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Re: Prior Authorization for Non-Small Cell Lung Cancer Therapy

Dear Drs. Lockwood, Chitre, and Justice:

The undersigned patient advocacy groups, professional associations, and health policy organizations write to express our concern over a recent decision by Excellus BlueCross BlueShield (Excellus) to reduce coverage of cemiplimab, a programmed cell death protein 1 blocking antibodies treatment (anti-PD-1), in the middle of the plan year. This change effectively excludes cemiplimab from coverage, leaving vulnerable patients with non-small cell lung cancer (NSCLC) without access to it. Therefore, we recommend that Excellus amend its prior authorization policy to remove the step therapy requirements for patients with advanced NSCLC whose tumors have high PD-L1 expression.

I. Overview of NSCLC

NSCLC is a disease in which malignant cancer cells form in the tissues of the lung.[1] It is the most common form of lung cancer, making up 84 percent of all lung cancer diagnoses.[2] The five-year survival rate for NSCLC is only 25 percent, and the five-year survival rate for metastatic lung cancer, in particular, is only seven percent.[3] Moreover, between 30 percent and 55 percent of individuals with NSCLC will face a recurrence, and approximately three in 10 people will experience relapse with stage 1 NSCLC, increasing to roughly seven in 10 by stage 4.[4] Yet, immunotherapies, such as PD-1 blocking antibodies, are allowing people with metastatic lung cancer to live longer than ever before.[5] These statistics demonstrate the need for immediate access to effective treatments before disease progression, recurrence, or relapse can occur.

II. Excellus's Formulary Changes Effectively Block Access to Cemiplimab

[1] https://www.cancer.gov/types/lung/patient/non-small-cell-lung-treatment-pdq
[2] https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics
[3] https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics
[4] https://www.verywellhealth.com/lung-cancer-recurrence-treatment-and-prognosis-2249264
[5] https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics

Effective May 10, 2021, Excellus's Pharmacy Management Drug Policy, "Immune Checkpoint Inhibitor Clinical Review Prior Authorization," now requires patients with advanced NSCLC whose tumors have high programmed death-ligand 1 (PD-L1) expression to meet new prior authorization criteria to access cemiplimab. Patients must first demonstrate a proven contraindication to two PD-L1 inhibitors: pembrolizumab and atezolizumab.[6] Yet, pembrolizumab and atezolizumab have no contraindications listed on their FDA labeling.[7] As such, the only way to prove that these medications are contraindicated is for the patient to try and fail on them before accessing cemiplimab, a process known as step therapy. Yet, paradoxically, the Excellus policy also requires that cemiplimab be used as a first-line treatment. Furthermore, the policy states that a patient cannot use an anti-PD-1 if the patient has already tried a different anti-PD-1 or PD-L1 ("use of [cemiplimab] following disease progression on a prior anti-PD-1/PD-L1 therapy is considered "experimental and investigational and will be subject to an off-label review"). Therefore, there is effectively no way that a patient can access cemiplimab.

III. Excellus's Requirements Are Inconsistent with Clinical Guidance and Its Own Policy

Excellus's step therapy and prior authorization requirements are inconsistent with clinical guidance and Excellus's own internal policy. The American Society of Clinical Oncology (ASCO) has stated that "[s]tep therapy policies are generally inappropriate in oncology due to the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options. Medically appropriate cancer care demands patient access to the most appropriate drug at the most appropriate time."[8] Given the chance of recurrence of NSCLC, in particular, and the tendency for the body to build a resistance to previous treatments, patients must have access to all treatments available to them. Therefore, imposing step therapy for NSCLC is inappropriate.

Additionally, Excellus's requirements for cemiplimab are inconsistent with Excellus's own policy. The policy states that its prior authorization criteria are based on each medication's FDA labeled indication or NCCN level of evidence 1 or 2A. However, the NCCN guidance for NSCLC states that cemiplimab is a preferred, category 1, first-line therapy for patients with NSCLC whose tumors have high PD-L1 expression.[9] Therefore, requiring a finding of a contraindication of a PD-L1 inhibitor prior to accessing cemiplimab is inconsistent with NCCN guidance. NCCN's guidance is also consistent with cemiplimab's FDA-approved labeling, which recommends it as a first-line therapy.[10] Therefore, a requirement that a patient try and fail on two other drugs before being able to access cemiplimab is inconsistent with both the FDA labeling and NCCN guidance. Instead, Excellus should provide access to cemiplimab as well as pembrolizumab and atezolizumab and allow the health care practitioner to determine which medication is most appropriate for the patient.

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[6] https://provider.excellusbcbs.com/documents/20152/127109/Immune+Checkpoint+Inhibitor+CRPA.pdf/021843e2-e4f9-fdcc-b528-73e60d900327?t=1621347837741

[7] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125514s096lbl.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761034s028lbl.pdf

[8] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2017-ASCO-Utilization-Management-Statement.pdf

[9] Non-Small Cell Lung Cancer, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), Version 4.2021 (March 3, 2021).

[10] https://www.libtayohcp.com/?gclid=Cj0KCQjwzYGGBhCTARIsAHdMTQy70uygxnllbdKGsk1ultC6VWzvNvMAcdVgDuINwkk3gm7EQXDRV6caAu59EALw_wcB

IV. Conclusion

We strongly encourage Excellus to reconsider using burdensome prior authorization and step therapy practices. Instead, it should allow physicians to choose the best medication for their patients with NSCLC. Thank you for considering our recommendations on this matter.

Sincerely,

Aimed Alliance
CancerCare
GO2 Foundation for Lung Cancer
TriageCancer