

PHYSICIAN/PRACTICE LETTERHEAD

[Payer Name]

[Date]

ATTN: [Contact Title/Medical Director]

[Contact Name (if available)]

[Payer Address] [City, State ZIP]

Re: Letter of Medical Necessity for COSELA™ (trilaciclib)

Patient: [Patient First and Last Name]

Date of Birth: [MM/DD/YYYY]

Subscriber ID Number: [Insurance ID Number] Subscriber Group Number: [Insurance Group Number]

Case ID Number: [Case ID Number (if available)] Dates of Service: [Dates]

Dear [Contact Name/Medical Director]:

I am writing on behalf of my patient, [Patient First and Last Name], to document medical necessity for treatment with COSELA (trilaciclib) for injection. This letter provides information about my patient's medical history and diagnosis and a summary of [his/her] treatment plan.

[Patient Name] is [a/an] [age]-year-old [male/female] diagnosed with extensive-stage small cell lung cancer (ES-SCLC) as of [date]. [He/She] has been in my care since [date], having been referred to me by [Referring Physician Name] for [reason].

[Brief summary of relevant past medical history/prior therapies for SCLC, including a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, prescribed drug names and doses, duration of and responses to therapy, disease relapses/recurrences, rationale for dose modifications/discontinuations as well as other factors, such as underlying health issues or advanced age].

[Brief summary of rationale for treatment with COSELA. This includes history of neutropenia and/or anemia with prior treatment(s), presence of chemotherapy-induced myelosuppression (CIM) risk factors [see prior authorization checklist for list of CIM risk factors], extenuating epidemiologic circumstances (eg, COVID-19 pandemic), and/or other reasons].

On February 12th, 2021, the FDA approved COSELA 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. In addition, the National Comprehensive Cancer Network® (NCCN®) added trilaciclib as an option to decrease the incidence of chemotherapy-induced myelosuppression when administered before certain regimens for extensive-stage small cell lung cancer (ES-SCLC).^{1,2} The [insert name of Health System/Clinic] treatment plan for patients like [Patient First and Last Name] with ES-SCLC includes [Include treatment plan that includes COSELA and specify dosage, length of treatment]. [Consider adding any additional information that supports treatment with COSELA for this patient].

In summary, I believe COSELA is medically necessary for this patient. Please contact me at [Physician Phone Number] or via email at [Physician Email] if you require additional information to ensure the prompt approval of this request.

Sincerely,

[Physician Signature]

[Physician Name and Credentials]

Enclosures: [List enclosures, which may include prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, relevant treatment guidelines, such as NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)/ASCO® myelosuppression guidelines, FDA approval letter, scans showing progressive disease, pathology reports].

REFERENCES

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Growth Factors V.4.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed May 27, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer V.3.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed April 1, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org.

ADDITIONAL REFERENCES

3. Cosela (trilaciclib). Prescribing information. G1 Therapeutics, Inc; 02/2021.
4. 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.
5. 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.
6. 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.
7. Weiss JM, Csozsi 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.