NICE National Institute for Health and Care Excellence

NICE guidance

Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer

Technology appraisal guidance
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Contents

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1 Recommendations

1.1 Nintedanib in combination with docetaxel is recommended, within its marketing authorisation, as an option for treating locally advanced, metastatic or locally recurrent non-small-cell lung cancer of adenocarcinoma histology that has progressed after first-line chemotherapy, only if the company provides nintedanib with the discount agreed in the patient access scheme.

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2 Information about nintedanib

2.1 Nintedanib (Vargatef, Boehringer Ingelheim) is a small molecule tyrosine-kinase inhibitor. It blocks 3 receptor classes that promote angiogenesis and tumour growth: vascular endothelial growth factor receptors; fibroblast growth factor receptors; and platelet-derived growth factor receptors α and β. Nintedanib has a UK marketing authorisation for use 'in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small-cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy'.

2.2 The summary of product characteristics lists the following adverse reactions for nintedanib as being the most frequently reported: diarrhoea, increased plasma liver enzyme concentrations (alanine transaminase and aspartate aminotransferase) and vomiting. For full details of adverse reactions and contraindications, see the summary of product characteristics.

2.3 The recommended dose is 200 mg twice daily. This can be reduced to 150 mg or 100 mg twice daily in patients who experience adverse events. Nintedanib costs £2,151.10 for a 30-day pack of 150 mg or 100 mg capsules for oral use (excluding VAT, MIMS online accessed March 2015). The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nintedanib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.

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3 Committee discussion

The company's submission

The Appraisal Committee considered evidence submitted by Boehringer Ingelheim and a review of this submission by the Evidence Review Group (ERG).

Clinical effectiveness

3.1 The company did a systematic literature review of studies evaluating the efficacy and safety of all second-line treatments for non-small-cell lung cancer. For nintedanib, it identified 1 relevant randomised controlled trial, the LUME-Lung 1 trial, from which it took the key clinical evidence for the comparison of nintedanib plus docetaxel with placebo plus docetaxel (hereafter referred to as docetaxel alone).

3.2 The LUME-Lung 1 trial (n=1,314) was a phase 3, multicentre, placebo-controlled, double-blind, randomised (1:1) controlled trial comparing nintedanib plus docetaxel with docetaxel alone. The trial was carried out in 211 centres in 27 countries (including the UK). Eligible patients were adults who had locally advanced, metastatic or locally recurrent non-small-cell lung cancer and whose disease had progressed on or after treatment with only 1 prior chemotherapy regimen. Randomisation was stratified by 4 variables: Eastern Cooperative Oncology Group (ECOG) score (0 or 1); previous bevacizumab treatment (yes or no); presence of brain metastases (yes or no); and histology (squamous or non-squamous). Patients in the nintedanib group received nintedanib (200 mg) twice daily, on day 2 to 21 of a 21-day cycle, plus docetaxel (75 mg/m^2) on day 1 of the 21-day cycle. If patients experienced adverse events, the trial design specified reducing the dose of nintedanib from 200 mg twice daily to 150 mg twice daily and then to 100 mg twice daily, and reducing the dose of docetaxel from 75 mg/m^2 to 60 mg/m^2. Patients in the nintedanib group who had at least 4 cycles of nintedanib plus docetaxel could then have nintedanib alone. Patients in the placebo group received placebo twice daily on day 2 to 21 of a 21-day cycle, and docetaxel dosing as in the nintedanib group. In the placebo group, reducing the dose of docetaxel (from 75 mg/m^2 to 60 mg/m^2) was permitted if

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adverse events occurred. Treatment in both groups stopped when patients' disease progressed or if they experienced unacceptable adverse events. The trial investigators followed-up patients every 6 weeks before disease progression and every 6 to 8 weeks after disease progression, until the patient died or was lost to follow-up.

3.3 Progression-free survival, measured radiologically, was the primary outcome in the LUME-Lung 1 trial and was defined as time from randomisation to death or disease progression when progression preceded death. Progression-free survival was determined by a central independent review by radiologists using the modified Response Evaluation Criteria in Solid Tumours (RECIST). The key secondary outcome in LUME-Lung 1 was overall survival. Overall survival was defined as the time from randomisation to death (irrespective of cause of death). Other secondary outcomes included progression-free survival by local investigator review, tumour response by both central independent review and investigator review, clinical improvement (defined as lengthening the time to deterioration in body weight), health-related quality of life, safety, and tolerability.

3.4 The primary progression-free survival analysis was to be done when 713 patients had experienced (centrally assessed) disease progression or death (cut-off November 2010) to detect a hazard ratio of 0.78 with 90% statistical power. The primary analysis was based on the intention-to-treat population. According to the company, the study remained unblinded between final analysis for progression-free survival and for overall survival. The final analysis of overall survival was done when 1,151 patients had died, and was designed to permit investigators to detect an 18% increase in median overall survival or a hazard ratio of 0.85. At final analysis of overall survival, the company did a follow-up analysis of all events including disease progression or death (February 2013).To be considered statistically significant, the p value had to be less than 0.00043 for primary progression-free survival, less than 0.05 for final progression-free survival and less than 0.04984 for the final overall survival analysis.

3.5 The analyses in LUME-Lung 1 were extended beyond the original specification of the statistical analysis plan to validate findings from a hypothesis-generating analysis of the LUME-Lung 2 trial which compared nintedanib plus pemetrexed with placebo plus pemetrexed. This change to the statistical analysis plan was introduced after the initial analysis for primary progression-free survival analysis,

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but before database lock for the final overall survival analysis (February 2013). From the analysis of LUME-Lung 2, the company identified that patients whose disease had progressed within 9 months after the start of their first-line therapy, and patients who had adenocarcinoma, would benefit most from treatment with nintedanib. A hierarchical overall survival statistical analysis was therefore introduced into the LUME-Lung 1 trial, by amending the trial statistical analysis plan. In LUME-Lung 1, the company tested overall survival in an intention-to-treat sequential fashion: first, patients with adenocarcinoma whose disease had progressed within 9 months of starting first-line therapy, followed by all patients with adenocarcinoma, and finally the overall trial population.

3.6 The focus of the company's submission to NICE was on patients with adenocarcinoma because this was the population specified in the marketing authorisation for nintedanib. In LUME-Lung 1, of the 1,314 patients randomised, 759 patients had non-squamous cell carcinoma of whom 658 had adenocarcinoma. The company considered the baseline characteristics of patients in LUME-Lung 1 with adenocarcinoma, including sex, age, race, smoking status and ECOG score, to be similar between the treatment groups, and similar to patients seen in clinical practice with adenocarcinoma. Of the patients in the trial with adenocarcinoma, 62.5% were men, the mean age was 58.5 (standard deviation 10.1) years, 76.9% were white, 70.4% had an ECOG performance status of 1, and 7.4% of patients had brain metastases. In the LUME-Lung 1 trial, 18.0% of the patients with adenocarcinoma in the nintedanib group and 18.2% in the docetaxel alone group had pemetrexed–platinum therapy as first-line therapy; 0.9% of patients in the nintedanib plus docetaxel group and 0.6% of patients in the docetaxel alone group had pemetrexed–non-platinum therapy. Data on epidermal growth factor receptor (EGFR) mutations were not routinely collected in the LUME-Lung 1 trial. During the clarification stage of the appraisal, the company stated that this had been retrospectively collected from a sample of patients in the LUME-Lung 1 trial. The results from the sample are considered to be academic in confidence and therefore cannot be reported.

3.7 The results for progression-free and overall survival for the adenocarcinoma population in LUME-Lung 1 are given in table 1. The company presented the results of the primary progression-free survival analysis for the overall trial population and for people with adenocarcinoma whose disease had progressed within 9 months of starting first-line therapy (see table 1 for the adenocarcinoma

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group).

Table 1 Progression-free and overall survival results for the adenocarcinoma population in LUME-Lung 1 (cut-off November 2010 and February 2013)

Outcome	Nintedanib plus docetaxel	Docetaxel alone	Hazard ratio (95% confidence interval)
Progression-free survival (central independent review) Primary analysis at November 2010, 7.1 month follow-up (median, months)	4.0	2.8	0.77 (0.62–0.96)
Progression-free survival (central independent review) Final analysis at February 2013, 31.7 month follow-up (median, months)	4.2	2.8	0.84 (0.71–1.00)
Overall survival (final analysis at February 2013; median, months)	12.6	10.3	0.83 (0.70–0.99)

3.8 The company provided Kaplan–Meier curves for patients with adenocarcinoma for progression-free survival (primary analysis [November 2010]) and follow-up analysis [February 2013]) and overall survival (final analysis, February 2013). The Kaplan–Meier curves for progression-free survival (primary analysis) separated after 6 weeks and remained separated until approximately 7 months. The Kaplan–Meier curves for overall survival (final analysis) in patients with adenocarcinoma separated after 6 months and remained apart over the entire observation period up to 36 months.

