Service Notification in response to DHSSPS endorsed NICE Technology Appraisal

Health and Social Care Board

NICE TA 258: **Erlotinib for the first-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small-cell lung cancer**

1 Name of Commissioning Team

Specialist Services Commissioning Team

2 Summary of NICE TA 258

Erlotinib is recommended as an option for the first-line treatment of people with locally advanced or metastatic non-small-cell lung cancer (NSCLC) if:

- they test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation **and**
- the manufacturer provides erlotinib at the discounted price agreed under the patient access scheme (as revised in 2012)

Erlotinib is not considered a major change in treatment, but is an incremental advance.

3 Number of people in Northern Ireland expected to take up service/therapy (new cases per year)

There are likely to be 14 patients eligible to take up treatment with erlotinib for this indication annually (See Table 1).

Table 1 Number of people eligible to receive erlotinib

Description	**Percentage**	**Number of people (NI)**
Total population		1,775,003
Incidence of lung cancer	0.06%	1,065
Proportion and number of confirmed NSCLC	80%	852
Proportion and number of people presenting with stage III (advanced) or stage IV (metastatic) NSCLC	78.17%	666
Proportion and number of people with stage III or stage IV lung cancer who receive chemotherapy as first-line treatment	23%	153
Proportion and number of people expected to have EGFR-TK mutation status results that may be evaluated	60%	92
Proportion and number of people expected to have a positive EGFR-TK mutation status	15%	14
Estimated total number of people eligible to receive erlotinib as first-line treatment		14

4	**Outcomes**
4.1	**Additional life expectancy gain / progress improvement** The EURTAC trial found a median progression-free survival of 9.7 months with erlotinib. The median overall survival was 19.3 months with erlotinib.
4.2	**Reduction in morbidity** The main aim of treatment of people with locally advanced or metastatic EGFR-TK mutation-positive NSCLC is to extend progression-free and overall survival with the fewest adverse reactions and with the best quality of life possible for the remaining months of life. For this patient population an oral treatment with a tyrosine kinase inhibitor, such as gefitinib or erlotinib, is usually associated with an improved quality of life compared with platinum doublet chemotherapy.
4.3	**Cost per patient per annum** A patient access scheme (revised 2012) has been agreed with the Department of Health and is in place for erlotinib. Trust/s will ensure they avail of this scheme. NICE concluded that implementation of this guidance is unlikely to result in a significant change in resource use in the NHS. This is because erlotinib represents a *treatment option* for people with locally advanced or metastatic epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive NSCLC and the cost of treatment with erlotinib will not be significantly different to the cost of the current standard treatment with gefitinib.
4.4	**In year cost per patient per annum (for new and prevalent cases)** A patient access scheme (revised 2012) has been agreed with the Department of Health and is in place for erlotinib. Trust/s will ensure they avail of this scheme. NICE have concluded that implementation of this guidance is unlikely to result in a significant change in resource use in the NHS. This is because erlotinib represents a *treatment option* for people with locally advanced or metastatic epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive NSCLC and the cost of treatment with erlotinib will not be significantly different to the cost of the current standard treatment with gefitinib.
4.5	**Any cost savings and how these will be secured** None expected

4.6	**Recurrent overall cost** A patient access scheme (revised 2012) has been agreed with the Department of Health and is in place for erlotinib. Trust/s will ensure they avail of this scheme. NICE have concluded that implementation of this guidance is unlikely to result in a significant change in resource use in the NHS. This is because erlotinib represents a *treatment option* for people with locally advanced or metastatic epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive NSCLC and the cost of treatment with erlotinib will not be significantly different to the cost of the current standard treatment with gefitinib.
4.7	**Cost per QALY** Results from the manufacturer's base-case analyses (including the discount under the patient access scheme as revised in 2012) for erlotinib compared with gefitinib show an incremental cost-effectiveness ratio (ICER) of £21,874 per QALY gained.
4.8	**Other treatments available for this condition** Current standard practice for the first-line treatment of locally advanced or metastatic EGFR-TK mutation positive NSCLC is gefitinib. The Committee concluded there was insufficient evidence to suggest a difference in clinical effectiveness between erlotinib and gefitinib and it heard from clinical specialists that erlotinib and gefitinib are very similar treatments with similar efficacy. The Committee concluded that the cost effectiveness of erlotinib compared with gefitinib could be best assessed from the updated economic model which assumes equal clinical benefit for the treatments and focuses on their differential costs. The Committee agreed that the results from the economic model showed that on balance the sums of money lost or saved are small given the uncertainties in the analysis, and so it recommended erlotinib as a treatment option. The adverse reactions associated with erlotinib and gefitinib are modest but slightly different. NICE concluded that the adverse reactions associated with erlotinib were relatively mild in most patients and that from a clinical perspective there may be some advantage to having a choice of tyrosine kinase inhibitors for this patient group.
4.9	**Readiness to implement** This is an oral formulation which supports early implementation. There is no reason which would delay implementation. Trusts are currently able to offer erlotinib in line with NICE criteria as a treatment option.

5	**DHSSPS Legislative / Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.
6	**What will Commissioning Team do to secure funding for the implementation of this TA including any proposals for disinvestment** A patient access scheme (revised 2012) has been agreed with the Department of Health and is in place for erlotinib. Trust/s will ensure they avail of this scheme. NICE have concluded that implementation of this guidance is unlikely to result in a significant change in resource use in the NHS. This is because erlotinib represents a *treatment option* for people with locally advanced or metastatic epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive NSCLC and the cost of treatment with erlotinib will not be significantly different to the cost of the current standard treatment with gefitinib.
7	**Commissioning arrangements** Following final policy endorsement by the DHSSPSNI and agreement the regime can be consolidated into the core commissioning arrangements in place for cancer drugs.
8	**Monitoring arrangements** HSCB currently reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team. SSCT has a long-established working relationship with NICaN D&T committee, which meets on a bi-monthly basis. Service monitoring including the review of the quarterly monitoring of data returns is a key function of this group. Progress with the implementation of this regime will be formally reported at the annual presentation by the NICaN D&T committee to the Specialist Services Commissioning Team.