Pathways approach

# Treatments for non-small cell lung cancer [ID6234]

# Pilot process statement [withdrawn]

This process statement has been withdrawn. Please see the project information for more details.

**Project summary**

1. NICE has made a commitment to helping practitioners and commissioners get the best care to people fast, while ensuring value for the taxpayer. To achieve this NICE is transforming to deliver more relevant, timely and useable guidance. One way in which NICE is aiming to meet this goal is a pathways approach.
2. The overall goal of this work is to develop a single health economic model to inform the development of NICE guidance in non-small cell lung cancer (NSCLC). Time and resource efficiencies for NICE and external stakeholders are expected to be realised by building and maintaining an evolving core cost-effectiveness model. That will enable comparative assessment of multiple technologies in a disease pathway. It is also expected to address issues of repetition in key modelling assumptions, structural uncertainty, and to improve consistency of decision making across NICE.
3. The output of this initial phase of work will be a NICE owned pathway model, for a section of the NSCLC pathway, with preferred modelling assumptions that have been agreed by an independent committee. There will also be a summary of the cost-effectiveness of various technologies at the decision points identified in the NSCLC pathway, based primarily on publicly available data and data provided by stakeholders, in line with section 6.3 of the [NICE health technology evaluations guidance development manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation). The outputs of this initial phase of work will not affect the recommendations in existing NICE technology appraisal guidance.
4. This process statement is limited to the pilot for the NSCLC pathway approach: Treatments for non-small cell lung cancer (ID6234).
5. The phases of the work are as follows
   * Phase 1 – Scoping and preparatory work (identification of decision spaces of the pathway to include in first iteration)
   * Phase 2 – Evidence synthesis and health economic modelling work
   * Phase 3 – Evaluation of pathway and decision on preferred assumptions
   * Phase 4 – Maintenance phase (assessing future technologies through the NICE NSCLC pathway model)
6. The technology appraisal processes are detailed in the [NICE health technology evaluations guidance development manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation). Pathway appraisals correspond to the steps in the guidance development manual but are re-sequenced and with different timelines to allow the exploration of a new proportionate approach (in a test and learn environment) that will develop overall process efficiencies and improvements. The overview of each phase outlined below details how the guidance development steps in the manual are followed and timelines are available in tables 1 to 4.

**Timelines**

Table 1: Timelines for phase 1 of the NSCLC pathways pilot

|  |  |
| --- | --- |
| **Date** | **Stage** |
| April 2023 | Scoping workshop |

Table 2: Timelines for phase 2 of the NSCLC pathways pilot

|  |  |
| --- | --- |
| **Date** | **Stage** |
| July 2023 | External assessment group and NICE develop analysis plan |
| September to October 2023 | Consultation on analysis plan |
| October 2023 | Stakeholder information meeting |
| February 2024 | Final report, model and lay summary shared with stakeholders |
| March 2024 | Stakeholders return suggested scenario analyses |

Table 3: Timelines for phase 3 of the NSCLC pathways pilot

|  |  |
| --- | --- |
| **Date** | **Stage** |
| March 2024 | **First appraisal committee meeting** |
| April - June 2024 | Final report and model published |

Table 4: If a second committee meeting is required to address comments on the final report and model, the subsequent indicative timelines are currently:

|  |  |
| --- | --- |
| **Date** | **Stage** |
| June 2024 | Second appraisal committee meeting |
| July - September 2024 | Final report and model published |

1. Timelines for phase 4 (maintenance) will be shared in due course.

**Phase 1 – Scoping and preparatory work**

1. The activities in phase 1 broadly correspond to section 2 of the guidance development manual. See section 1.3.10 to section 1.3.19 of the manual for details on the nomination and selection of experts.
2. The scoping process aimed to define what questions the evaluation was going to answer, which decision spaces existed in the NSCLC pathway and what would and would not be included in the modelling.
3. A scoping workshop was held with attendees from NICE, an External Assessment group and relevant stakeholders including clinical and patient experts and company representatives.
4. The resulting final scope provides the framework for the evaluation, giving a description of the NSCLC pathway, the various decision points that will be modelled and the technologies currently placed in those decision points.
5. The NSCLC pathway is expansive with numerous decision points covering both locally advanced, advanced and metastatic disease as well as a range of disease specific biomarkers. Twenty-four separate decision points were identified. It was decided that 11 of these decision points would be modelled in the first iteration of the NSCLC pathways approach. These are detailed in the final scope and scoping workshop supporting document.
6. The scope of the first iteration of the NSCLC pathway will focus on development of the evidence synthesis of currently available data and the core model development.
7. To promote maximum engagement with the process, NICE will be inclusive regarding stakeholders. The stakeholder list will include any companies with technologies already recommended by NICE and located in the NSCLC pathway. Any companies with a medicine that meets the eligibility and selection criteria for technology appraisal guidance (see sections 4.1.4 and 6.2.1 of [the manual](https://www.nice.org.uk/process/pmg37/chapter/about-this-guide)) can request to become a NSCLC pathway company stakeholder. Companies with medicines which are expected to get appropriate regulatory approval beyond 24 months are also eligible to request to become a pathway stakeholder. Pathway companies are defined as organisations that are invited to engage in the development of a pathway and can submit evidence in response to consultation but do not have right of appeal of recommendations.
8. Stakeholders will only be able to participate in this process, if they have signed confidentiality agreements

