the guideline update.
17	SH	Bristol Myers Squibb UK	4	20	Does this group (Adults with relapsed NSCLC) include patients with NSCLC EGFR T790 mutation (who are resistant/refractory to EGFR TKIs)?	Thank you for your comment. The scope includes all types of NSCLC, therefore EGFR T790 is included in the scope of the guideline update.
18	SH	Action on Smoking and Health	4	23	This draft states here that "no specific subgroups of people have been identified as needing specific consideration." However, on page 2 line 8, the draft states lung cancer "is strongly linked to socioeconomic deprivation." We suggest it is beneficial to highlight the way in which different groups will be affected by lung cancer. Smoking is linked to 89% of lung cancer cases, but smoking rates vary among different groups. For example, 40.5% of adults with a serious mental illness smoke in England, compared to an overall figure of 15.5%. (Source: PHE, Local tobacco control profiles) Different socioeconomic groups have varying rates of addiction, and so require special consideration.	<p>Thank you for your comment. As you have noted, the Equalities Impact Assessment (EIA) identifies that socioeconomic status should be given specific consideration when the committee make recommendations.</p> <p>We understand that smoking is linked to lung cancer, but a person who smokes who has lung cancer and a person who does not smoke who has lung cancer would have the same diagnostic and management pathway. Therefore there will not be a subgroup for people who smoke in the scope.</p> <p>As identified in the equalities impact assessment, socioeconomic status has been identified as requiring specific attention during the development of the guideline update and any recommendations that result from the update.</p>
19	SH	Medtronic UK	5	24-26	ENB could offer a less invasive alternative to CT-guided fine needle aspiration or surgical resection; especially in patients with comorbidities at high risk of complications (risk of pneumothorax & associated incidence of significant bleeding)	<p>Thank you for your comment. No new evidence on the use of Electromagnetic Navigation Bronchoscopy (ENB) that would impact on current recommendations was identified in the surveillance review or the scoping searches.</p> <p>One stakeholder did identify a study on ENB, https://bmcpulmed.biomedcentral.com/articles/10.1186/s12890-017-0403-9 that was published after the surveillance review was published. We note that the results from this study are the results from only 1 month after enrolment (focussing on adverse events</p>

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						only), and that the planned study duration is 24 months, when true negative rate and diagnostic yield will be reported. Given the available evidence on ENB, at this time there is not sufficient new evidence to include this area in the update. We will pass the details of this study onto the surveillance team for review in future surveillance reviews.
20	SH	Bristol Myers Squibb UK	5	19	BMS would like to highlight that consideration should be given to the type of biopsies obtained for diagnostic purposes given that a) the commercially available PDL1 assays are not currently validated for fine needle aspiration (FNA) sampling and b) fresh frozen tissue is optimal for DNA extraction.	Thank you for your comment. We will consider this information during the development of the guideline update. The committee will take all relevant evidence, and the clinical context into account when making any recommendations.
21	SH	Bristol Myers Squibb UK	5	28	BMS would like to ensure inclusion of diagnostic PD-L1 testing and rapidly emerging biomarker testing.	Thank you for your comment. As set out in the scope we will be referring to relevant technology appraisal guidance for the section on 'testing to inform treatment decisions'.
22	SH	Clinical Expert Group for Lung Cancer, NHSE	7		Please clarify which staging system is being used – stage M1b (we suppose) refers to the version 7	Thank you for your comment. We understand that the 8 th edition of the staging classification has recently been published. The outline of the guideline is taken from the previous 2011 update which we understand used version 7: this will be checked for accuracy and amended as appropriate during the guideline update.
23	SH	Clinical Expert Group for Lung Cancer, NHSE	7		Diagnosis in suspected lung cancer also merits discussion about the probability of cancer that justifies the use of minimally invasive investigations. This has been well worked through in the British Thoracic Society Guidelines on the management of pulmonary nodules – NHS evidence accredited. There needs to be some reference to this guideline and some attention to the threshold for investigation of the smaller, peripheral lesions.	Thank you for your comments. We note that there is a published guideline on the subject of minimally invasive investigations, and these are NHS evidence accredited. No new evidence was identified in the surveillance review and scoping searches that would impact on current guideline recommendations, therefore, this area of the guideline will not be updated at this time.