3.9 The company did subgroup analyses at the time of the final overall survival analysis (February 2013). Most pre-specified and post-hoc progression-free survival subgroup analyses showed the effect of nintedanib plus docetaxel to be consistent with the treatment benefit seen in the primary analysis of adenocarcinoma.

3.10 The company collected health-related quality of life in the LUME-Lung 1 trial. This was measured at the screening visit, at 21-day intervals during treatment, at the end of treatment and at the first follow-up visit. The investigators used 3 questionnaires: EQ-5D, European Organisation for Research and Treatment of

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Cancer Quality of Life Questionnaire (EORTC QLQ-C30), and EORTC lung cancer-specific supplementary module (EORTC QLQ-LC13). Investigators found no differences in global health status, quality of life or self-reported health-related quality of life reported for the time to deterioration for coughing, breathlessness or pain between the nintedanib plus docetaxel group compared with the docetaxel alone group. Health-related quality-of-life scores at the time of randomisation were available for the whole trial population but not for the adenocarcinoma subgroup. Statistically significant improvements were seen in 3 individual pain items ('have pain' [p=0.0332], 'pain in chest' [p=0.0196] and 'pain in arm and shoulder' [p=0.0004]) in favour of nintedanib plus docetaxel, while time to deterioration for diarrhoea was significantly shorter with nintedanib plus docetaxel.

3.11 The company did a mixed treatment comparison to compare nintedanib plus docetaxel with erlotinib because erlotinib was specified as a comparator in the final scope issued by NICE. However, the company commented that it did not consider erlotinib to be the main comparator to nintedanib plus docetaxel because patients considered fit enough to have treatment with nintedanib plus docetaxel would also be considered fit enough to have docetaxel alone rather than erlotinib. The company did a systematic review and identified 9 trials to include in its mixed treatment comparison. The trials included erlotinib, pemetrexed and gefitinib. The company assumed that the effectiveness of docetaxel and pemetrexed do not differ, to allow as many treatments as possible to be compared with nintedanib plus docetaxel.

3.12 The results of the analysis from the mixed treatment comparison for nintedanib plus docetaxel compared with docetaxel alone (4 trials) showed that nintedanib plus docetaxel significantly improved overall survival (hazard ratio [HR] 0.83, 95% confidence interval [CI] 0.70 to 0.99) and progression-free survival (HR 0.77, 95% CI 0.62 to 0.96) compared with docetaxel alone. Nintedanib plus docetaxel also significantly improved overall survival (HR 0.64, 95% CI 0.46 to 0.90) and progression-free survival (HR 0.70, 95% CI 0.50 to 1.00). The Bucher indirect comparisons supported these findings (overall survival HR 0.56, 95% CI 0.38 to 0.82; progression-free survival HR 0.58, 95% CI 0.39 to 0.87) for nintedanib plus docetaxel compared with erlotinib.

3.13 The company provided data on drug-related adverse events that occurred with

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an incidence of 5% or more in both treatment groups in the adenocarcinoma subgroup for the duration of the trial. Diarrhoea (43.4% compared with 24.6%), nausea (28.4% compared with 17.7%) and vomiting (19.4% compared with 12.3%) occurred more often with nintedanib plus docetaxel than with docetaxel alone. Deaths from adverse events, not attributed to disease progression, were more common with nintedanib plus docetaxel (6.3%) than with docetaxel alone (2.4%). However, in the nintedanib plus docetaxel group, the median duration of nintedanib plus docetaxel treatments was 4.2 months (with 5 cycles of docetaxel) and the docetaxel alone group received treatment for a median duration of 3.0 months (with 4 cycles of docetaxel). There were more grade 3 or greater adverse events and grade 3 or greater serious adverse events in the nintedanib plus docetaxel group (75.9% and 31.3% respectively) than in the docetaxel alone group (68.5% and 27.6% respectively).

3.14 To compare the adverse events of nintedanib with chemotherapeutic regimens other than docetaxel, the company compiled data on fatigue, nausea and diarrhoea. These were the only safety outcomes reported in a consistent format in more than 1 trial. The company also stated that, because few trials reported these outcomes and because of the low incidence of adverse events, it compared nintedanib plus docetaxel with other treatments using the sensitivity analysis in which the company assumed docetaxel and pemetrexed were equally effective. In the mixed treatment comparison of adverse events, the LUME-Lung 1 did not connect with the other studies. The results suggested that nintedanib plus docetaxel was significantly more likely to lead to diarrhoea than docetaxel alone or pemetrexed, but was not more likely to lead to diarrhoea than erlotinib. The risk of fatigue was similar for all treatments.

Cost effectiveness

3.15 The company provided a partitioned survival Markov model containing 3 health states: progression-free (on or off treatment); progressed disease; and death. All patients enter the model in the progression-free state. At the beginning of each time period patients could either remain in the same health state or progress to a worse health state, that is, from progression free to progressed or death, or from progressed disease to death. The model used the partitioned survival method to determine the proportion of patients in each of the 3 health states during each

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model cycle. The company modelled 3-weekly cycle lengths, a half-cycle correction and a time horizon of 15 years. All costs and outcomes were discounted by 3.5% and the company stated that all costs were from the NHS and Personal Social Services perspective, although the company included only NHS costs in the model. In the company's base-case analysis, it compared nintedanib plus docetaxel with docetaxel alone. In the company's secondary analysis, it compared nintedanib plus docetaxel with erlotinib. The model included people with locally advanced, metastatic or locally recurrent adenocarcinoma whose disease progressed following first-line chemotherapy. The company assumed that 70% of patients have best supportive care on stopping second-line treatment, although some people in the progressed-disease state can have subsequent treatments (5% erlotinib or 25% platinum doublet therapy). The company included the cost of subsequent treatments in the model but made no assumptions about their efficacy.

3.16 Kaplan–Meier survival curves for overall survival and progression-free survival for nintedanib plus docetaxel and for docetaxel alone were available from the LUME-Lung 1 trial and informed the proportion of patients in the model's 3 health states at each time point. Progression-free survival data from LUME-Lung 1 were mature and the proportions of censored patients in both treatment groups were similar. To extrapolate trial data beyond the time horizon of the trial, the company analysed overall survival and progression-free survival data using parametric survival curves fitted using 2 approaches:

- Joint models including data from both treatment groups using a term for treatment and the same distributions for each group.
- Separately modelled curves to each randomised treatment group.

The company tested the 'fit' of the curves using Akaike information criteria (AIC). The company interpreted the intercept and scale parameters of the separately fitted curves to indicate that the curves should not be forced into the same model, and therefore selected separate curves by treatment group for progression-free survival and overall survival. The log-normal model had the lowest AIC among the separate progression-free survival fits and the Weibull model had the lowest AIC among the separate proportional hazard models for progression-free survival; therefore, these were selected to model progression-free survival. The log-logistic model had the lowest AIC among

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the separately fitted overall survival models and the Weibull model had the lowest AIC among the separate models for overall survival; therefore, these were selected to model the overall survival data. The company stated that it tested the validity of the data by showing the results to a group of 'key opinion leaders' (clinicians) and by comparing it with registry data from the National Lung Cancer Audit (LUCADA, UK) and Surveillance, Epidemiology, and End Result (SEER, USA).

3.17 Progression-free and overall survival curves were not available for erlotinib. The company obtained these by taking the progression-free survival and overall survival curves for nintedanib plus docetaxel and applying the hazard ratio from the mixed treatment comparison to reflect the relative effectiveness of erlotinib to nintedanib plus docetaxel. The company considered that proportional hazards could only be used if the survival distribution was a proportional hazards model using the exponential, Weibull or Gompertz extrapolations. Based on the goodness of fit, a Weibull distribution was chosen for erlotinib and, therefore, erlotinib could only be evaluated in the model if this distribution was selected for both progression-free survival and overall survival. The cost-effectiveness analysis that compared erlotinib plus docetaxel compared with docetaxel alone used hazard ratios from the mixed treatment comparison base case, with the hazard ratio being 0.7 (95% CI 0.5 to 1.0) for progression-free survival and 0.64 (95% CI 0.46 to 0.90) for overall survival.

