The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.*** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

**Description**

Epidermal growth factor receptor (EGFR) is a receptor tyrosine kinase (TK) frequently over-expressed and activated in non-small cell lung cancer (NSCLC). Mutations in two regions of the EGFR gene (exons 18-24)—small deletions in exon 19 and a point mutation in exon 21 (L858R)—appear to predict tumor response to tyrosine kinase inhibitors (TKIs) such as erlotinib. This Protocol summarizes the evidence for using EGFR mutations to decide which patients with advanced NSCLC should be considered for erlotinib therapy and which are better suited for alternative therapies.

**Corporate Medical Guideline**

Except as noted below, analysis of two types of somatic mutation within the EGRF gene—small deletions in exon 19 and a point mutation in exon 21 (L858R) may be considered **medically necessary** to predict treatment response to erlotinib in patients with advanced NSCLC.

Analysis of two types of somatic mutation within the EGRF gene—small deletions in exon 19 and a point mutation in exon 21 (L858R) is considered **investigational** for patients with advanced NSCLC of squamous cell-type.

Analysis for other mutations within exons 18-24, or other applications related to NSCLC is considered **investigational**.

**Policy Guideline**

The test is intended for use in patients with advanced NSCLC. Patients with either small deletions in exon 19 or a point mutations in exon 21 (L858R) of the tyrosine kinase domain of the epidermal growth factor gene are considered good candidates for treatment with erlotinib. Patients found to be wild type are unlikely to respond to erlotinib; other treatment options should be considered.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. **For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.**
It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