24	SH	AstraZeneca UK Ltd	7	Section 1.3	EGFR Testing <ul style="list-style-type: none"> - EGFR testing at the point of progression is now a critical aspect within this clinical setting and has been incorporated into other recent international guidelines [NCCN Clinical Practice Guidelines in Oncology 2016, ESMO Clinical Practice Guidelines 2016, International Association for the Study of Lung Cancer Guidelines 2016] - Complimentary testing strategy recommending both tissue and plasma testing for EGFRm at primary 	Thank you for your comment. As stated in the scope we plan to refer to relevant NICE technology appraisal guidance regarding molecular and phenotypic testing for the sections on 'targeted therapies for NSCLC' and 'testing to inform treatment decisions'. We will not be carrying out an original systematic review for this section due to the existing guidance in this subject produced by NICE. Please also note that the Chief Medical Officer has

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					Please insert each new comment in a new row diagnosis and EGFR T790M at disease progression to ensure all patients whose NSCLC contains these mutations are correctly identified [NCCN Clinical Practice Guidelines in Oncology 2016, ESMO Clinical Practice Guidelines 2016, International Association for the Study of Lung Cancer Guidelines 2016]	published her Annual Report in which a molecular diagnostics strategy is set out (work to be carried out by NHS England).
25	SH	Medtronic UK	7	Table 1.3	Recommend to review evidence of ENB in diagnosis & staging as an alternative option as a continuation of comment 2 above. Navigate ENB_ https://bmcpulmed.biomedcentral.com/articles/10.1186/s12890-017-0403-9	Thank you for your comment and for bringing this study to our attention. We note that these are the results from only 1 month after enrolment (focussing on adverse events only), and that the planned study duration is 24 months, when true negative rate and diagnostic yield will be reported. Alongside the fact that no studies on Electromagnetic Navigation Bronchoscopy (ENB) were identified in the surveillance review, at this time there is not sufficient new evidence to include this area in the update. We will pass the details of this study onto the surveillance team for review in future surveillance reviews.
26	SH	NHS England	7	Section 1.3	The draft scope is planning to review the evidence for EBUS/ EUB and TBNA for both diagnosis and mediastinal staging. The group should consider making a clear recommendation regarding the situations where EBUS staging is felt equivalent to mediastinoscopy and equally important when it should not i.e. if operator dependent and if so what evidence is needed to deem an EBUS operator competent.	Thank you for your comment. We will consider this information when we develop the review protocols. However, please note that NICE does not accredit individuals or organisations to undertake medical procedures.