3.18 The company collected health-related quality-of-life data in the LUME-Lung 1 trial using EQ-5D questionnaires, which it used in a longitudinal model to adjust for certain baseline characteristics including ECOG score, prior treatment with bevacizumab, presence of brain metastases, health status and key adverse events. In the progression-free survival health state, the company estimated utility values from week 0 to 30 in 3-week intervals in both treatment arms. The company extrapolated the trend it observed up to week 30 to provide data beyond this time point, which it incorporated into its base case. To estimate utility values for the progressed disease state, the company used utility values from the LUME-Lung 1 trial. In sensitivity analyses, the company used utility values for progression-free survival and progressed disease from the literature (Chouaid et al. 2013), which included patients with non-small-cell lung cancer in the UK, Europe, Canada, Australia and Turkey. The model also incorporated the impact of adverse events on health-related quality of life using utility decrements

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associated with each adverse event. The company acknowledged that the model may have double counted disutility as people may have more than 1 adverse event.

3.19 In the model, the company assumed that patients would take two 100 mg capsules of nintedanib. The company also modelled an option of patients taking one 150 mg capsule. The price of both formulations is the same. In the model, nintedanib plus docetaxel was given for a minimum of 4 cycles before nintedanib could be administered alone. The model included no administration cost associated with nintedanib, but a cost of £155 for docetaxel. Intravenous docetaxel was modelled at a concentration of 75 mg/m^2 on day 1 of a 21-day cycle. For the comparison of nintedanib plus docetaxel with erlotinib, a 30-tablet pack of erlotinib was £1,631.53 (MIMS list price [2013]). The company noted that erlotinib has a patient access scheme, which it took into account by doing several sensitivity analyses in which a range of discounts were applied to the list price of erlotinib. The company assumed that the cost of best supportive care was £406.63 per 3-week cycle.

3.20 The company used resource questionnaires and an interview with an oncologist who specialises in lung cancer to determine health state costs. Three main areas of resource use were considered: routine follow-up (type and frequency of physician visit, laboratory tests and radiological scans); treatment at time of progression (hospitalisations, physician visits, laboratory tests, radiological scans and procedures used); and resource use during best supportive care or palliative care (initial tests, procedures, hospitalisations, physician visits, laboratory tests, radiological scans and procedures). The unit costs of visit procedures and laboratory tests were mainly derived from the National Schedule of reference costs (2012 to 2013) and some visit costs were taken from the Personal Social Services Research Unit.

3.21 The company provided deterministic and probabilistic incremental cost-effectiveness ratios (ICER) for nintedanib plus docetaxel compared with docetaxel alone in its original submission and after consultation on the appraisal consultation document. The ICERs generated using the company's original model have been superseded by those using the revised model that included a patient access scheme and was provided after consultation on the appraisal consultation document (see section 3.47). Only the ICERs from the revised model are referred

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to in this document.

3.22 The company did a range of deterministic sensitivity analyses. These included alternative hazard ratios for progression-free survival, hazard ratios for overall survival, utility values for progressed disease, model costs for progressed disease, risk of stopping nintedanib and docetaxel per cycle, and percentage of patients switching to best supportive care.

3.23 The company also did various scenario analyses on the survival modelling. Its original base case included separately modelled curves for the trial period and beyond (log-normal curves for both treatment and placebo arms of modelled progression-free survival and log-logistic for both arms of modelled overall survival). One scenario replaced these curves with Weibull distributions. Another scenario incorporated Kaplan–Meier trial data, after which the company chose Weibull parametric curves instead of the curves chosen for the base case to extrapolate both progression-free survival and overall survival. Another scenario used the LUME-Lung 1 trial data in the form of Kaplan–Meier curves for the period of the trial only, and not for the 15-year time horizon; it used a restricted mean for overall survival, acknowledging that although all people in the trial had progressed, not all had died. The restricted mean assumed that all patients died immediately after final data lock. For the remaining scenarios, the company used the progression-free survival Kaplan–Meier curve from the LUME-Lung 1 trial and, for overall survival, the Kaplan–Meier curves. It used these for the duration of the time horizon, extrapolated in 2 different ways: using registry data (LUCADA or SEER), or modelled using a parametric curve (log-normal curve, log-logistic curve or Weibull curves).

3.24 The company did several other scenario analyses replacing resource use costs (with those from NICE's technology appraisal guidance on afatinib for treating epidermal growth factor receptor mutation-positive locally advanced or metastatic non-small-cell lung cancer), and altering utility values (using published values) and the time horizon.

3.25 In its original submission, the company also provided an analysis for the comparison of nintedanib plus docetaxel compared with erlotinib.

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ERG's critique and exploratory analyses

3.26 The ERG considered that the LUME-Lung 1 trial was well designed, with a low risk of bias and good randomisation, and noted that the trial was unblinded only at the end and provided mature data. The characteristics of patients with adenocarcinoma at baseline were well balanced between the nintedanib plus docetaxel and docetaxel alone groups in the ERG's opinion.

3.27 The ERG was concerned about the generalisability of the results from LUME-Lung 1 to patients seen in clinical practice in England. It considered that patients in the trial were potentially fitter and younger than those seen in clinical practice in England. The ERG highlighted the following dissimilarities in patient characteristics:

- The trial excluded patients with clinically significant pleural effusion, or evidence of cavitary or necrotic tumours, with significant coronary disease, or on anticoagulation (except low-dose heparin) or antiplatelet therapy (except aspirin). The ERG considered the trial population to have a better prognosis than patients seen in clinical practice in England.
- There were differences in the proportion of patients having third-line treatments. The ERG commented that patients in England are less likely to have third-line treatment than those in the trial (55.8%).
- The proportion of patients in the trial aged 65 years or older was smaller than the proportion seen in clinical practice.

3.28 The ERG noted that, in LUME-Lung 1, only 18.8% of patients with adenocarcinoma had pemetrexed as first-line therapy, and that most had platinum-based therapies. Conversely, the ERG considered that most patients in England would have pemetrexed as first-line treatment. The company did not include subgroups by first-line treatment (other than bevacizumab) in its submission.

3.29 The ERG was concerned that the company limited its submission to patients with adenocarcinoma even though only around 50% of patients in the LUME-Lung 1 trial had adenocarcinoma, which itself was neither a stratification factor at randomisation nor a pre-defined subgroup. However, the ERG noted that, in the trial, patients with adenocarcinoma constituted most of the patients with

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non-squamous cell carcinoma, which was a stratification factor. Also, because baseline characteristics among patients with adenocarcinoma were well-balanced across the 2 treatment groups, the ERG suggested that the analyses were acceptable.

3.30 The ERG questioned the validity of the hazard ratios calculated by the company using Cox proportional hazards modelling from the LUME-Lung 1 trial data for progression-free survival and overall survival. This model requires that the hazard (that is, the risk of an event occurring at a particular time conditional on having survived to that time) is a constant ratio between the patterns of events in the 2 treatment arms at any time since randomisation. The ERG noted that the progression-free survival curve for the LUME-Lung 1 trial groups diverge after 6 weeks and then converge after approximately 1 year so the proportional hazards assumption was not likely to be met. The ERG did a similar analysis of the overall survival data to test whether the proportional hazards assumption applied and concluded that it did not. The ERG stated that, because the proportional hazards assumption was not supported by the LUME-Lung 1 trial data for estimating the relative effectiveness of nintedanib plus docetaxel compared with docetaxel alone, using methods based on proportional hazard assumptions is inappropriate.

3.31 The ERG considered it inappropriate to do a mixed treatment comparison because:

- The proportional hazards assumption was not supported by the LUME-Lung 1 trial data for progression-free or overall survival. Because the LUME-Lung 1 trial is the only trial providing evidence for nintedanib plus docetaxel, any comparison with this trial means that any estimation of the relative effectiveness of nintedanib plus docetaxel compared with erlotinib (that is, a calculated hazard ratio) lacks credibility and invalidates the comparison.
- The trials included in the mixed treatment comparisons varied with respect to patient baseline characteristics and so were heterogeneous between trials. Trials varied by age, EGFR mutation status, ECOG score, sex, whether patients had smoked and response to prior therapy. This heterogeneity may mean that the trials are too dissimilar to allow a valid comparison of outcomes in a mixed treatment comparison.

