VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Iressa® (gefitinib tablets – AstraZeneca)

**TAC APPROVAL DATE:** 08/15/2018

## OVERVIEW

Iressa is a tyrosine kinase inhibitor (TKI) indicated for the first-line treatment of patients with 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.[1] The safety and efficacy of Iressa have not been established in patients whose tumors have other *EGFR* mutations. Iressa binding affinity for EGFR exon 19 deletion or exon 21 point mutation L858R mutations is higher than its affinity for the wild-type EGFR.

## Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 5.2018) recommend *EGFR* mutation testing in patients with nonsquamous NSCLC (i.e., adenocarcinoma, large cell) or in NSCLC not otherwise specified (NOS).[2] Tarceva® (erlotinib tablets), Iressa, Gilotrif™ (afatinib tablets), and Tagrisso™ (osimertinib tablets) are all recommended for first-line treatment in patients with sensitizing *EGFR*-mutation positive NSCLC discovered before first-line chemotherapy (all category 1). If *EGFR* mutation is discovered during first-line chemotherapy, it can be interrupted or completed and then followed by treatment with Tarceva, Iressa, Gilotrif, or Tagrisso (all category 2A). Upon progression on first-line therapy with Tarceva, Iressa, or Gilotrif, T790M mutation testing is recommended. Tagrisso is the only agent specifically FDA-approved and recommended in guidelines (category 1) for T790M-positive tumors as subsequent therapy, after progression on first-line Tarceva, Iressa, or Gilotrif. In patients with symptomatic progression to the brain or for asymptomatic progression, Tagrisso is the recommended option (category 1) or patients can be continued on Tarceva, Iressa, or Gilotrif (all category 2A). For single isolated systemic lesion can be continued on Tarceva, Iressa, or Gilotrif, in addition to considering local therapy (category 2A). For multiple systemic lesions, Tagrisso is a category 1 recommended option if T790M-positive and if it has not been previously given. For T790M-negative systemic progression, other immunotherapy or chemotherapy regimens are recommended..

## POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Iressa. All approval durations are noted below.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Iressa is recommended in those who meet the following criteria:

### FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** The patient has metastatic NSCLC; AND
   - **B)** The patient meets ONE of the following conditions (i or ii):
     - **i.** The patient has epidermal growth factor receptor (*EGFR*) exon 19 deletions as detected by an approved test; OR
     - **ii.** The patient has exon 21 (L858R) substitution mutations as detected by an approved test.

   Iressa is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a FDA-approved test.[1]

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Iressa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Iressa® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2015.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 5.2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 13, 2018.

## HISTORY

| Type of Revision | Summary of Changes* | TAC Approval Date |
|---|---|---|
| New Policy | -- | 07/22/2015 |
| Annual revision | Deleted reference to "FDA"- approved test. Criteria now just refer to an "approved test." | 08/10/2016 |
| Annual revision | No criteria changes | 08/16/2017 |
| Annual revision | No criteria changes | 08/15/2018 |

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.