DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Gefitinib Drug Quantity Management Policy – Per Rx
- Iressa® (gefitinib tablets – AstraZeneca, generic)

REVIEW DATE: 11/18/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Indication

Iressa, a tyrosine kinase inhibitor, is 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 with metastatic NSCLC whose tumors have *EGFR* mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Dosing

The recommended dose of Iressa for treatment of NSCLC is 250 mg once daily (QD).[1] The dose may need to be withheld due to adverse events, hepatic enzyme elevations or drug interactions with cytochrome P450 (CYP)3A4 inhibitors. CYP3A4 inducers may decrease gefitinib plasma concentrations. Therefore, the dose of Iressa should be increased to 500 mg QD, as tolerated, in patients taking strong CYP3A4 inducers (e.g., rifampicin, phenytoin, or tricyclic antidepressant). The dose should be decreased to 250 mg QD 7 days after discontinuation of the CYP3A4 inducer.

Availability
Iressa is available as 250 mg tablets in bottles containing 30 tablets each.[1]

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Iressa. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limit

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Iressa® (gefitinib tablets, generic)	250 mg tablets	30 tablets	90 tablets

Oncology – Gefitinib Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA
1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery. Note: CYP3A4 inducers include, but are not limited to, rifampicin, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and St. John's Wort.

REFERENCES
1. Iressa® tablets [prescribing information]. Wilmington, DE: AstraZeneca; May 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Generic gefitinib added to the policy. The same quantity limits and override criteria apply to the generic products as apply to brand Iressa. Name of the policy changed from "Oncology – Iressa Drug Quantity Management Policy – Per Rx" to "Oncology – Gefitinib Drug Quantity Management Policy – Per Rx".	11/15/2023
Annual Revision	No criteria changes.	11/18/2024