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- The company assumed that docetaxel and pemetrexed were equally effective in the mixed treatment comparison. The ERG was not aware of any evidence that supported this assumption in an adenocarcinoma population.

3.32 The ERG commented on the way in which the company had fitted a variety of parametric functions to the available trial data and used these in its original model to predict the results beyond those available from the trial. The ERG was concerned about the company's approach to curve fitting because the main reason for curve fitting is to anticipate what will happen to patients who remain 'at risk' at the time of the data cut-off point. In LUME-Lung 1, however, most patients had died, their disease had progressed or they had stopped treatment at the time of the data cut-off point. Therefore, extrapolating in this situation could have biased projections because it was based on the few survivors still at risk and could have led to fitting inappropriate functions.

3.33 To extrapolate beyond the end of the trial, the company fitted parametric functions based on descriptive data from SEER and LUCADA in its original model, but it was not possible for the ERG to assess whether this approach was valid. The ERG inferred from the company's submission that the SEER results were related to all-cause mortality from the date of stage 4 diagnosis. For the LUCADA data, the ERG understood that the data were related to second-line chemotherapy, but had no information on first-line treatments. The ERG commented that it was difficult to assess whether the company's chosen parametric survival functions were valid and reflected the patient population in this appraisal because it did not have access to patient level data.

3.34 The ERG identified 11 aspects of the company's original base-case model that involved errors in data analysis, parameter values or methodology. The ERG corrected these to estimate the ICER, but still considered that the model generated uncertainty in overall survival, progression-free survival and time to treatment. The ERG applied 11 different amendments to the company's base case. These are outlined in sections 3.35 to 3.45.

3.35 The company's original base-case assessment of nintedanib plus docetaxel compared with docetaxel alone estimated an undiscounted overall mean survival gain of 4.7 months. The ERG noted that only 15% of this gain occurred in the pre-progression phase. The ERG stated that this is unusual because, in locally

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advanced and metastatic cancers, the benefit from treatment normally occurs before disease progression while patients have active treatment. The ERG did its own analysis using the data for overall survival and progression-free survival from the trial, and noted that overall survival was linear for both groups after 300 days and continued indefinitely. This showed that the extrapolation used in the exponential model is appropriate, and the ERG calculated a long-term hazard ratio of 0.83 for overall survival in favour of nintedanib plus docetaxel. The ERG produced a cumulative hazard plot that suggested that patients in LUME-Lung 1 who survived beyond disease progression continued to gain survival benefit associated with treatment. The ERG estimated overall survival using the area under the curve (AUC) by applying the Kaplan–Meier results directly, and then projected long-term overall survival using the exponential trends. The ERG estimated mean overall survival in the docetaxel treatment arm as 453.0 days (14.9 months) and 545.7 days (17.9 months) for the nintedanib plus docetaxel treatment group, resulting in an estimated mean overall survival difference of 92.7 days (3.05 months), which was considerably lower than the company's estimate of a mean overall survival gain of 4.7 months.

3.36 The ERG noted that the company's original model base-case assessment of nintedanib plus docetaxel compared with docetaxel alone indicated a mean gain in (undiscounted) progression-free survival of 28.6 days. This was based on calibrating a log-normal hazard distribution to each group in the trial and replacing the trial data with the log-normal curve for the duration of the model time horizon until all patients' disease had progressed or they died. Here, the extent of advantage in mean progression-free survival can be readily estimated directly from the Kaplan–Meier analysis results because the progression-free survival data were mature, by comparing the AUC estimates up to the point when the curves converge. The ERG identified that the curves converged at day 375. The difference in the AUCs at this time was 36.4 days, which suggested that the company's model had underestimated progression-free survival (28.6 days). The ERG incorporated its own result into the company's model and used a common long-term exponential model from day 375 onwards.

3.37 The ERG used a similar approach to estimate duration of treatment in the 2 groups of patients in the LUME-Lung 1 trial. This increased the discounted cost per patient and the incremental cost per patient increased by 2.2% in both groups.

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3.38 The ERG commented that in its original model the company costed both nintedanib plus docetaxel and docetaxel alone using the average number of patients having treatment across each cycle. The ERG commented that adjusting mid cycle is not accurate for docetaxel treatment in either group because patients have treatment on the first day of a 3-week cycle. The error underestimated the quantity and cost of drugs used in the trial.

3.39 The ERG commented that the company calculated the average cost per dose of docetaxel using body surface area relevant to the UK population, but did not take into account the sex of the patients. The company also only costed the full 75 mg/m^2 dose rather than the reduced dose of 60 mg/m^2. The ERG considered it more accurate to cost the reduced dose, and then create a weighted average based on the proportions of the 2 doses recorded in the trial. The ERG considered that the nintedanib capsules would likely be dispensed with docetaxel, so any missed dosing was unlikely to have an effect on the dispensing pattern. Therefore, the ERG considered a reduction in cost through a randomised dose intensity index from trial data to be inappropriate. The ERG re-estimated the overall average cost per dose of docetaxel using separate subgroups for men and women, and also re-estimated the randomised dose index multiplier to match the balance of full and reduced doses. The ERG estimated an overall mean cost for nintedanib treatment per cycle using the LUME-Lung 1 trial data.

3.40 The cost of treating the adverse event of febrile neutropenia was included in the company's original model at £2,012.10 per patient affected. The ERG noted that this is substantially lower than the figure estimated by the NICE Decision Support Unit in 2007 and the updated figure used in the ongoing multiple technology appraisal for erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed following prior chemotherapy, which used £5,240.40 per episode and a mean cost per patient of £7,352.54 (assuming 1.4 episodes per patient).

3.41 The ERG also noted that there were discrepancies in monitoring costs in the progression-free health state when patients were still on active treatment. In the company's original model, monitoring costs of £188 per cycle were assigned to patients in the nintedanib plus docetaxel group and £205 per cycle to those having docetaxel alone. The ERG noted that this was because the company had incorrectly applied additional physician monitoring every 2 to 3 months for patients who had completed active treatment, to patients still on active treatment

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with docetaxel.

3.42 In the opinion of the ERG, the company modelled discounting incorrectly, basing the discounting on the 3-weekly cycle rather than annually.

3.43 The main adverse events in LUME-Lung 1 trial were stage 3 or 4 diarrhoea and fatigue. The company indicated that the disutility for diarrhoea was low (-0.04), whereas for fatigue it was much higher (-0.21). The ERG also noted that the company indicated a statistically significant difference between effect sizes in the 2 treatment groups, with a disutility of -0.326 for the nintedanib plus docetaxel group and of -0.101 for the docetaxel alone group. The ERG suggested that fatigue was a more serious side effect for those having nintedanib plus docetaxel. The company used an average disutility for the 2 treatment groups, whereas the ERG applied a disutility to the 2 groups separately. In the model, the company assumed that patients who had finished active treatment accrued the costs of having palliative nursing care every week and a bone scan every 3 weeks, in addition to a chest X-ray every 2 to 3 months and a physician visit once a year. The company's clinical experts suggested that only a chest X-ray would be needed and not palliative care or a bone scan. In the ERG's opinion, this reflected an error that significantly reduced the care costs of patients in a stable condition after second-line treatment.

3.44 The ERG noted that the company's model followed the protocol used in the LUME-Lung 1 trial, which allowed patients to have unlimited docetaxel treatment (exceeding 40 cycles). The ERG explained that, in the UK, patients have up to 4 cycles of docetaxel because of unacceptable adverse events. Although the company's original model allowed the number of cycles to be restricted, the ERG found an error that limited the number of cycles to 5 rather than to 4. When the ERG applied its own model adjustment and restricted the cycles to 4, this affected only the drug acquisition and administration costs, but not whether limiting docetaxel treatment would have an effect on the adverse events profile or patient prognosis. Both of these could affect the costs associated with treatment and the quality-of-life effects.

3.45 The ERG's original exploratory sensitivity analyses provided an ICER that incorporated all ERG amendments simultaneously to produce an ICER for nintedanib plus docetaxel. It also provided an ICER that included all amendments

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excluding analyses of the number of cycles of docetaxel. All ICERs from the ERG's exploratory analyses, generated using the company's original model, have been superseded by those using the revised model provided after consultation on the appraisal consultation document in January 2015 (see section 3.53).

