ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Tarceva® (erlotinib) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Tarceva® (erlotinib)

Diagnosis (documentation supportive of diagnosis is required)

☐ **Pancreatic Cancer (please indicate):**

☐ Locally advanced, unresectable, or metastatic pancreatic cancer, as 1st-line treatment in combination with gemcitabine ***(documentation supportive of diagnosis and use of Tarceva + gemcitabine required)***

☐ **NSCLC (please indicate):**

☐ Monotherapy for the treatment of locally advanced or metastatic NSCLC ***(documentation is required showing failure of at least one prior chemotherapy regimen)***

☐ Monotherapy for maintenance in locally advanced or metastatic NSCLC ***(documentation is required showing no disease progression following 4 cycles of platinum-based first-line chemotherapy)***

☐ 1st line treatment for metastatic NSCLC ***(documentation of EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA approved test is required)***

☐ Other (please state): _____

Physician Specialty

☐ Oncology

☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

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

Tarceva (erlotinib)

CLASSIFICATION

- Antineoplastic, tyrosine kinase inhibitor

DESCRIPTION

- Erlotinib hydrochloride reversibly inhibits tyrosine kinase activity of the epidermal growth factor receptor (EGFR), which results in the inhibition of autophosphorylation of tyrosine residues associated with EGFR and dampened tumor cell signalling, survival, and proliferation. Binding affinity for EGFR exon 19 deletion or exon 21 substitution (L858R) mutations is higher than binding affinity for the wild type receptor. Erlotinib inhibition of other tyrosine kinase receptors has not been fully characterized.
- Erlotinib is a quinazoline derivative chemically similar to gefitinib and with similar pharmacologic activity. The binding site of erlotinib has been demonstrated to be the intracellular kinase domain of the EGFR. The activity of erlotinib against EGFR tyrosine kinase is at least 1000-fold that of other human kinases (e.g. c-src). It is about 10 times as potent as gefitinib.
- Limitations of Use: TARCEVA is not recommended for use in combination with platinum-based chemotherapy. Safety and efficacy of TARCEVA have not been evaluated as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

Non-Small Cell Lung Cancer - Locally Advanced or Metastatic Disease, Monotherapy:

- Erlotinib was effective in prolonging progression free survival in a randomized, double-blind, placebo-controlled trial in patients with locally advanced or metastatic NSCLC whose disease did not progress during first-line platinum-based chemotherapy (n=889). Progression free survival was significantly prolonged in patients who received maintenance therapy with erlotinib compared with patients who received placebo (2.8 months vs 2.6 months; $p < 0.0001$). Additionally, progression-free survival was significantly improved in patients who were EGFR immunohistochemistry (EGFR IHC) positive and received erlotinib compared EGFR IHC patients who received placebo (hazard ratio, 0.69; 95% CI, 0.58 to 0.82).
- Erlotinib was effective in prolonging survival in a randomized, placebo-controlled trial in patients with stage IIIB/IV NSCLC following failure of first or second line chemotherapy. Overall survival was significantly improved in the erlotinib arm versus the placebo arm (6.7 months versus 4.7 months; p=0.001), respectively.
- Survival and other treatment outcomes were not improved with the combination of erlotinib plus chemotherapy in 2 placebo-controlled, randomized trials.

Non-Small Cell Lung Cancer - Epidermal Growth Factor Receptor Mutation-positive Metastatic Disease, First-Line Treatment:

- Erlotinib is indicated for first-line treatment of metastatic non-small cell lung cancer in adults whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a US FDA-approved test.
- Erlotinib statistically significantly improved progression-free survival compared with standard chemotherapy (9.7 vs 5.2 months) in predominantly white adults with EGFR mutation-positive, NSCLC in the multicenter, open-label, randomized, phase 3 European Tarceva versus Chemotherapy trial (EURTAC; n=174).

