



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2016
LAST REVIEW DATE: 8/19/2021
LAST CRITERIA REVISION DATE: 8/19/2021
ARCHIVE DATE:

IRESSA® (gefitinib) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2016
LAST REVIEW DATE: 8/19/2021
LAST CRITERIA REVISION DATE: 8/19/2021
ARCHIVE DATE:

IRESSA® (gefitinib) oral

Criteria:

- **Criteria for initial therapy:** Iressa (gefitinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - a. Metastatic non-small cell lung cancer (**NSCLC**) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions **OR** exon 21 (L858R) substitution mutations as detected by an FDA-approved test
 - b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Eastern Cooperative Oncology Group (ECOG) Performance Status (also known as World Health Organization Performance Status) of 0-2
 5. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Iressa (gefitinib) is considered *medically necessary* and will be approved with documentation of **ALL** of the following:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual's condition responded while on therapy
 - a. Response is defined as:
 - i. No evidence of disease progression
 - ii. Documented evidence of efficacy, disease stability and/or improvement
 3. Individual has been adherent with the medication



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2016
LAST REVIEW DATE: 8/19/2021
LAST CRITERIA REVISION DATE: 8/19/2021
ARCHIVE DATE:

IRESSA® (gefitinib) oral

4. Individual has not developed any significant adverse drug effects that may exclude continued use
 - a. Significant adverse effect such as:
 - i. Confirmed interstitial lung disease
 - ii. Severe hepatic impairment (Child-Pugh Class C)
 - iii. Gastrointestinal perforation
 - iv. Persistent ulcerative keratitis or other severe or worsening ocular disorder
 - v. Severe bullous, blistering or exfoliative skin disorder
5. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Iressa (gefitinib) is a tyrosine kinase inhibitor indicated for the first line treatment of metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. The safety and efficacy of Iressa (gefitinib) have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

The epidermal growth factor receptor (EGFR) is expressed on the cell surface of both normal and cancer cells and plays a role in the processes of cell growth and proliferation. Some EGFR activating mutations (exon 19 deletion or exon 21 point mutation L858R) within NSCLC cells have been identified as contributing to the promotion of tumor cell growth, blocking of apoptosis, increasing the production of angiogenic factors and facilitating the processes of metastasis.

Gefitinib reversibly inhibits the kinase activity of wild-type and certain activating mutations of EGFR, preventing autophosphorylation of tyrosine residues associated with the receptor, thereby inhibiting further downstream signaling and blocking EGFR-dependent proliferation.

Gefitinib offers a new chemotherapeutic agent with a unique mechanism of action. It is indicated as monotherapy for the treatment of patients with locally advanced or metastatic NSCLC after failure of both platinum-based and docetaxel chemotherapies. The FDA believes that the potential benefit of this agent in these patients outweighs the risk of its pulmonary toxicity, while some special interest groups do not support this decision.



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2016
LAST REVIEW DATE: 8/19/2021
LAST CRITERIA REVISION DATE: 8/19/2021
ARCHIVE DATE:

IRESSA[®] (gefitinib) oral

Resources:

Iressa (gefitinib) product information, revised by AstraZeneca Pharmaceuticals, LP 05-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on June 23, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]): Non-small cell lung cancer. Version 5.2021 – Updated June 15, 2021. Available at <https://www.nccn.org>. Accessed on June 23, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.