3.46 The ERG's original exploratory sensitivity analyses also provided an ICER that applied 7 of the 11 amendments it had identified when analysing nintedanib plus docetaxel compared with docetaxel alone to the modelling of nintedanib plus docetaxel compared with erlotinib. The ERG also took into account the impact of the patient access scheme for erlotinib by assuming different discounts. However, the ERG still concluded that it did not consider erlotinib to be a suitable comparator.

Company's additional evidence in response to consultation

3.47 In response to consultation on the appraisal consultation document, the company provided a revised economic analysis, which contained all of the ERG's revisions (see section 3.34) except the cost of febrile neutropenia and the ERG's overall survival modelling. However, the company also changed its approach to survival modelling, and submitted new cost-effectiveness estimates analyses based on the following:

- using the data from Kaplan–Meier curves directly from the LUME-Lung 1 trial until a chosen point and then extrapolating beyond this for the lifetime horizon of the model
- choosing the point at which 5% of the original patients in both arms of the trial were still alive in the base case (alternatively, 2.5% and 7.5% in exploratory analyses)
- calculating the probability of a patient remaining alive in each cycle using a log-normal parametric curve fitted using data from LUCADA to extrapolate from this point
- incorporating a patient access scheme, a confidential simple discount on the list price of nintedanib.

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This modelling approach resulted in a deterministic ICER of £46,580 per quality-adjusted life year (QALY) gained. The probabilistic ICER was £46,517 per QALY gained.

3.48 The company also provided several scenario analyses, all of which incorporated the patient access scheme. When the company used a cut-off point of 2.5% of the population still alive in both arms in its sensitivity analyses, the ICER was £46,813 per QALY gained. When it used a cut-off point of 7.5% alive in both arms, the ICER was £49,894. The company carried out additional scenario analyses using utility values from the last observation carried forward (ICER £47,825 per QALY gained) and using utility values taken from the Chouaid et al. (2013) study (ICER £57,473 per QALY gained).

3.49 The company tested how robust the survival modelling was to various assumptions around survival extrapolation. To estimate the average extension of life associated with nintedanib plus docetaxel compared with docetaxel alone, the company carried out probabilistic sensitivity analyses. Using the updated model, the company noted that 4,277 out of 5,000 simulations (86%) resulted in an overall survival gain of at least 3 months (table 2).

Table 2 Incremental overall survival for nintedanib plus docetaxel compared with docetaxel monotherapy (taken from page 5 in the company's response to consultation on the appraisal consultation document)

Overall survival	Incremental life years	Incremental life months
Mixed: Kaplan–Meier from LUME- Lung 1 then to extrapolate LUCADA-Log-normal (5% patients alive cut-off)	0.27	3.24
Mixed: Kaplan–Meier from LUME- Lung 1 then to extrapolate LUCADA-Log-normal (2.5% patients alive cut-off)	0.27	3.24
Mixed: Kaplan–Meier from LUME- Lung 1 then to extrapolate LUCADA-Log-normal (7.5% patients alive cut-off)	0.25	3.00
Mixed: Kaplan–Meier from LUME- Lung 1 then to extrapolate LUCADA-Log-normal (5% patients alive cut-off), average of probabilistic sensitivity analyses	0.27	3.24
Separate – Log-logistic (base-case)	0.34	4.08

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Overall survival	Incremental life years	Incremental life months
Mixed: Kaplan–Meier from LUME- Lung 1 then to extrapolate (5% patients alive cut-off) SEER-Log-normal	0.28	3.36
Mixed curves: Kaplan–Meier from LUME-Lung 1 then to extrapolate (5% patients alive cut-off) Log-logistic	0.34	4.08

Abbreviations: LUCADA, National Lung Cancer Audit; SEER, Surveillance, Epidemiology and End Result

3.50 The company also provided the restricted mean for the overall survival gain (2.87 months) for nintedanib plus docetaxel compared with docetaxel alone in LUME-Lung 1. The company explained that this did not accurately represent true overall survival because 15% of the patients in the trial were still alive at this point.

ERG's critique of the company's additional evidence

3.51 The ERG focused its critique of the company's revised economic model on the overall survival modelling, noting that changing the cost of febrile neutropenia, not included by the company, had only a minor effect on the ICER.

3.52 The ERG raised concerns about the method used by the company to calculate the overall survival in the company's revised economic analyses:

- By using the same LUCADA data for both arms to extrapolate beyond the trial, the company presumed that the long-term risk for the 2 treatment groups was equal. This removed any relative differences in survival caused by increasing or decreasing the survival advantage of nintedanib beyond the cut-off point.
- By combining the 2 arms to estimate a proportion of patients alive (5%) at the cut-off for extrapolation, the company introduced a risk of bias. This was because up to this point, patients in the nintedanib plus docetaxel arm were more likely to survive than patients in the docetaxel alone arm, and because of random differences in the number of patients censored, as evidenced by the extrapolations starting at different points in the Kaplan–Meier curve

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(more than 15% estimated probability of survival for nintedanib plus docetaxel and less than 12% for docetaxel alone). This means that any uncertainty in the parameters estimated for the log-normal representation of the LUCADA data would have a proportionally larger effect on the nintedanib plus docetaxel group than on the docetaxel alone group, which may lead to larger biases in this group.

3.53 The ERG did exploratory analyses starting the extrapolation using the LUCADA data from the time in the Kaplan–Meier curves of the LUME-Lung 1 trial when the probability of overall survival was 12.6% in each arm. The resulting ICER (incorporating the patient access scheme) was £56,804 per QALY gained for nintedanib plus docetaxel compared with docetaxel alone. The ERG calculated an overall survival, using this extrapolation of 0.224 incremental life years (2.69 months).

3.54 Full details of all the evidence are available in the committee papers.

Consideration of the evidence

3.55 The Appraisal Committee reviewed the data available on the clinical and cost effectiveness of nintedanib plus docetaxel, having considered evidence on the nature of non-small-cell lung cancer and the value placed on the benefits of nintedanib plus docetaxel by people with the condition, those who represent them, and clinical experts. It also took into account the effective use of NHS resources.

3.56 The Committee heard from the clinical and patient experts about the nature of locally advanced, metastatic and locally recurrent non-small-cell lung cancer that has progressed after chemotherapy. The Committee heard that the symptoms from non-small-cell lung cancer can be debilitating, and many symptoms such as breathlessness are difficult to manage. It understood that the prognosis for patients with non-small-cell lung cancer is poor, and heard from the clinical and patient experts that only about half of people with non-small-cell lung cancer that has progressed after chemotherapy have good general health, and very few of these people have an Eastern Cooperative Oncology Group (ECOG)

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performance status score of 0 (fully active) or 1 (restricted in strenuous activity, but ambulatory). The Committee also heard that treatment options currently available to people whose disease has progressed after chemotherapy are limited to docetaxel and erlotinib, neither of which has a substantial impact on survival. The clinical and patient experts emphasised that any extension to survival and improvement in quality of life are important for people with non-small-cell-lung cancer and their families. The Committee recognised the importance of having effective and tolerable treatment options for people with non-small-cell lung cancer that has progressed after chemotherapy.