Pancreatic Cancer:

- Erlotinib is indicated, in combination with gemcitabine, for the first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer.
- In a large, randomized trial, erlotinib in combination with gemcitabine significantly increased overall survival and progression-free survival compared with gemcitabine alone for the first-line treatment of patients with locally advanced or metastatic pancreatic cancer.
- In a randomized study, capecitabine plus erlotinib (first-line) followed by gemcitabine (second-line) compared with gemcitabine plus erlotinib (first-line) followed by capecitabine (second-line) produced a noninferior time to treatment failure (TTF) after first- and second-line therapy (TTF2), but TTF after first-line therapy was significantly better with gemcitabine plus erlotinib followed by capecitabine.
- EGFR family overexpression has been observed in numerous human cancers, including breast, prostate, renal-cell, hepatocellular, gastric, non-small cell lung, bladder, and ovarian carcinomas, and this overexpression has correlated with more aggressive tumor activity and poor clinical outcome; EGFR tyrosine kinase activation has been identified as a key initiating event for cell proliferation.
- The National Comprehensive Cancer Network recommends testing for EGFR mutations and ALK gene rearrangements to allow effective treatment for genetic abnormalities identified. EGFR mutations commonly found in patients with NSCLC are deletions in exon 19 and a mutation in exon 21. Both result in activation of the tyrosine kinase domain and are associated with sensitivity to the small molecule TKIs, erlotinib and gefitinib. Patients with wild-type EGFR have poorer outcomes.
- Chemotherapeutic efficacy may be adversely affected with the addition of erlotinib to chemotherapy in patients with K-ras mutations.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Tarceva® (erlotinib) meets the definition of **medical necessity** for any FDA approved indication not otherwise excluded from Part D including the following:

FOR PANCREATIC CANCER:

- Locally advanced, unresectable or metastatic pancreatic cancer, as 1st-line treatment in combination with gemcitabine. (Documentation of diagnosis and treatment regimen required).

FOR NSCLC (documentation supportive of diagnosis required):

- As monotherapy for treatment of locally advanced or metastatic NSCLC (Documentation is required showing failure of at least one prior chemotherapy regimen) ; **OR**
- As monotherapy for maintenance in locally advanced or metastatic NSCLC. (Documentation is required showing no disease progression following 4 cycles of platinum based first-line chemotherapy); **OR**
- For metastatic NSCLC as 1st-line treatment. (Documentation of EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA approved test is required).

Tarceva® (erlotinib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported including:
  - NSCLC, first-line use in combination with platinum-based chemotherapy.
  - Use as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.
  - Colorectal cancer
  - Glioblastoma multiforme of brain, newly diagnosed or recurrent
  - Head and neck cancer, squamous cell, recurrent and/or metastatic
  - Metastatic renal cell carcinoma
  - Ovarian carcinoma
  - Prostate cancer

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

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

- NSCLC: 150 mg ORALLY 1 hour before or 2 hours after ingestion of food once daily until disease progression or unacceptable toxicity
- Pancreatic cancer: 100 mg ORALLY 1 hour before or 2 hours after ingestion of food once daily, in combination with gemcitabine 1000 mg/m(2) IV weekly for 7 weeks followed by 1-week rest (cycle 1), then 1000 mg/m(2) IV weekly for 3 weeks followed by 1-week rest (subsequent cycles); treat until disease progression or unacceptable toxicity.

Dosing adjustments:

- Consult package insert/ prescribing information

PRECAUTIONS:

- Cerebrovascular accidents, including a fatality, have been reported.
- Dose adjustment recommended if cigarette use.
- Avoid concomitant use with CYP3A4 inducers if possible (e.g. St John wort, phenobarbital, carbamazepine, phenytoin, rifapentine, rifabutin, rifampin); dose adjustment recommended.
- Avoid concomitant use with dual CYP3A4 and CYP1A2 inhibitors if possible (e.g. ciprofloxacin); dose reduction may be required.
- Avoid concomitant use with proton pump inhibitors if possible.
- Avoid concomitant use with strong CYP3A4 inhibitors if possible (e.g. grapefruit or grapefruit juice, voriconazole, troleandomycin, telithromycin, saquinavir, ritonavir, nelfinavir, nefazodone, ketoconazole, itraconazole, indinavir, clarithromycin, atazanavir); dose reduction may be required.
- Concomitant use with warfarin; bleeding events, including fatalities, have been reported; monitoring recommended.
- Corneal perforation and severe ulceration have been reported; known risk factors include abnormal eyelash growth, keratoconjunctivitis sicca, and keratitis; discontinue use if occurs.
- Dehydration, particularly in patients at increased risk for renal failure (e.g. preexisting renal disease, advanced age) may require therapy interruption. Monitoring recommended for patients at risk of dehydration.

- Diarrhea, severe and not responsive to loperamide. Interruption of therapy and dose adjustment are recommended.
- Gastrointestinal perforation, some cases fatal, has been reported; increased risk with peptic ulceration or diverticular disease and with concomitant anti-angiogenic agents, corticosteroids, NSAIDs, and/or taxane-based chemotherapy. Permanently discontinue therapy if a GI perforation occurs.
- Hepatotoxicity, including hepatic failure, hepatorenal syndrome, and fatalities, has been reported, particularly among patients with baseline hepatic impairment; monitoring recommended; therapy interruption and discontinuation may be required.
- Patients with hepatic impairment or biliary obstruction are at increased risk for hepatotoxicity. Monitoring is recommended. Therapy interruption and discontinuation may be required.
- Interstitial lung disease (ILD), including fatal cases, has occurred; in the event of acute onset of new or progressive, unexplained pulmonary symptoms (e.g. dyspnea, cough, fever), withhold erlotinib during diagnostic evaluation; discontinue therapy if ILD confirmed.
- Keratitis, grade 3 to 4 or grade 2 for more than 2 weeks; interruption of therapy and dose adjustment recommended.
- Microangiopathic hemolytic anemia with thrombocytopenia has been reported.
- Myocardial infarction/ischemia (including a fatality) has been reported.
- Acute or worsening ocular disorders may require therapy interruption and/or discontinuation.
- Rash that is severe and not responsive to medical therapy may require interruption of therapy and dose adjustment.
- Renal insufficiency, hepatorenal syndrome, and acute renal failure (including fatalities) have been reported; hepatic impairment and severe dehydration may increase risk; monitoring recommended; therapy interruption and discontinuation may be required.
- Severe skin disorders (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis), some cases fatal, have been reported; discontinue therapy for severe bullous, blistering, or exfoliative skin conditions.

Billing/Coding information

CPT Coding:

C9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (April 2010):
  - 25mg tablet (1): $51.75
  - 100mg tablet (1): $142.13
  - 150mg tablet (1): $160.76
- AWP (January 2012):
  - 25mg tablet (1): $61.03
  - 100mg tablet (1): $167.63
  - 150mg tablet (1): $189.60

- AWP (May 2013):
  - 25mg tablet (1): $74.06
  - 100mg tablet (1): $203.41
  - 150mg tablet (1): $230.08
- AWP (May 2014):
  - 25mg tablet (1): $79.98
  - 100mg tablet (1): $219.69
  - 150mg tablet (1): $248.48

COMMITTEE APPROVAL:

- January 2005

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
January 2012	Coverage Policy updated
May 2013	Coverage Policy updated
May 2014	Coverage Policy updated

REFERENCES:

- DRUGDEX®, accessed 4/02/2010, 1/4/12, 5/31/2013, 5/11/2014
- Product Information: TARCEVA® oral tablets, erlotinib oral tablets. OSI Pharmaceuticals, Inc., Northbrook, IL, 2009, 2014.
- ©National Comprehensive Cancer Network, Inc. 2011. Non-Small Cell Lung Cancer. Version 2.2011, 10/04/11.