DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Daurismo Drug Quantity Management Policy – Per Rx
- Daurismo™ (glasdegib tablets – Pfizer)

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

Daurismo, a hedgehog pathway inhibitor, is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed **acute myeloid leukemia** in adults who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.[1]

Dosing

The recommended dose of Daurismo is 100 mg once daily (QD) on Days 1 through 28 in combination with cytarabine 20 mg subcutaneous (SC) twice daily (BID) on Days 1 to 10 of each 28-day cycle, until unacceptable toxicity or loss of disease control.[1] Treat for a minimum of 6 cycles to allow time for clinical response (unless unacceptable toxicity). Daurismo tablets should not be split or crushed.

To manage adverse events, the dose of Daurismo may need to be reduced (to 50 mg QD), interrupted, or discontinued.[1] Use of Daurismo with moderate or strong cytochrome P450 (CYP)3A4 inducers should be avoided. If concomitant use with moderate CYP3A4 inducers cannot be avoided, the dose of Daurismo should be increased from 100 mg QD to 200 mg QD (or from 50 mg QD to 100 mg QD). The

original Daurismo dose may be resumed 7 days after the moderate CYP3A4 inducer has been discontinued.

Availability

Daurismo is available as 100 mg tablets in bottles of 30 tablets each and 25 mg tablets in bottle of 60 tablets each.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Duarismo. 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
Daurismo™ (glasdegib tablets)	25 mg tablets	60 tablets	180 tablets
	100 mg tablets	30 tablets	90 tablets

Oncology – Daurismo 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

Daurismo 25 mg tablets

No overrides recommended.

Daurismo 100 mg tablets

1. If the patient is taking a moderate cytochrome P450 (CYP)3A4 inducer, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery. Note: Examples of moderate CYP3A4 inducers include, but are not limited to, modafinil, nafcillin, rifabutin, and St. John's wort.

REFERENCES

1. Daurismo™ tablets [prescribing information]. New York, NY: Pfizer; March 2023.

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