27	SH	Action on Smoking and Health	7	Section 1.4 Treatment, Smoking Cessation	<ul style="list-style-type: none"> NICE has published guidance on tobacco harm reduction and is in the process of updating a smoking cessation guidance, both of which are worthy of consideration for this section. There is also an established evidence base to show higher rates of dependence in different socioeconomic groups, for example, people with a mental health condition, which is important to consider when making smoking cessation recommendations. Since 2011, guidance on smoking cessation has also been published for acute, maternity and mental health settings. 	<p>Thank you for your comment. Relevant related NICE guidance will be referred to in the guideline update and NICE pathway.</p> <p>With regard to socioeconomic status, this has been identified as an issue within the Equalities Impact Assessment (EIA) that was consulted on alongside the draft scope. Any issues identified in the EIA will be specifically considered when making any recommendations.</p> <p>NICE is currently updating its guidance on smoking cessation interventions and services (GID-PHG94), which will make specific provision for people with a mental health condition.</p> <p>With regard to 1.4.4, we are aware of multiple benefits of stopping smoking, however this recommendation is specifically</p>

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					<ul style="list-style-type: none"> In reference to 1.4.4 in the “Lung cancer: diagnosis and management” document: There are a range of benefits to quitting for those undergoing surgery beyond reducing risk of pulmonary complications. (Source: RCP and ASH Joint Briefing: Smoking and surgery) 	<p>about the effects of stopping smoking pre-operatively on post-operative outcomes when undergoing treatment for lung cancer. As you have highlighted, other benefits of smoking cessation are well documented in other NICE guidelines.</p> <p>The section on smoking cessation is not being updated because no evidence was identified in the 4 year surveillance review or scoping searches that would impact current recommendations.</p>
28	SH	AstraZeneca UK Ltd	7	Section 1.4	<p>Treatment: Radiotherapy with curative intent for NSCLC as well as combination treatment for NSCLC</p> <ul style="list-style-type: none"> Please be aware that we anticipate a NICE Technology appraisal in <u>2018</u> for the following: Durvalumab for treating unresectable non-small-cell lung cancer after platinum-based chemoradiation (NICE ID1175) 	Thank you for your comment. We will ensure that an up to date list of related NICE guidance is published in the final scope. We have now added this guidance to the scope.
29	SH	AstraZeneca UK Ltd	7	Section 1.4	<p>Treatment - Systemic anti-cancer therapies for NSCLC</p> <p>Please be aware that we anticipate to conduct NICE Technology appraisals in <u>2018</u> for the following</p> <ul style="list-style-type: none"> Durvalumab in combination with tremelimumab for non-small cell lung cancer (NICE ID1143). Durvalumab for the treatment of patients with locally advanced or metastatic NSCLC whose tumours express PD-L1 with no sensitizing EGFR mutation or ALK rearrangement. 	Thank you for your comment. These have been added to the list of related guidance in development. We will ensure that an up to date list of related NICE guidance is published in the final scope.
31	SH	Bristol Myers Squibb UK	7	Section 1.4	<p>Treatment – BMS feels there should be a statement on the role of adjuvant therapy post-surgery (whether it has a role or not). Systemic anti-cancer therapies – can we presume that there will be reference to current approved immunotherapies – e.g., checkpoint inhibitors?</p>	<p>Thank you for your comment.</p> <p>No new evidence was identified in the 4 year surveillance review or scoping searches that would impact the current recommendations on adjuvant therapy.</p> <p>As set out in the scope, we will incorporate (unchanged or unchanged subject to approval following a review proposal) approved immunotherapies in section 1.4 (Treatment) under the subheading ‘targeted therapies for NSCLC’.</p>
32	SH	Medtronic UK	7	Table 1.4	<p>Suggest to review the evidence for VATS lobectomy based on publication_ Agostini P et al; Interactive CardioVascular and</p>	Thank you for your comment. Evidence on video assisted thoracoscopic surgery (VATS) lobectomy will not be updated at

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					<p>Thoracic Surgery (2017) 1–7 and update guideline based on NICE CG 121 _ Research recommendation 3:</p> <p>Research should be undertaken into the benefits of pulmonary rehabilitation, optimisation of drug treatment and enhanced recovery programmes before and after surgery. Outcomes should include mortality, survival, pulmonary complications, pulmonary function and quality of life (including assessment by EQ-5D).</p> <p>There is some evidence that pulmonary rehabilitation, optimisation of drug treatment and enhanced recovery programmes are effective patients undergoing surgery for some conditions but none for patients undergoing surgery for lung cancer. Fitness for surgery, and the ability of the patient to recover following surgery are key factors in the success of this treatment for lung cancer. The effectiveness of interventions to improve these factors should be evaluated.</p>	<p>this time because during surveillance of this guideline, a large ongoing trial was identified which is not planned to be published during the development of this update; it is considered that this may affect the evidence base, and therefore this area will be assessed for updating in the next round of surveillance. We will pass the details of the study you have highlighted onto surveillance for consideration at the next review.</p> <p>This research recommendation was identified as a high priority by the GDG during the previous update and a search was undertaken to look for evidence on this area during the 4 year surveillance review. New evidence was identified, but it was thought that it would be useful to wait for more evidence to be published before undertaking a systematic review on this topic.</p>
33	SH	Clinical Expert Group for Lung Cancer, NHSE	8		Since publication of the RCT by Temmel at all, that showed the benefit of early specialist palliative care, there have been further randomised studies published that have confirmed the merit of this intervention. There is some uncertainty about the impact on mortality and it would be important for NICE to provide guidance on this.	Thank you for your comment. This area was not identified as requiring updating during the 4 year surveillance review as the new evidence identified was in agreement with current recommendations. CG121 also cross refers to the NICE Cancer Services Guidance 4, Improving supportive and palliative care for adults with cancer, which contains comprehensive guidance on palliative care in cancer services.