**Phase 2 – Evidence synthesis and modelling work**

1. The activities in phase 2 broadly correspond to section 5.6 of the guidance development manual.
2. An external assessment group (EAG) will be undertaking the evidence synthesis and an internal team at NICE will be undertaking modelling work required in phase 2 of the evaluation.
3. The EAG and NICE will develop an analysis plan which will be shared with stakeholders to allow for comments on the intended approach proposed by the EAG and an internal team at NICE. Specific questions or requests for evidence from stakeholders may be made by the EAG and NICE, if appropriate. Requests for data are likely to be primarily clinical trial data. Stakeholders will have at least 21 days to submit comments and provide evidence.
4. A stakeholder information meeting will be held to consider the decision problem and discuss the analysis plan, during the consultation on the analysis plan.
5. The EAG and NICE will carry out an assessment of the publicly available clinical evidence within the decision points of the NSCLC pathway that are included in this iteration of the pathways pilot (see section 5.6.15 of the guidance development manual). The assessment will include:
   * Systematic evidence reviews for technologies currently in the selected decision points of the NSCLC pathway.
   * Targeted evidence reviews of cost-effectiveness literature and model parameters based on systematic literatures reviews in previous NICE STA evaluations.
   * A targeted evidence review for data input parameters and natural history for the economic evaluation, based on systematic literature reviews in previous NICE STA evaluations.
   * A targeted review of retrospective real world evidence of people with NSCLC will be undertaken, depending on availability of evidence.
6. The EAG and the internal team at NICE will be given unredacted access to previous NICE STA evaluations (the original submitting company will be notified) to inform the model development and evidence synthesis but any confidential data that was previously redacted will not be used in the model or evidence synthesis, unless found to be publicly available or the data owners give permission for its use in the pathway.
7. An economic model(s) will be constructed in Microsoft Excel to model the progression and outcomes of the disease.
8. The EAG and NICE will incorporate relevant stakeholder evidence into the model and evidence syntheses, where appropriate.
9. Model development and validation will be completed during phase 2. Validation will be aligned with the guidance development manual. It is expected that model outputs will be compared to the data used as model inputs (including any real world evidence), to ensure accuracy of model structure and data derivation. The model will then be compared to the projections from other models previously used for NICE technology appraisals in the same decision node. Previous models submitted to NICE in the pathway may be used for validation purposes. Scenario analyses may encompass values from previous submissions within a range.
10. The EAG and NICE will create a confidential appendix to its report where necessary, which would include confidential price discounts or confidential data submitted by stakeholders. This will only be shared with NICE and the committee.
11. The EAG and NICE will develop a final report, presenting an assessment of the publicly available clinical outcomes and costs throughout the included decision points of the NSCLC disease pathway. The report will also detail the expected model structure and document and justify any expected assumptions transparently.
12. The final report will be produced and sent to stakeholders to provide comments. An executable model will also be produced and sent to stakeholders to provide comments. The model will contain the functionality to implement scenarios representing assumptions identified by the EAG and internal NICE team. Stakeholders will have at least 10 working days to comment on the final report and request additional scenario analyses.
13. A lay summary of the final report will also be available.
14. During the consultation on the final report, NICE and the lead team committee members will also risk assess the final report and model to highlight differences in approaches and additional analyses the EAG and NICE should model.
15. Information will be handled as outlined in section 3.2 of the [interim proportionate approach methods and process guide](https://www.nice.org.uk/process/pmg40/chapter/introduction). Information marked as confidential should be kept to an absolute minimum.

**Phase 3 – Evaluation and decision making**

1. Committee papers will be assembled which contain the model, final report, and the comments received at consultation. These will be sent out to the committee in advance of the committee meeting.
2. Attendees at the committee meeting will include the committee and chair, the EAG and NICE teams, the NICE technical team and stakeholders.
3. The committee will consider the model, final report and the scenarios and assumptions provided by the EAG and NICE. It will also consider the stakeholder comments. It will conclude on its preferred assumptions which will make up the base case model.
4. The committee’s decisions on the assumptions in the model will be summarised in a pathways report and will include conclusions about the model structure, sources used to estimate baseline event rates, utilities, resource costs and severity at the different decision points. The pathways report will be sent to stakeholders to provide comments, aligning with the principles in section 7 of the guidance development manual.
5. Any comments received will be considered at a second committee meeting, if a discussion with the committee is needed. The model will be updated in line with the committee preferences and will become the final model of the first iteration of the NSCLC pathways approach.

**Phase 4 – Maintenance and recommendations**

1. Following conclusion of phase 3 it is anticipated that the maintenance phase of the NSCLC pathway will begin. It is expected that the final model will be used for the assessment of new medicines, significant license extensions, or reviews of existing NICE guidance indicated for included decision spaces in the first iteration of the NSCLC pathway approach.
2. NICE are currently considering options as to how this phase will be delivered. An updated interim process statement will be released by NICE before this phase to cover the aims, objectives and activities of the maintenance phase. To inform the development of this phase of the project NICE will facilitate engagement with stakeholders.