Prior Authorization Checklist

MEMBER INFORMATION

Patient name:	Male: ◯ Female: ◯	DOB:
Insurance policy #:	Address:	Phone:

PROVIDER INFORMATION

Provider/Facility name:	Provider ID #:	Provider Tax ID #:
	Phone:	Fax:
Other contact:	Phone:	Fax:

DIAGNOSIS/TREATMENT PLAN/LETTER OF MEDICAL NECESSITY[1-9]

Small cell lung cancer (SCLC) Diagnosis Code (ICD-10-CM): C34.XX Malignant neoplasm of bronchus and lung	Date of Diagnosis:	Treatment plan[1,2]: ◯ Platinum/etoposide-based chemotherapy ◯ Topotecan Line of therapy: 1st-line ◯ 2nd/3rd-line ◯
ECOG PS 0-1 ◯ ECOG PS ≥2 ◯	KPS >70 ◯ KPS ≤70 ◯	Prior or concurrent therapies: G-CSF ☐ ESA ☐

Comorbidities/Patient-Specific Risk Factors for CIN/FN[3]

- ☐ Age >65 years
- ☐ Prior chemotherapy or RT
- ☐ Persistent neutropenia
- ☐ Recent surgery and/or open wounds
- ☐ Liver dysfunction (Tbili >2 mg/dL)
- ☐ Renal dysfunction (CrCl <50 mL/min)
- ☐ Chronic immunosuppression in the transplant setting
- ☐ HIV infection
- ☐ Poor performance status
- ☐ Invasive fungal infection
- ☐ Hospitalization at time of fever
- ☐ Prior episode of febrile neutropenia

Comorbidities/Patient-Specific Risk Factors for CIA[3,4]

- ☐ Uncontrolled hypertension
- ☐ Erythropoietin resistance due to neutralizing antibodies
- ☐ Older age
- ☐ Poor performance status
- ☐ Baseline anemia prior to chemotherapy or pre-chemotherapy Hb <11 g/dL
- ☐ Poor nutritional status
- ☐ Renal dysfunction (CrCl < 50 mL/min)

Disease-Specific Risk Factors[3,5,6]

- ☐ Bone marrow involvement by tumor
- ☐ Advanced disease
- ☐ Presence of metastases

Treatment-Specific Risk Factors[3,7-9]

- ☐ CIN[3]:
  - ☐ Febrile neutropenia risk >20% (topotecan)
  - ☐ Febrile neutropenia risk 10%-20%/≥Grade 3 CIN risk (platinum/etoposide-based regimens)
- ☐ CIA[7-9]:
  - ☐ >10% incidence of ≥Grade 3 anemia (etoposide/carboplatin)

Letter of Medical Necessity template is available at: G1toOne.com.

Appeal Support: For assistance call: 1-833-G1toOne (1-833-418-6663)

Complete appeal form(s) and required documentation, including supporting documentation for:	Appeal information:	Additional relevant information:
☐ Addressing myelosuppression consequences	☐ Patient information ☐ Rationale for use: myeloprotection of bone marrow ☐ Summary of patient diagnosis (ES-SCLC) ☐ Summary of patient history	☐ Imaging results ☐ Pathology results ☐ Product prescribing information ☐ Peer-reviewed journal articles ☐ Nationally recognized guidelines

Formal letter appealing the claim denial template is available at: G1toOne.com.

Trilaciclib Information[1]

FDA-approved 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.	Dosage: 240 mg/m^2 Administration: IV infusion over 30 minutes on each day chemotherapy is administered. Complete infusion within 4 hours prior to the start of chemotherapy.	
BILLING AND CODING OPTIONS		
HCPCS Codes: J3490 – unclassified drug C9399 – unclassified drug or biologic	CPT® Code: 96365 – Therapeutic, prophylactic, and diagnostic injections and infusions; initial up to 1 hour	Diagnosis Code (ICD-10-CM): C34.XX Malignant neoplasm of bronchus and lung
PATIENT ACCESS		
Benefits Investigation	Commercial Copay Program	Patient Assistance Program (PAP)
ADDITIONAL INFORMATION		
Sample uniform prior authorization information: https://www.hcasma.org/attach/Prior_Authorization_Form.pdf		

Abbreviations: CIA, chemotherapy-induced anemia; CIN, chemotherapy-induced neutropenia; CPT, Current Procedural Terminology; CrCl, creatinine clearance; DOB, date of birth; ECOG, Eastern Cooperative Oncology Group; ES, extensive-stage; ESA, erythropoiesis-stimulating agent; FDA, Food and Drug Administration; FN, febrile neutropenia; G-CSF; granulocyte colony-stimulating factor; HCPCS, Healthcare Common Procedure Coding System; Hb, hemoglobin; ICD, International Classification of Disease; IV, intravenous; KPS, Karnofsky Performance Status; PS, performance status; RT, radiation therapy; Tbili, total bilirubin.

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IMPORTANT SAFETY INFORMATION

COSELA™
trilaciclib for injection 300 mg

INDICATION

COSELA is 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 (ES-SCLC).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

WARNINGS AND PRECAUTIONS

Injection-Site Reactions, Including Phlebitis and Thrombophlebitis

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

Interstitial Lung Disease/Pneumonitis

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

Embryo-Fetal Toxicity

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

ADVERSE REACTIONS

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.
- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).
- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

To report suspected adverse reactions, contact G1 Therapeutics at **1-800-790-G1TX** or FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

This information is not comprehensive. Please see the full **Prescribing Information**.

G1 THERAPEUTICS™

References:

1. COSELA (trilaciclib). Prescribing information. G1 Therapeutics, Inc; 02/2021.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer V.2.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed February 17, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Growth Factors V.1.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed February 17, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org.
4. Xu H, Lanfang X, Page JH, et al. Incidence of anemia in patients diagnosed with solid tumors receiving chemotherapy: 2010-2013. *Clin Epidemiol*. 2016;8:61-71.
5. Smith TJ, Bohlke K, Lyman G, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2015;33:3199-3212.
6. Bryer E and Henry D. Chemotherapy-induced anemia: etiology, pathophysiology, and implications for contemporary practice. *Transfus Med*. 2018;6:21-31.
7. Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK 4/6 inhibitor trilaciclib in patients with small cell lung cancer receiving first-line chemotherapy: a phase 1b/randomized phase 2 trial. *Ann Oncol.* 2019; 30:1613-1621.
8. 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;38:350-365.
9. 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 multicentre, randomised, double-blind, placebo-controlled phase II trial. *Int J Cancer*. 2021;148:2557-2570.