3.57 The Committee considered the clinical pathway for people with non-small-cell lung cancer. The Committee was aware that the presence of epidermal growth factor receptor (EGFR)-tyrosine kinase (TK) mutation in the tumour influences prognosis and determines treatment choice in first- and second-line settings. It understood that most EGFR-TK mutation positive non-small-cell lung cancer is treated with an EGFR-TK inhibitor as first-line treatment (in line with NICE's technology appraisal guidance on gefitinib for the first-line treatment of locally advanced or metastatic non-small-cell lung cancer and erlotinib for the first-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer), followed by either erlotinib (in line with NICE's technology appraisal guidance on erlotinib for the treatment of non-small-cell lung cancer [now replaced by NICE's technology appraisal guidance on erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy]) or docetaxel (in line with NICE's guideline on lung cancer [now replaced by NICE's guideline on lung cancer: diagnosis and management]) if the disease has progressed after chemotherapy. It also understood that EGFR-TK negative mutation non-small-cell lung cancer is treated with either pemetrexed (in line with NICE's technology appraisal guidance on pemetrexed for the first-line treatment of non-small-cell lung cancer) or docetaxel (in line with NICE's guideline on lung cancer [now replaced by NICE's guideline on lung cancer: diagnosis and management]) followed by either docetaxel or erlotinib (in line with NICE's technology appraisal guidance on erlotinib for the treatment of non-small-cell lung cancer [now replaced by NICE's technology appraisal guidance on erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy]) if disease has progressed after chemotherapy. The Committee was aware that the mechanism of action of nintedanib is independent of EGFR-TK mutation status, and therefore noted that either erlotinib or docetaxel

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might, in principle, be considered as comparators to nintedanib. The Committee heard from the clinical expert that, until recently, erlotinib and docetaxel were considered to be equally effective but that erlotinib has a more favourable side-effect profile. However, the clinical expert explained that clinical practice has changed since the publication of NICE's technology appraisal guidance on erlotinib for the treatment of non-small-cell lung cancer (now replaced by NICE's technology appraisal guidance on erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy): now, people considered to be fit (ECOG performance score of 0 or 1) are offered docetaxel as a second-line treatment, while those with poor fitness (an ECOG status of 2) are offered erlotinib. The Committee was aware that the marketing authorisation for nintedanib specifies giving it with docetaxel, and agreed that most people likely to be offered nintedanib have similar patient characteristics to those offered docetaxel, such as ECOG performance status of 0 or 1 and having had first-line treatment. The clinical expert explained that, in clinical practice, patients might stay on nintedanib plus docetaxel even after disease progression if symptoms are controlled. However, the Committee was aware that this differed from the protocol of the LUME-Lung 1 trial on which the clinical evidence is based, and agreed with a comment from NHS England received during consultation stating that nintedanib treatment should be stopped at disease progression. The Committee also agreed that most people treated with erlotinib second line would differ from people treated with nintedanib plus docetaxel in terms of ECOG performance status and first-line treatments. The Committee concluded that docetaxel alone was the only appropriate comparator to nintedanib plus docetaxel, and that it would not need to consider any comparison of nintedanib plus docetaxel with erlotinib.

Clinical effectiveness

3.58 The Committee considered the clinical-effectiveness data from the LUME-Lung 1 trial comparing nintedanib plus docetaxel with docetaxel alone, which formed the basis of the clinical-effectiveness evidence in the company's submission. The Committee noted that the LUME-Lung 1 trial was a good quality trial, that patients remained on treatment until disease progression, that the study remained unblinded between analysing the primary outcome of progression-free survival and the secondary outcome of overall survival, and that treatment

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crossover was not permitted. The Committee discussed the Evidence Review Group (ERG)'s concerns about the generalisability of the results to clinical practice in England (see section 3.27). The Committee was aware that patients with cavitary or necrotic tumours were more likely to have squamous cell lung cancer rather than adenocarcinoma, and are not included in this appraisal. The Committee also heard from the clinical expert that patients with adenocarcinoma are generally not treated with anticoagulants other than low molecular weight heparin, and would only receive 75 mg aspirin per day, meaning that these exclusion criteria were unlikely to affect the generalisability of the trial. The Committee noted the ERG's concerns and the clinical expert comments that the population in the trial was generally younger than those seen in clinical practice, where the average age is over 65 years. The Committee noted comments received in consultation stating that the marketing authorisation for nintedanib is in combination with docetaxel. It also noted that, because patients must be able to tolerate docetaxel treatment, the population to be treated with nintedanib is younger and fitter than all people with non-small-cell lung cancer waiting for second-line therapy who are seen in clinical practice in England, and is therefore similar to the trial population. The Committee agreed that the trial was not generalisable to all patients with adenocarcinoma whose disease had progressed after chemotherapy or for patients with an ECOG score of 2, but it was generalisable to patients offered docetaxel monotherapy as second-line treatment, such as those with an ECOG status of 0 and 1. The Committee also discussed the ERG's concerns about the LUME-Lung 1 trial protocol allowing unlimited docetaxel treatment, with the maximum number of docetaxel cycles being 41 cycles. The clinical expert explained that, in clinical practice in England, patients would generally have 4 cycles of docetaxel, because a higher number of cycles would produce unacceptable adverse effects, although rarely some may have up to 6 cycles. The Committee concluded that the results from the LUME-Lung 1 trial were relevant and generalisable to most, but not all, patients in routine clinical practice in England.

3.59 The Committee considered the results of the LUME-Lung 1 trial. It noted that the company presented results for the overall trial population (n=1,314) and also for a subgroup (658 of the total trial population) with adenocarcinoma, which had not been a pre-specified subgroup. However, nintedanib plus docetaxel has a marketing authorisation only for treating adenocarcinoma, and not for other histological subtypes. The Committee, however, accepted that adenocarcinoma

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constituted most cases of non-squamous carcinoma, a pre-specified subgroup in the LUME-Lung 1 trial (658 of 759 patients). The Committee would have preferred adenocarcinoma to have been a stratification factor. However, it accepted that the efficacy data from the subgroup with adenocarcinoma were the most relevant for decision-making because this was the population that was specified in the marketing authorisation for nintedanib.

3.60 The Committee considered the clinical effectiveness of nintedanib plus docetaxel compared with docetaxel alone for treating people with adenocarcinoma. The Committee was aware at the first meeting that, based on the final analysis after a median follow-up of approximately 32 months, the gain in median progression-free survival was 1.4 months and the gain in median overall survival was 2.3 months. The Committee considered that a difference in median overall survival of 2.3 months reflected a statistically significant effect but agreed that this was a clinically small benefit. The Committee noted that the data from the trial were mature, meaning that most people had died and all people had experienced disease progression but that, for the mean values to be calculated with certainty, all patients would have to have died. The Committee noted that, following consultation and in response to its question during the first meeting, the company provided the restricted mean difference in overall survival, which was 2.87 months (see section 3.50) and that the mean overall survival would likely be greater than this (see section 3.73). The Committee concluded that nintedanib plus docetaxel was more effective than docetaxel alone in people with adenocarcinoma whose disease has progressed after chemotherapy.

3.61 The Committee discussed concerns about safety and adverse effects associated with nintedanib plus docetaxel. It heard from the clinical and patient experts that most of the adverse events associated with nintedanib plus docetaxel were related to docetaxel rather than nintedanib. The clinical and patient experts highlighted that patients are willing to tolerate adverse events associated with nintedanib, such as diarrhoea, because of the added benefit from nintedanib. The Committee noted that there was an increase in the number of deaths associated with nintedanib plus docetaxel compared with docetaxel alone. The Committee accepted the company's explanation that the deaths in the nintedanib plus docetaxel treatment arm of the trial, although attributed to nintedanib, resulted instead from patients' underlying comorbidities. The Committee was aware that, overall, fewer patients treated with nintedanib plus docetaxel died than those

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treated with docetaxel alone. The Committee concluded that current evidence suggests that nintedanib plus docetaxel has an acceptable safety profile compared with docetaxel alone and that patients are willing to tolerate the adverse effects.

Cost effectiveness

3.62 The Committee considered the structure of the model submitted by the company and whether it captured the natural history of adenocarcinoma of the lung. The Committee agreed that the company had structured the model well, and that it was similar to other economic models submitted to NICE for the same disease area and that the 15-year time horizon was appropriate for this disease. The Committee noted that the company had used utility values in its model that had been obtained from EQ-5D data collected during the LUME-Lung 1 trial in line with the NICE reference case. The Committee concluded that the structure of the model was acceptable for assessing the cost effectiveness of nintedanib plus docetaxel.

3.63 The Committee discussed how the company extrapolated overall survival in the original model by fitting parametric curves to the data and the ERG's critique of this. The Committee observed that the Kaplan–Meier curves for progression-free survival from the final analyses for nintedanib plus docetaxel and docetaxel alone converged after approximately 1 year into the trial (see sections 3.16 and 3.17). The ERG explained that the proportional hazards assumption (the relative risk of an event is fixed irrespective of time) is fundamental for applying a Weibull parametric curve, but is not needed for log-normal or log-logistic curves. The Committee understood that this means that the proportional hazards assumption cannot be applied to the nintedanib data.

3.64 The Committee then considered whether each treatment should be modelled separately or jointly using a hazard ratio for progression-free survival and a hazard ratio for overall survival (see section 3.16). The Committee accepted that separate modelling was more appropriate than joint modelling because only separate modelling could accommodate the possibility that nintedanib might fundamentally alter the natural history of the disease.

