AstraZeneca proposal for a Patient Access Scheme

1 Overview

- The AZ Innovative Pricing Proposition delivers a flexible solution for the NHS, patients and government by improving patient outcomes through the access and uptake of new cancer medicines.
- A one-off fixed payment allows stakeholders to know the budgetary impact of using a new AstraZeneca cancer medicine regardless of patient survival and treatment duration. Over time the Fixed Price may be adjusted (within 2009 PPRS provisions) to reflect the patient benefits of gefitinib.
- This proposition uses a simple anonymised registry that will help the NHS to realise the value of AZ cancer medicines based on real life data. The registry, for which AstraZeneca will be responsible, will be maintained and reviewed independently by a third party.

2 Background

The 2009 PPRS makes provision for schemes to provide patient access to medicines unlikely to be deemed cost-effective at list price. We wish to propose a patient access scheme for gefitinib in the treatment of non-small cell lung cancer (NSCLC).

3 Glossary of Terms

NHS List Price	The Drug Tariff price for a pack of 30 Tablets
Fixed Price	The total cost of gefitinib, regardless of duration of treatment
Third Party	The party identified by AstraZeneca responsible for capturing Registry Data, and where required, delivering medicine to the hospital (or patient if requested)
Registry Data	The data used to track patient outcomes (progression-free survival, overall survival, and duration of treatment)

4 Timings

AstraZeneca will submit an evidence package for gefitinib to NICE in May 2009 as part of the STA process. We anticipate obtaining a marketing authorisation in June 2009. We wish to seek DH approval of our proposed scheme prior to HTA submission in May 2009.

5 Details of the scheme

We propose to charge the NHS a single Fixed Price for each patient treated with gefitinib. This fee will include the entire cost of gefitinib for the life of the patient, irrespective of treatment duration. For clarity the Fixed Price does not include any other elements of care. NB Patients with NSCLC are usually treated for a few months before the disease progresses, and treatment is discontinued.

5.1 Gefitinib pricing

1. AstraZeneca set NHS List price in the usual way
2. AstraZeneca set the Fixed Price and incorporate this into the economic sections of the scheduled NICE STA submission. The Fixed Price and the NHS List Price will not be directly linked. The Fixed Price will contain an element of discount (compared with the List Price multiplied by the average progression free survival) sufficient to achieve cost-effectiveness.
3. NICE review the submission in line with existing methodology and decide whether or not gefitinib should be made available to NHS patients

4. Assuming a successful outcome (of the NICE HTA process) gefitinib will be made available to the NHS on the basis described in the section 'How it Will Work'

5.2 Prescription and data flow

1. Oncologist prescribes gefitinib using the hospital's existing prescription system. AstraZeneca will provide a simple form, which captures a limited number of data fields. Personal data will not be collected. The patient's Hospital Number will be used as a means of tracking patients in order to ensure anonymity.
2. The prescription will be dispensed by the hospital pharmacy. Where data are collected, these will be sent by the hospital to the Third Party by the hospital pharmacy. AstraZeneca will ensure that this process is compliant with the Data Protection Act.
3. The patient will be reviewed on a monthly basis by their oncologist, as per the current standard treatment protocol
4. If the hospital has chosen to participate in the registry, the following key data points will be captured:
    a. The date that the patient's disease progresses
    b. The date that gefitinib is discontinued
    c. The date of death
5. The patient specific data points will be sent to a third party, who will capture the anonymised data on a simple registry, thereby minimising any administrative burden on the hospital. AstraZeneca will be responsible for the provision of running costs associated with the registry and data collection.

5.3 Financial flows

The scheme is compatible with current NHS financial flows. The hospital will reclaim the cost of treatment from the PCT in the usual way (local "high cost drug" arrangements).

6 How it will work

We propose to use the data collected in the registry to revise the Fixed Price of gefitinib after around three years, at the time when NICE would normally re-review. We undertake not to change the Fixed Price prior to an agreed NICE review. The mechanism for reviewing the Fixed Price would be:

1. Provision of the relevant data points from the registry (Overall Survival, Progression Free Survival, Duration of Treatment) by The Third Party to AstraZeneca.
2. AstraZeneca enter data points into the Cost-Effectiveness Model, which was used for the original economic sections of the NICE STA Submission and include this in the scheduled NICE submission.
3. AstraZeneca derive a revised Fixed Price for gefitinib and include both it, and the justification within the economic section of the scheduled NICE review.
4. Assuming a successful outcome of the scheduled NICE review, the gefitinib Fixed Price would be reset or revised.
5. The list price would be unchanged, unless under exceptional circumstances, where AstraZeneca would request a change under the flexible pricing provisions of 2009 PPRS.

For audit purposes, the NHS may access the registry data at any time. It is envisaged that an analysis of the data will be available twice per year to hospitals. Data will be anonymised, but it is envisaged that an individual hospital would be able to see how its patients fared on treatment with gefitinib relative to the national dataset. Hospital to Hospital comparisons would not be supported.