34	SH	NHS England	8	Section 1.4	The draft suggests a review of evidence for NSCLC 'To incorporate relevant NICE technology appraisal guidance unchanged into the update'. Given the speed of developments with immunotherapy the group should consider reviewing the evidence for this also.	<p>Thank you for your comment. We will be incorporating NICE technology appraisal guidance, either unchanged or subject to approval following a review proposal.</p> <p>New evidence will be reviewed by future surveillance reviews. We will note this area as an emerging evidence area and will pass onto the surveillance team for their information.</p>
35	SH	AstraZeneca UK Ltd	8	Section 1.6	Testing to inform treatment decisions – using phenotypic and molecular testing to inform treatment decisions	Thank you for your comment. For the section on 'testing to inform treatment decisions' we will be incorporating (either unchanged

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					<p>Please insert each new comment in a new row</p> <p>Consider incorporation of harmonisation data in PD(L)-1 testing done across a variety of testing platforms to select for anti PD(L)-1 therapy in NSCLC (Hirsch et al. 2017)</p> <p>Also please be aware that different levels of PDL-1 status may be required to inform for different immunotherapies / immunotherapy combinations</p>	<p>Please respond to each comment</p> <p>or subject to approval following a review proposal) to published NICE technology appraisal guidance, not undertaking new systematic reviews.</p>
36	SH	AstraZeneca UK Ltd	8	5	<p>Please be aware that we anticipate to conduct NICE Technology appraisals in 2018 for the following</p> <ul style="list-style-type: none"> - Durvalumab in combination with tremelimumab for non-small cell lung cancer (NICE ID1143). - Durvalumab for the treatment of patients with locally advanced or metastatic NSCLC whose tumours express PD-L1 with no sensitizing EGFR mutation or ALK rearrangement. - Durvalumab for treating unresectable non-small-cell lung cancer after platinum-based chemoradiation (NICE ID1175) - Osimertinib for locally advanced or metastatic non-small cell lung cancer, EGFR mutation positive (Ex19del or L858R) - first line 	<p>Thank you for your comment. We will check for updated related guidance prior to final publication of the scope to ensure the most up to date list is in the scope.</p> <p>The most up to date related guidance will be inserted into the guideline update and the NICE pathway for lung cancer. This will continue to be regularly checked for updates after publication of this guideline update.</p>
37	SH	British Dietetic Association	8	14 (table)	<p>Palliative interventions and supportive and palliative care</p> <p>There is considerable evidence indicating a high prevalence of malnutrition, sarcopenia and cachexia in lung cancer patients including the impact of these on clinical outcomes including mortality and treatment related toxicity, however, these are not really considered within the guidelines including the importance of nutritional screening and assessment. There is also evidence that supports the benefits of dietary counselling and nutritional supplementation in this group as well as wider cancer rehabilitation programmes which should also be addressed within the guidance.</p>	<p>Thank you for your comment. The following recommendation covers palliative care (including dietary issues):</p> <p>1.5.18 Other symptoms, including weight loss, loss of appetite, depression and difficulty swallowing, should be managed by multidisciplinary groups that include supportive and palliative care professionals. [2005]</p> <p>The 4 year surveillance review did not identify any new evidence that would impact the above recommendation. Without further details of the evidence that you are referring too, we are unable to assess if there is further evidence at this time that would impact on current guideline recommendations.</p> <p>Nutritional screening is covered in CG32 Nutrition support in adults, and is out with the scope of this update. NICE reviewed</p>

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						the evidence in July 2017 for CG32 and “found no new evidence that affects the recommendations in this guideline”.
