Medical Policy

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

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Policy Number: 563
BCBSA Reference Number: 2.04.45

Related Policies
None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue SM and Medicare PPO Blue SM Members

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 MEDICALLY NECESSARY to predict treatment response to erlotinib or afatinib 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) for patients with advanced NSCLC of squamous cell-type, is INVESTIGATIONAL.

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

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>No</td>
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<td>Commercial PPO and Indemnity</td>
<td>No</td>
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<tr>
<td>Medicare HMO Blue SM</td>
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<td>Medicare PPO Blue SM</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>81235</td>
<td>EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)</td>
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Description
Epidermal growth factor receptor (EGFR) is a receptor tyrosine kinase 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 such as erlotinib.

Treatment options for NSCLC depend on disease stage and include various combinations of surgery, radiation therapy, chemotherapy, and best supportive care. In up to 85% of cases the cancer has spread locally beyond the lungs at diagnosis, precluding surgical eradication. Additionally, up to 40% of patients with NSCLC present with metastatic disease. When treated with standard platinum-based chemotherapy, patients with advanced NSCLC have a median survival of 8 to 11 months and a 1-year survival of 30 to 45%. Studies have shown that therapeutic interdiction of the EGFR pathway could be used to halt tumor growth in solid tumors that express EGFR.

Summary
Non-concurrent prospective studies, single-arm enrichment studies, and one small randomized study 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. 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.

Patients who are found to have wild-type tumors are unlikely to respond to erlotinib. They should be considered candidates for alternative therapies.

EGFR mutational analysis may be considered medically necessary to predict treatment response to erlotinib in patients with advanced NSCLC; however, EGFR mutational analysis is investigational in patients with NSCLC of squamous-cell type.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>7/2014</td>
<td>BCBSA National medical policy review. Medically necessary indications updated to include afatinib. Effective 7/1/2014.</td>
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<tr>
<td>2/2013</td>
<td>New references from BCBSA National medical policy.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


