

Prior Authorization DRUG Guidelines

IRESSA(Gefitinib)

Effective Date: 7/28/05

Restricted Distribution in the US

Date Developed: 7/11/05 by C. Wilhelmy

Last Approval Date: 1/27/15, 1/24/17, 1/26/16, 1/23/18, 1/22/19

(Archived 1/22/19)

Prescribing and Access Restrictions

As of September 15, 2005, distribution of gefitinib (IRESSA®) is limited to patients enrolled in the IRESSA® Access Program. Under this program, access to gefitinib will be limited to the following groups:

Patients who are currently receiving and benefiting from gefitinib

Patients who have previously received and benefited from gefitinib

Previously-enrolled patients or new patients in non-Investigational New Drug (IND) clinical trials involving gefitinib if these protocols were approved by an IRB prior to June 17, 2005

New patients may also receive gefitinib if the manufacturer (AstraZeneca) decides to make it available under IND, and the patients meet the criteria for enrollment under the IND

Additional information on the IRESSA® Access Program, including enrollment forms, may be obtained by calling AstraZeneca at 1-800-601-8933 or via the web at www.Iressa-access.com

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