38	SH	Bristol Myers Squibb UK	10	9 and 16	BMS would like to understand the criteria used to distinguish between “NICE guidance that will be incorporated unchanged” and “NICE guidance that will be incorporated subject to approval following a review proposal”. Additionally, we would like to understand the review criteria and process the review proposal will follow which we feel should be subject to consultation. Thank you.	Thank you for your comment. The Technology Appraisals listed under “will be incorporated unchanged” will be incorporated verbatim into the guideline, please see ‘Developing NICE guidelines: the manual’ for more details. Those listed under incorporated subject to approval” are Technology Appraisals which have not yet undergone the Technology Appraisal review process. These Technology Appraisals will be undergoing this process to see if they should be incorporated into the guideline.
39	SH	Clinical Expert Group for Lung Cancer, NHSE	5 and 7	19	The previous update (CG121) did not include the diagnostic approach to diagnosis and staging of lung cancer presenting as a pleural effusion. This led to the rather unhelpful inclusion in the diagnostic algorithm of “not the subject of this update” for pleural effusion. There are British Thoracic Society guidelines that include this topic but we still see a wide variation in the use of medical thoracoscopy, a very effective diagnostic and staging test. The issue that need to be addressed are the effectiveness of radiological biopsy, medical thoracoscopy and video-assisted thoracic surgery. There is therefore an opportunity to complete the diagnostic and staging section by including the approach to suspect lung cancer in the pleural.	Thank you for your comment. We note that lung cancer presenting as a pleural effusion is not specifically excluded from the scope of the guideline update. The current NICE guidance notes that the diagnostic and management pathway is distinct. We will consider this information during development of the guideline update.
40	SH	Bristol Myers Squibb UK	13	16-17	<ul style="list-style-type: none"> Query: what does “docetaxel doublet therapy” refer to? Is this docetaxel plus nintedanib? Some clarity would be helpful. Thanks. BMS would also like to include docetaxel monotherapy vs checkpoint inhibitors in this section (3.5.3) 	Thank you for your comment. Docetaxel doublet therapy could refer to a combination of docetaxel with another systemic anti-cancer therapy, including but not limited to, cisplatin and carboplatin. However, after stakeholder feedback, and consideration by clinical experts, the question on ‘docetaxel monotherapy v docetaxel doublet therapy has been removed from the scope due to lack of relevant evidence and other licensed therapies being available for this indication. The relevant Technology Appraisal guidance in this area will be referred to in the guideline as appropriate.
41	SH	Pfizer UK Ltd	13	Section 3.6	The draft scope does not include any measures to assess equity of testing for phenotypic and molecular testing of lung cancer, highlighted as an issue on page 2.	Thank you for your comment. As outlined in the scope in section 3.3 ‘key areas that will be covered, 2- testing to inform treatment decisions’ we will refer to relevant NICE technology appraisal guidance on molecular and phenotypic testing; we will incorporate the different NICE guidance on molecular and

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ID	Type	Organisation name	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					Additionally "Testing to inform treatment decisions" is one of the key areas being reviewed, however there are no outcome metrics included to assess equitable access to molecular diagnostics, which is fundamental for treatment decision making i.e for access to targeted therapies or immunotherapy agents.	phenotypic tests so that it is clear which tests are recommended. It is worth noting that NHS England have an ongoing strategy to support a model for molecular diagnostics and to establish which tests will form part of a molecular diagnostics portfolio. Therefore molecular diagnostics will not be covered by this update. As highlighted in section 3.3 of the scope under 'proposed outline of the guideline', there will not be a new evidence review for the sections on 'targeted therapies for NSCLC' or for the section on 'testing to inform treatment decisions'; we will refer to relevant NICE technology appraisal guidance and will incorporate the recommendations from these guidelines.
