Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Cosela™ (trilaciclib)

Effective: July 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Cosela was based on combined data from three randomized, double-blind, placebo-controlled studies in patients with ESSCLC who were randomly assigned to receive either Cosela or placebo prior to chemotherapy. Cosela-treated patients who received had a lower chance of having severe neutropenia compared to placebo-treated patients. Among patients who had severe neutropenia, Cosela-treated patients had it for a shorter time compared to placebo-treated patients. In addition, 35% of patients treated with Cosela still required G-CSFs (67% with placebo), and overall survival was similar.

Food and Drug Administration (FDA) Approved Indications:

Cosela (trilaciclib) is a kinase inhibitor indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

Note: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline for coverage of oncology-related indications, located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Cosela for Members when all the following criteria are met:

1. Documented diagnosis of extensive-stage small cell lung cancer

AND

2. Documentation the patient is receiving a platinum/etoposide-containing regimen or topotecan containing regimen

AND

3. Patient is 18 years of age or older

Limitations

- Authorizations for Cosela will be provided in six-month intervals.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1448	Injection, Trilaciclib, 1mg

References:

1. Cosela (trilaciclib) [prescribing information]. Durham, NC: GI Therapeutics, Inc.; Aug 2023.
2. Daniel D, Kuchava V, Bondarenko I et al. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive-stage small cell lung cancer. A multicenter, randomized, double-blind, placebo-controlled phase II trial. Int J Cancer. 2020.1-14.
3. Hart LL, Ferrarotto R, Andric ZG et al. Myelopreservation with trilaciclib in patients receiving topotecan for small cell lung cancer: results from a randomized, double-Blind, placebo-controlled phase II study. *Adv Ther.* 2021; 38(1):350-65.
4. Weiss JM, Csoszi T, Maglakelidze M et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: a phase Ib/randomized phase II trial. *Ann Oncol.* 2019; 30 (10):1613-21.
5. Weiss J, Goldschmiidt J, Andric Z et al. Myelosuppression and reduced use of supportive care with trilaciclib in patients with small cell lung cancer. Presented at the American Society of Clinical Oncology (ASCO) Virtual Meeting 2020. May 29-31, 2020. Poster #384. URL: https://www.g1therapeutics.com/file.cfm/34/docs/384_Weiss_ASCO_2020_Poster_15May2020.pdf.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023.
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939.
- May 17, 2023: Annual review, no change, effective July 1, 2023.
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- May 14, 2024: No changes. Minor wording updates (eff 7/1/24).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.