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3.65 The Committee then considered whether it was more appropriate to replace the trial data with a parametric model (as the company did in its original base case), or to use the trial data and a parametric model only for the period beyond the end of the trial. The Committee was aware of 2 divergent views: that modelled data might be more generalisable than data from a single trial; and, that it can also be considered preferable to 'maximise' use of trial data, particularly when the data are mature. The Committee concluded from the model's residual values that the company's base-case log-logistic curve did not provide a good fit to the actual trial data. The Committee preferred the use of the Kaplan–Meier curves from the LUME-Lung 1 trial for the base-case analysis, followed by extrapolation beyond the trial data, using a similar method to the ERG. However, the Committee was aware that such an approach depends on the point at which the extrapolation starts. The Committee queried at its first meeting how sensitive the results were to the point of extrapolation, but the ERG explained that it had not done such exploratory analyses. The Committee concluded that the ERG's approach to modelling therefore also resulted in uncertainty. When looking at the original models and the extrapolated data beyond the trial period, the Committee noted that the company's overall survival curves for nintedanib plus docetaxel and docetaxel alone continued to diverge for the 15-year time horizon, suggesting ongoing and indefinite benefit beyond the end of treatment. The Committee considered the magnitude of this benefit to be implausible, and noted that the respective curves from the ERG remained parallel after 9 to 10 years. The Committee was not persuaded that any of the overall survival projections presented in the company's original model were plausible for a population with a poor prognosis. The Committee was aware that alternative methods of modelling the data, such as piecewise modelling, may have better reflected the data. The Committee concluded, after its first meeting, that both the company's and ERG's modelling approaches led to uncertainty in the survival results.

3.66 The Committee discussed the company's original scenario analyses which used registry data to validate the parametric curves, namely the National Lung Cancer Audit Data (LUCADA) from the UK and data from the Surveillance, Epidemiology and End Result (SEER) from the USA. The Committee understood that the company took the last point of the trial data and extrapolated from it with the registry data over the remaining time horizon. The Committee heard from the company that it was unable to provide any further details of the registries other than: the LUCADA data were matched by age, sex and histology and contained

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information from patients in the UK, and the SEER data were matched for age, sex and race, but not for line of treatment and contained information from patients in the USA. The Committee heard that the company had access only to summarised stratified LUCADA data which it used to generate a log-normal curve. The Committee appreciated that this approach was associated with more uncertainty than had the company used individual level data. Although the LUCADA registry data were limited because the data did not provide information on line of therapy, the Committee agreed that, of the 2 sources of registry data, LUCADA was the more appropriate to use in this appraisal.

3.67 The Committee considered the company's revised economic analyses for this appraisal including the Committee's preferred approach to overall survival modelling – using the Kaplan–Meier data from the trial and extrapolating with the LUCADA registry data (see section 3.47).

- Regarding cut-off points: the Committee was concerned that the company and the ERG arbitrarily chose cut-off points from which to start extrapolating. The Committee heard that the ERG prefers its own method as the basis of the cut-off (that is, using the point at which both treatments have the same probability of survival, which occurred at different times during follow-up) because the ERG's method takes censoring into account. In addition, the ERG further informed the Committee that this point balances 'the maximum use of direct Kaplan–Meier data whilst reducing as far as possible the inevitable uncertainty from the small numbers of survivors towards the end of the trial'.

- Regarding modelling both treatments using the same data during extrapolation: the Committee heard from the ERG that this assumption was 'conservative' because it could not account for the possibility that nintedanib modifies disease, and that disease progression may differ between patients who have, or have not, received nintedanib. The Committee heard from the ERG that the cumulative hazards, for both overall survival and post-progression survival, suggest that this is a possibility.

- Regarding approaches to modelling: the Committee was aware that the company and ERG could have used other modelling approaches, such as piecewise modelling, including identifying the shape of the Kaplan–Meier curve, which is most likely to reflect subsequent mortality, or extrapolating from a point based on a biologically-plausible hypothesis. The Committee

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was also aware that using individual patient level data from LUCADA, even with a different parametric model, would not address the modelling uncertainties or take into account the disease modification suggested by the trial data.

The company explained that it had carried out sensitivity analyses varying the risk of mortality from the LUCADA data and that the incremental cost effectiveness ratio (ICER) was not sensitive to such changes. The Committee accepted the ERG's rationale for its approach to defining a cut off point. It also accepted that assuming the same hazard in the extrapolation period for both the nintedanib and docetaxel arm may underestimate the treatment effect of nintedanib .The Committee concluded that both the company and the ERG used plausible methods, that other methods exist, and that it is not possible to establish 1 correct extrapolation method.

3.68 The Committee discussed how health-related quality of life was incorporated into the economic model, noting that the ICER was sensitive to the utility values used. The Committee appreciated that the company had used EQ-5D values derived directly from the LUME-Lung 1 trial in its base-case analysis for progression-free survival and progressed disease. The Committee was concerned that the progressed-disease utility value was not much lower than those for progression-free disease, which may be because utility was measured early in the course of the progressed-disease health state. The Committee noted that the company had also used alternative utility values published by Chouaid et al. (2013) in its sensitivity analyses, which had a higher utility value for progression-free survival and a much lower utility value for progressed disease than those taken from the LUME-Lung 1 trial. The Committee agreed that these alternative utility values were extreme and improbable values. The Committee appreciated that the utility values used in the base-case analysis, being EQ-5D values based on a trial, were in line with the recommendations of the NICE guide to the methods of technology appraisal 2013. The Committee acknowledged that the utility value from the LUME-Lung 1 trial overestimated the average value throughout the course of progressed disease because it was measured early in the disease state. However, the Committee was aware that the company had carried out sensitivity analyses which were overly pessimistic because the analyses used third- or fourth-line utility values, which were considerably lower than the second-line utility values in the Chouaid et al. (2013) study. However,

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the Committee acknowledged that using a lower utility value than that in the company's base case would lead to a higher ICER for nintedanib plus docetaxel compared with docetaxel alone. The Committee concluded that a lower utility value than in the base case would be more appropriate for the progressed disease state in this appraisal, but higher than used in the company's sensitivity analysis.

3.69 The Committee discussed the costs of the adverse events in the company's economic model, and particularly the figure of £2,012.10 to treat febrile neutropenia. The ERG explained that this was substantially lower than the costs used in previous appraisals (review of TA162 and TA175) of more than £5,000 when adjusted for inflation to current costs. The Committee heard from the clinical expert that this figure seemed high and that a range of £2,000 to £3,000 was reasonable. The Committee noted that the company had not amended the cost of febrile neutropenia in its revised analyses (see section 3.47). The company explained that the values used in its models were within the range that the clinical experts consider reasonable and that the ICER was not particularly sensitive to the cost of febrile neutropenia. Therefore, the Committee concluded that it would not pursue any further the cost included in the model of a patient being treated for febrile neutropenia.

3.70 The Committee discussed the use and cost of docetaxel in clinical practice in England. It heard from the clinical expert that patients normally have up to 4 cycles of docetaxel and occasionally up to 6 cycles, but very rarely more because of the associated adverse events. In the LUME-Lung 1 trial, and therefore in the company's model, patients were able to have up to 41 cycles of docetaxel. The Committee noted that the ERG did exploratory analyses in which it restricted the number of docetaxel cycles to 4. The Committee was aware this would reduce the costs of docetaxel in both treatment groups. However, the Committee noted that the ERG could not determine what effect reducing the number of docetaxel cycles would have on the adverse events profile, patient prognosis and the resulting effects on costs and quality of life. The Committee concluded that some uncertainty exists as to the effect of a reduction in docetaxel cycles.

3.71 The Committee considered the results from the company's revised base-case analyses (see section 3.47) and the ERG's sensitivity analyses (see sections 3.52

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and 3.53). The Committee noted that the company's revised analyses resulted in an ICER of £46,580 per quality-adjusted life year (QALY) gained for nintedanib plus docetaxel compared with docetaxel alone, and that the ERG's updated base-case ICER was £56,804 per QALY gained (see section 3.47and 3.53). The Committee concluded that, because of the issues related to utility values and uncertainties around the overall survival modelling, the most plausible ICER would lie between the company's and the ERG's estimates. However, it also concluded that the most plausible ICER was likely to be closer to the company's estimate, in part, because the ERG's extrapolation methods led to an estimated mean overall survival benefit lower than the restricted mean from the trial. The Committee therefore concluded that the ICER for nintedanib plus docetaxel compared with docetaxel alone was below £50,000 per QALY gained.

