

## Corporate Medical Policy

### Epidermal Growth Factor Receptor (EGFR) Mutation Analysis for Patients with Non-Small Cell Lung Cancer (NSCLC)

**File Name:** epidermal\_growth\_factor\_receptor\_mutation\_analysis  
**Origination:** 4/12/11  
**Last CAP Review:** 8/2011  
**Next CAP Review:** 8/2012  
**Last Review:** 8/2011

#### Description of Procedure or Service

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Epidermal growth factor receptor (EGFR) is a receptor tyrosine kinase (TK) frequently overexpressed 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 policy 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.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**BCBSNC will provide coverage for epidermal growth factor receptor mutation analysis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

#### When Epidermal Growth Factor Receptor Mutation Analysis is covered

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Analysis of two types of somatic mutation within the EGFR 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.

#### When Epidermal Growth Factor Receptor Mutation Analysis is not covered

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Analysis of two types of somatic mutation within the EGFR 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.

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

## Policy Guidelines

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The test is intended for use in patients with advanced NSCLC. Patients with either small deletions in exon 19 or a point mutation 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.

Both nonconcurrent prospective and one-armed enrichment studies demonstrate that the detection of EGFR gene mutations identifies patients who are likely to benefit from use of erlotinib and who therefore represent ideal candidates for treatment with this drug. Patients who are found to have wild-type tumors are unlikely to respond to erlotinib. They should be considered candidates for alternative therapies. These observations have been made in a population composed primarily of tumors with adenocarcinoma histology. There is currently no evidence to indicate whether this behavior is also seen in patients with squamous cell histology.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: There is no specific code for this service.*

*This laboratory test would likely be coded using a series of nonspecific genetic testing codes. Providers may use a series of the following CPT codes: 83891, 83896, 83898, 83901, 83907, 83912, 88313, 88323, and/or 88381*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.45, 1/13/2011

Medical Director – 3/2011

Specialty Matched Consultant Advisory Panel – 8/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.45, 1/12/2012

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## Policy Implementation/Update Information

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- 4/12/11 New policy. Medical Director review 3/23/11. "Except as noted below, analysis of two types of somatic mutation within the EGFR 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 EGFR 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." Notification given 4/12/2011 Policy effective 7/19/2011. (btw)
- 9/30/11 Specialty Matched Consultant Advisory Panel review 8/31/2011. No change to policy. (btw)
- 4/17/12 Reference added. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.