DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Tagrisso Drug Quantity Management Policy – Per Rx
- Tagrisso® (osimertinib tablets – AstraZeneca)

REVIEW DATE: 09/18/2024

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

Tagrisso, a tyrosine kinase inhibitor, is indicated for the following uses:[1]

- **Non-Small Cell Lung Cancer (NSCLC) – Epidermal growth factor rector (*EGFR*) Mutation-Positive:** First-line treatment of metastatic NSCLC tumors that have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in adults.
  - Tagrisso, **in combination with Alimta®** (pemetrexed for intravenous use) **and platinum-based chemotherapy** is indicated for the first-line treatment of locally advanced or metastatic NSCLC that have EGFR exon 19 or exon 21 L858R mutations, as detected by an FDA-approved test, in adults.
- **NSCLC – *EGFR* T790M Mutation-Positive:** Treatment of metastatic *EGFR* T790M mutation-positive NSCLC, as detected by an FDA-approved test, in adults whose disease has progressed on or after *EGFR* tyrosine kinase inhibitor (TKI) therapy.
- **NSCLC – *EGFR* Mutation-Positive, Post Tumor Resection:** Adjuvant therapy after tumor resection in adults with NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Dosing

The recommended dosing of Tagrisso is as follows[1]:

- Adjuvant treatment of EGFR mutation-positive NSCLC: 80 mg once daily (QD) for a total of 3 years or until disease recurrence or unacceptable toxicity.
- First-line treatment of EGFR mutation-positive metastatic NSCLC: 80 mg QD until disease recurrence or unacceptable toxicity.
- First-line treatment of EGFR mutation-positive locally advanced or metastatic NSCLC: 80 mg QD until disease progression or unacceptable toxicity.
- Previously treated EGFR T790M mutation-positive metastatic NSCLC: 80 mg QD until disease progression or unacceptable toxicity.

A dose reduction to 40 mg QD may be needed to manage adverse events.[1] Use of Tagrisso with strong cytochrome P450 (CYP)3A4 inducers should be avoided. However, if concurrent use is unavoidable, increase the Tagrisso dose to 160 mg QD during co-administration. Resume Tagrisso at 80 mg QD 3 weeks following the discontinuation of the strong CYP3A4 inducer.

Availability

Tagrisso is available as 40 mg and 80 mg tablets in bottles of 30 tablets each.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Tagrisso. 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.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Tagrisso® (osimertinib tablets)	40 mg tablets	30 tablets	90 tablets
	80 mg tablets	30 tablets	90 tablets

Oncology – Tagrisso 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

Tagrisso 40 mg tablets

No overrides recommended.

Tagrisso 80 mg tablets

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: Examples of strong CYP3A4 inducers include, but are not limited to, carbamazepine, phenytoin, rifampin, and St. John's wort.

REFERENCES

1. Tagrisso® tablets [prescribing information]. Wilmington, DE: AstraZeneca; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New policy was created to provide overrides to existing quantity limits.	09/18/2024