3.72 The Committee considered supplementary advice from NICE that should be taken into account when appraising treatments that may extend the life of patients with a short life expectancy and that are licensed for indications that affect small numbers of people with incurable illnesses. For this advice to be applied, all the following criteria must be met:

- The treatment is indicated for patients with a short life expectancy, normally less than 24 months.
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months compared with current NHS treatments.
- The treatment is licensed or otherwise indicated for small patient populations.

  In addition, when taking these criteria into account, the Committee must be persuaded that the estimates of the extension to life are robust and that the assumptions used in the reference case of the economic modelling are plausible, objective and robust.

3.73 The Committee heard from the clinical and patient experts that the life expectancy of patients needing second-line treatment for non-small-cell lung cancer was shorter than 2 years and accepted that the criterion of short life expectancy was met. The Committee accepted the company's estimate that the

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total population was less than 800 patients. The Committee discussed whether the evidence was sufficient to show that nintedanib plus docetaxel offered an additional 3 months compared with current NHS treatment (that is, docetaxel). The Committee concluded that the ERG's updated base case for a mean extension to life of 2.69 months was implausible, because this was lower than the trial restricted mean of 2.87 months, provided by the company in response to consultation. Considering that the estimates modelled in the company's sensitivity analyses for the mean extension to life without using the most optimistic assumptions ranged between 3.00 months and 4.08 months, the Committee agreed that an extension of greater than 3 months was probable. The Committee concluded that nintedanib plus docetaxel fulfilled the NICE supplementary advice criteria to be considered as a life-extending, end-of-life treatment. It further concluded that the weight placed on the QALYs gained was appropriate for nintedanib plus docetaxel and that nintedanib could be considered a cost-effective use of NHS resources for previously treated, locally advanced, metastatic or locally recurrent non-small-cell lung cancer.

3.74 The Committee discussed whether nintedanib was innovative in its potential to make a significant and substantial impact on health-related benefits. It heard from the patient expert that patients consider nintedanib to be innovative. It also heard from the clinical and patient experts that there were few options for treating patients with non-small-cell lung cancer who need second-line treatment and that nintedanib would provide another option. The Committee agreed that nintedanib appeared to be pharmacologically innovative in its mechanism by appearing to provide benefits beyond progression, but that just having an extra treatment option for non-small-cell lung cancer did not mean that nintedanib was innovative. It concluded that there were no additional gains in health-related quality of life over those already included in the QALY calculations.

3.75 The Committee noted a potential equality issue raised during the scoping workshop. A workshop attendee suggested that the LUME-Lung 1 trial excluded patients whose disease progressed after maintenance therapy, but that some patients now have maintenance therapy after first-line induction therapy. The marketing authorisation wording implies that this group is included: 'in combination with docetaxel for adult patients with locally advanced, metastatic or locally recurrent non-small-cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy'. The Committee was aware that people

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who have maintenance therapy are not a 'protected group' according to the equality legislation, and that there is no trial evidence for the effectiveness of nintedanib in this group. Therefore, it concluded that it is unclear whether this group would benefit from nintedanib plus docetaxel and agreed that this did not present an equality issue.

3.76 The Appraisal Committee considered whether it should take into account the consequences of PPRS 2014, and in particular the PPRS Payment Mechanism, when appraising nintedanib. The Appraisal Committee noted NICE's position statement in this regard, and accepted the conclusion 'that the 2014 PPRS Payment Mechanism should not, as a matter of course, be regarded as a relevant consideration in its assessment of the cost effectiveness of branded medicines'. The Committee heard nothing to suggest that there is any basis for taking a different view with regard to the relevance of the PPRS to this appraisal of nintedanib. It therefore concluded that the PPRS Payment Mechanism was irrelevant for the consideration of cost effectiveness of nintedanib.

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4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.

4.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or fast track appraisal), at which point funding will switch to routine commissioning budgets. The NHS England and NHS Improvement Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

4.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

4.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has previously treated locally advanced, metastatic or locally recurrent non-small-cell lung cancer and the healthcare professional responsible for their care thinks that nintedanib is the right treatment, it should be available for use, in line with NICE's recommendations.

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5 Appraisal Committee members, guideline representatives and NICE project team

Appraisal Committee members

The Appraisal Committees are standing advisory committees of NICE. Members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. There are 4 Appraisal Committees, each with a chair and vice chair. Each Appraisal Committee meets once a month, except in December when there are no meetings. Each Committee considers its own list of technologies, and ongoing topics are not moved between Committees.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Dr Amanda Adler (Chair)
Consultant Physician, Addenbrooke's Hospital

Dr Ray Armstrong
Consultant Rheumatologist, Southampton General Hospital

Dr Jeff Aronson
Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford

Professor John Cairns
Professor of Health Economics, Public Health and Policy, London School of Hygiene and Tropical Medicine

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Mr Matthew Campbell-Hill
Lay member

Mr Mark Chapman
Health Economics and Market Access Manager, Medtronic UK

Dr Lisa Cooper
Echocardiographer, Stockport NHS Foundation Trust

Professor Daniel Hochhauser
Consultant in Medical Oncology, UCL Cancer Institute

Dr Neil Iosson
Locum General Practitioner

Mrs Anne Joshua
NHS 111 Pharmacy Lead, Patients and Information, NHS England

Dr Miriam McCarthy
Consultant, Public Health, Public Health Agency, Northern Ireland

Professor Ruairidh Milne
Professorial Fellow in Public Health, Wessex Institute, University of Southampton

Dr Peter Norrie
Principal Lecturer, De Montfort University, Leicester

Mr Chris O'Regan
Head of Health Technology & Outcomes Research, Merck Sharp & Dohme

Dr Sanjeev Patel
Consultant Physician and Senior Lecturer in Rheumatology, St Helier University Hospital

Dr John Pounsford
Consultant Physician, Frenchay Hospital, Bristol

Dr Danielle Preedy
Lay member

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Mr Alun Roebuck
Consultant Nurse in Critical and Acute Care, United Lincolnshire NHS Trust

Mr Cliff Snelling
Lay member

Professor Ken Stein
Professor of Public Health, Peninsula College of Medicine and Dentistry, University of Exeter

Mr David Thomson
Lay member

Dr Nicky Welton
Senior Lecturer in Biostatistics and Health Technology Assessment, University of Bristol

Dr Nerys Woolacott
Senior Research Fellow, Centre for Health Economics, University of York

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Caroline Hall
Technical Lead

Nicola Hay
Technical Adviser

Jeremy Powell
Project Manager

Sources of evidence considered by the Committee

The Evidence Review Group (ERG) report for this appraisal was prepared by Liverpool

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Reviews and Implementation Group:

- Fleeman N, Bagust A, Boland A et al., Nintedanib for previously treated locally advanced or metastatic non-small-cell lung cancer, October 2014

The following organisations accepted the invitation to participate in this appraisal as consultees and commentators. They were invited to comment on the draft scope, the ERG report and the appraisal consultation document (ACD). Companies were also invited to make written submissions. Professional or expert and patient or carer groups, and other consultees, had the opportunity to make written submissions. Companies, professional or expert and patient or carer groups, and other consultees, also have the opportunity to appeal against the final appraisal determination.

Company:

- Boehringer Ingelheim

Professional or expert and patient or carer groups:

- Roy Castle Lung Cancer Foundation
- British Thoracic Oncology Group
- British Thoracic Society
- Cancer Research UK
- Royal College of Pathologists
- Royal College of Physicians

Commentator organisations (did not provide written evidence and without the right of appeal):

- Roche Products
- National Collaborating Centre for Cancer

The following individuals were selected from clinical expert and patient expert nominations from the consultees and commentators. They gave their expert personal view on nintedanib by attending the initial Committee discussion and providing a written statement to the Committee. They were also invited to comment on the appraisal consultation

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document.

- Dr Thomas Newsom-Davis, Consultant Medical Oncologist, Chelsea & Westminster Hospital, nominated by NCRI, RCP, RCR, ACP – clinical expert
- Dr Jesme Fox, Medical Director, Roy Castle Lung Cancer Foundation, nominated by Roy Castle Lung Cancer Foundation – patient expert

Representatives from the following company attended Committee meetings. They contributed only when asked by the Committee chair to clarify specific issues and comment on factual accuracy. They were also invited to comment on the ACD.

- Boehringer Ingelheim

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