

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
 Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP  
2

Diagnosis	<input type="checkbox"/> Non Small Cell Lung Cancer	<input type="checkbox"/> Other (please state):
	Indicate if the cancer progressed despite prior regimens with docetaxel and platinum based chemotherapy [Platinol (cisplatin), Paraplatin (carboplatin), Eloxatin (oxaliplatin),] <input type="checkbox"/> YES <input type="checkbox"/> NO	
Physician Specialty	<input type="checkbox"/> Oncologist	<input type="checkbox"/> Other (please state):
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Iressa <sup>®</sup> (gefitinib) Strength _____ Sig _____ Qty _____ Refills _____	
	Please attach all relevant medical records and test results. <b>Incomplete forms will not be processed.</b>	

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge (please sign and date).**

\_\_\_\_\_  
 Prescriber Signature \_\_\_\_\_  
 Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:  
 970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

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## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Iressa (gefitinib)

#### CLASSIFICATION

- Antineoplastic, tyrosine kinase inhibitor

#### DESCRIPTION

- The mechanism of the clinical antitumor action of gefitinib is not fully characterized. Gefitinib inhibits the intracellular phosphorylation of numerous tyrosine kinases associated with transmembrane cell surface receptors. This includes the tyrosine kinases associated with the epidermal growth factor receptor (EGFR-TK), which is expressed on the cell surface of many normal cells and cancer cells.
- Single-agent gefitinib, 250 milligrams (IDEAL trial), is FDA approved as third- line therapy after failure of both platinum-based and docetaxel chemotherapies in patients with locally advanced/metastatic non-small cell lung cancer. Data from the INTACT trial demonstrated no benefit (tumor response rate, time to progression, or overall survival) in patients receiving gefitinib in combination with doublet chemotherapy (carboplatin/paclitaxel or gemcitabine/cisplatin) as first-line therapy in patients with non-small cell lung cancer
- Large trials are or have investigated the antitumor efficacy of gefitinib (usually in combination regimens with cytotoxic agents) in glioblastoma, head and neck cancer, renal-cell carcinoma, colorectal carcinoma, ovarian carcinoma, transitional-cell carcinoma, endometrial carcinoma, breast cancer, and prostate cancer. Combinations of gefitinib and trastuzumab are also under investigation. Results of these trials will clarify the role of this agent.
- Additional investigations are needed to clarify the mechanisms of gefitinib, contribution of erbB-2 receptor (and cooperation of EGFR and erbB-2) in various tumor types, and clinical efficacy of gefitinib in erbB-2 overexpressing cancers. Based on pharmacokinetic data, plasma levels high enough to inhibit erbB-2 may not be achievable with recommended oral doses.

#### FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: T4

Commercial Formulary: T4

Medicare Part D coverage: T4

#### COVERAGE CRITERIA

Iressa (gefitinib) meets the definition of **medical necessity** for the following:

- Non-small cell lung cancer, Continued monotherapy in patients with locally advanced/metastatic NSCLC who have failed both platinum and docetaxel-based chemotherapies, or in patients who are or have benefited from gefitinib

Iressa (gefitinib) is considered **experimental** for the following:

- Hormone refractory prostate cancer
- Non-small cell lung cancer, Advanced or metastatic, first-line treatment as monotherapy
- Non-small cell lung cancer, Combination therapy

Required Provider Specialty:

- Approval is limited to Oncology

## DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established):

- Non-small cell lung cancer, Continued monotherapy in patients with locally advanced/metastatic NSCLC who have failed both platinum and docetaxel-based chemotherapies, or in patients who are or have benefited from gefitinib: 250 mg orally once daily

Notes:

- Higher doses than 250 mg orally once daily have not improved clinical benefit and can increase toxicity

Dosing adjustments:

- Dermatologic toxicities: consider holding (for up to 2 wks) gefitinib in patients with severe skin reactions; re-institute at 250 mg/day
- Enzyme induction: consider increasing the dose of gefitinib to 500 mg in pts on concurrent potent enzyme inducers (CYP3A4) (ie. rifampicin, phenytoin)
- Gastrointestinal toxicities: consider holding (for up to 2 wks) gefitinib in patients with poorly tolerated diarrhea; re-institute at 250 mg/day
- Ocular toxicities: patients who experience new onset eye symptoms should be medically evaluated and have gefitinib therapy interrupted; remove aberrant eyelash if present (a clinical decision to re-institute gefitinib 250 mg therapy should be made)
- Pulmonary toxicities: interrupt gefitinib therapy, investigate, and treat pts who experience acute onset/worsening of pulmonary symptoms; discontinue therapy if a diagnosis of interstitial lung disease is confirmed
- Renal impairment: use caution in patients with severe renal impairment; no dosing guidelines exist

## PRECAUTIONS:

- Hepatic insufficiency; gefitinib has exhibited asymptomatic increases in liver transaminases
- Interstitial lung disease, interstitial pneumonia, pneumonitis, and alveolitis; rare but can be fatal
- Patients with squamous cell carcinoma of the head and neck; increased risk of tumor hemorrhage
- Pulmonary fibrosis; risk of interstitial lung disease and increased mortality if condition worsens

## Billing/Coding information

- n/a

## COST

- AWP (April 2010): Iressa 250 mg tablets (30): \$2,042.40

## COMMITTEE APPROVAL:

## GUIDELINE UPDATE INFORMATION:

April 2010	Policy created

## REFERENCES:

- DRUGDEX®, accessed 04/02/2010
- Product Information: IRESSA(R) oral tablets, gefitinib oral tablets. AstraZeneca Pharmaceuticals, Wilmington, DE, 2004.