



## DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Oncology (Oral – Epidermal Growth Factor Receptor Inhibitor) – Tagrisso Drug Quantity Management Policy – Per Rx
- Tagrisso® (osimertinib tablets – AstraZeneca)

**REVIEW DATE:** 09/03/2025

### 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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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:<sup>1</sup>

- **Non-Small Cell Lung Cancer (NSCLC) – Epidermal growth factor receptor (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.
- **NSCLC – *EGFR* Mutation-Positive, Unresectable (Stage III) Disease:** Treatment of locally advanced, unresectable (stage III) NSCLC in adults whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and 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<sup>1</sup>:

- 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.<sup>1</sup> 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.<sup>1</sup>

## 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®<br>(osimertinib tablets) | 40 mg tablets     | 30 tablets                     | 90 tablets                            |
|                                    | 80 mg tablets     | 30 tablets                     | 90 tablets                            |

**EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA 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; September 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  |
| Annual Revision  | The policy name was changed from “Oncology – Tagrisso DQM Policy – Per Rx” to “Oncology (Oral – Epidermal Growth Factor Receptor Inhibitor) – Tagrisso DQM Policy – Per Rx”. | 09/03/2025  |

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