Provision of plasma testing for the EGFR and EGFR T790M mutation in patients with locally advanced or metastatic non-small cell lung cancer in the UK

Key Facts at a Glance

- AstraZeneca is supporting the provision of plasma testing for the EGFR and any associated EGFR T790M resistant mutation in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)
- Plasma testing is less invasive, and can potentially provide faster results, than a tissue biopsy
- Plasma testing will be provided in eight laboratories in different cities, providing access for patients in England, Scotland, Wales and Northern Ireland

AstraZeneca is providing funding for epidermal growth factor receptor (EGFR) plasma blood testing service on the NHS for patients with advanced non-small cell lung cancer.

7. NICE Medtech innovation briefing [MBB137] - Plasma EGFR mutation tests for adults with locally advanced or metastatic non-small-cell lung cancer. Published date: January 2018

The Challenge

In patients with advanced non-small cell lung cancer (NSCLC), several mutations in genes which drive the growth of the tumour have been identified. One example is a mutation in the epidermal growth factor receptor (EGFR) gene.1,2,3

Physicians perform diagnostic testing, in the form of a tumour biopsy, to look for the presence or absence of the EGFR mutation (EGFRm) in patients with advanced NSCLC. These results help guide treatment decisions.4,5 If patients with advanced NSCLC are found to harbour the EGFR mutation they will be started on epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKI) as a first-line treatment.4,5

Conducting a tissue biopsy can be challenging for some patients, for example those who are unwell or when the tumour is in a difficult site to reach. Many patients will have circulating tumour DNA (ctDNA) present in the blood which can be tested using a blood sample (plasma testing). This provides a potential alternative to tumour biopsy at the point of primary diagnosis and at disease progression.6 Although the detection rates from plasma testing can be variable, this is a less invasive and potentially a quicker procedure than a tissue biopsy, so can support testing in patients who would not otherwise have had a test.
The Steps Taken
To support testing of UK patients with advanced NSCLC, AstraZeneca has provided funding on an interim basis for an EGFR plasma testing service. Originally, support was offered until 31st December 2017, to support set up and implementation of the service, but by 31st March 2019 the MEGS testing service will been closed.

AstraZeneca’s funding has been used to support plasma testing in eight laboratories in England, one in Wales, two in Scotland and one in Northern Ireland.

Any clinician can refer patients for ctDNA testing who have a confirmed diagnosis of advanced NSCLC, presenting with advanced non-small cell lung cancer or showing signs of disease progression whilst on first line treatment with an EGFR TKI.

The introduction of plasma testing provides a range of patient and clinician benefits including:

• Potentially providing results in a timely manner as it removes the need for a tissue biopsy in certain circumstances.7
• Plasma EGFR mutation tests do not need a biopsy to be taken and are less invasive than a tissue biopsy for patients.7
• They can provide testing in people who are unable to, or do not wish to, have an invasive tissue biopsy and whose disease otherwise would remain untested.7 People may have a lack of available tumour tissue, low-quality tissue sample or poor health making a tissue biopsy infeasible; about 30% of biopsies are classified as 'failed' (PHG Foundation 2017).7
• More than 15% of people with NSCLC in the UK do not have a histological confirmation of their diagnosis, (National Lung Cancer audit report 2016). PlasmaEGFR testing will support increased confirmation and specification which is important for determining treatment, as oncologic treatments are increasingly determined by histologic subtyping and molecular analysis.8

• Plasma EGFR mutation testing also avoids problems with tumour evolution and heterogeneity, when the presence of mutations may be missed in a biopsy of a single metastatic site or from using an existing sample.7
• Plasma testing can be repeated easily, allowing for mutation monitoring in people having EGFR-TKI therapy. This method can also detect resistance mutations. Quantitative plasma EGFR mutation tests can measure the levels of ctDNA, which may be a good predictor of treatment response. This is still being researched and not in clinical use.7

What We Achieved
• Between April 2017 and September 2018, there have been approximately 1,348 samples analysed
• Current laboratories providing ctDNA EGFR testing are in Aberdeen, Edinburgh, Belfast, Cardiff, Manchester, Birmingham, Guilford, and The Royal Marsden.