42	SH	Bristol Myers Squibb UK	14	7	Quality of life: we suggest adding EQ-5D. This is the preferred health-related quality of life (HR-QoL) tool by NICE and there are numerous studies which have used this tool with lung cancer patients.	Thank you for your comment. We have added this to the scope in section 3.6 main outcomes.
43	SH	Clinical Expert Group for Lung Cancer, NHSE	14	10	Should re-admission rates be included?	Thank you for your comment. This is the list of main outcomes of interest when the committee consider the evidence, it is not an exhaustive list, but is intended to include quality of life and condition or service-specific outcomes. Please see 'Developing NICE guidelines: the manual' for more details on how the scope and guideline updates are developed. If re-admission rates are deemed to be an important outcome for a particular question then this can be added as an outcome to the review protocols. We will consider this information during development of the guideline update.
44	SH	BSTI membership	general		As a Radiologist, the issue I'd like clarified is the role of image-guided biopsy of suspected lung cancer? Will EBUS be the recommended first line modality for peripheral lesions with low probability of mediastinal nodes? Given that EBUS has resulted in reduction in number of radiological percutaneous lung biopsies, how many of these procedures should a radiologist perform annually to maintain competence?	Thank you for your comment. Following stakeholder feedback the topic area of EBUS-guided TBNA, EUS-guided FNA, or non-ultrasound-guided TBNA first test will include all people with a risk of mediastinal malignancy and EBUS-guided TBNA and EUS-guided FNA (alone or in combination) as an alternative to surgical staging for the initial staging of the mediastinum is included in the scope of the guideline update. With regard to your point about maintaining competence in

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						undertaking these procedures, NICE does not accredit individuals or locations to undertake specific tests or investigations within its guidance.
45	SH	BSTI membership	general		<p><i>The document outlines that it plans to look at “testing to inform treatment decisions.” As well as looking at the phenotypic and molecular tests themselves, NICE should consider reviewing the methods by which these samples are obtained. Increasingly there is a requirement, for example, for repeat tissue biopsy in these patients.</i></p> <p><i>The update should include a review of the literature on microwave ablation for the treatment of lung cancer since 2011.</i></p> <p>In fact I don't even see RFA being mentioned in the 2011 guidance?</p>	<p>Thank you for your comment. For the section on testing to inform treatment decisions, we will be incorporating (either unchanged or subject to approval following a review proposal) relevant NICE technology appraisal guidance. How samples are collected remains outside the scope of the guideline.</p> <p>No information about microwave ablation as a treatment for lung cancer was identified in the surveillance review or scoping search. NICE Interventional procedures guidance 469 identifies that microwave ablation can be used in treating primary lung cancer using special arrangements.</p> <p>Radiofrequency ablation for primary or secondary lung cancer is covered by NICE interventional procedure guidance 372 using normal arrangements and is listed under related NICE guidance.</p>
46	SH	BSTI membership			<p>Is there a role for functional imaging (other than PET/CT) in the evaluation of thoracic malignancy?</p> <p>Are there different considerations for diagnosis and staging of multifocal/synchronous adenocarcinoma?</p> <p>Is there a role for vertebroplasty and ablation of bone metastases?</p>	<p>Thank you for your comment. No evidence was identified in the surveillance review or scoping search that would impact on current recommendations on imaging, therefore this area will not be updated at this time.</p> <p>Multifocal/ synchronous adenocarcinoma has been added to the scope as a subgroup to be considered throughout the guideline.</p> <p>Vertebroplasty and other treatments for bone metastases are covered by NICE guideline CG75 Metastatic spinal cord compression in adults: risk assessment, diagnosis and management (2008).</p>

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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