

All Cancers Congress

June 30, 2020

Steve Miller, MD
Chief Clinical Officer
Cigna Corporate Headquarters
900 Cottage Grove Road
Bloomfield, CT 06002

Re: 2020 National Preferred Formulary Exclusions Impact on Cancer Patients

Dear Dr. Miller,

The undersigned organizations convene under or support the All Cancers Congress (ACC), a group of cancer non-profits dedicated to working together for the benefit of all cancer patients. We write to make you aware of our opposition to the inclusion of oral oncology treatments in the 2020 National Preferred Formulary Exclusion list released by Express Scripts. Due to the nature of cancer, patient care is very individualized and access to every available treatment is necessary to ensure patients can slow or stop disease progression. The exclusion of any treatment from coverage will place an undue burden on patients to cover the full cost of treatment or force the provider to select a sub-optimal treatment plan.

Factors that affect treatment include the age and general health of the patient, stage and type of cancer, whether there are signs, symptoms, or health problems related to the disease, and whether the cancer responds to initial treatment or recurs. Not only will patients lose access to a potential treatment regimen with the exclusion of any treatment, but many of these treatments have no generic available and the **preferred alternatives are not equivalent**.

Multiple myeloma, for example, is an incurable cancer with a median survival of only 5 years and is the second most common form of blood cancer. Myeloma is a complex disease to treat, requiring different combinations of drugs over the course of a patient's lifetime. Substituting one proteasome inhibitor for another, as recommended on the Express Script exclusion list for myeloma, will not necessarily result in the same outcome for a patient and guidelines for the treatment of myeloma do not interchange proteasome inhibitors. In fact, there is a strategy to include **ALL** proteasome inhibitors in the care of patients over the course of their treatment.

Furthermore, the alternative proteasome inhibitors have a different route of administration than the orally administered excluded drug, creating yet another access barrier for patients, especially those in rural areas who may have to travel far for infusion treatment compared to prescription home delivery. Given the exclusion for the oral drug does not take effect until July 1st due to COVID-19, **the benefit to an at-home oral treatment is clearly recognized**.

Despite unprecedented advances in the treatment of multiple myeloma over the last several years, **almost all patients develop a disease that is resistant to the five most commonly used**

and active anti-myeloma agents. The prognosis for this patient population is particularly poor, resulting in an unmet need for additional therapeutic options. In some instances, the alternative treatments cost the same or more.

Another cancer represented on this list, lung, is equally adversely impacted by the treatments excluded. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, diagnosed in about 85 percent of people with the disease. The complex nature of this cancer requires personalized management plans for patients. Since the discovery of the first epidermal growth factor receptor (EGFR) mutation in lung cancer in 2004, targeted therapies have become a major component of the treatment arsenal of NSCLC patients. Now at least 10 driver mutations in adenocarcinoma have been identified (EGFR, ALK, ROS, RET, ERB2/HER2 mutations, ERB2/HER2 amplifications, MET amplifications, MET mutations, TRK, BRAF, KRAS) that have associated FDA-approved therapies or therapies in clinical development. For example, at present, there are FDA-approved drugs for seven of the driver mutations.

The 2020 Express Scripts National Preferred Formulary excludes treatments that are proven to benefit lung cancer patients and we strongly urge Express Scripts to expand the coverage of lung cancer therapies by following National Comprehensive Cancer Network (NCCN) guidelines (the most recent version, 6.2020, include updates on the treatment of NSCLC which utilize excluded therapies on the list) and considering evidence from clinical trials that clearly demonstrate the safety and efficacy of therapies.

There are other reasons why we urge you to abandon the formulary exclusions for oncology treatments:

- 1) The document states that, "...if you fill a prescription for one of these [excluded] drugs, you will pay the full retail price." **There is no mention of grandfathering patients on current regimens.** It only suggests that you contact your doctor to consider a new prescription. For patients who have found a stable treatment regimen, this places undue stress and burden on them to start a new treatment that may have undesirable results or side effects.
- 2) There appears to be no process by which a patient may access "excluded medications." No mention of an appeals or exceptions process for a provider to prescribe a treatment if the provider determines they are the best drug to treat the patient based on side effects, co-morbid conditions, or resistance profiles. If a patient were to take them, the cost would be in the tens of thousands of dollars per year, unaffordable to most people. If such an exception process exists, the protocols on accessing these treatments must be made clear.
- 3) Some of the "preferred alternatives" are not cheaper than the "excluded medication," especially when ancillary costs for site administration are factored into the price of non-oral medications. Absent another explanation for their exclusion, it is apparent that treatments appear on this list based on the level of rebates Express Scripts has negotiated with the drug manufacturer rather than the list price of the drug. **Patient treatment access should not be used as a negotiating chip between a pharmacy benefit manager and manufacturers.**

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- 4) The mid-year switch will impact patients' access to medication that they may already be taking and have found to benefit the treatment of their disease.

For these reasons, we respectfully request that oncology drugs be removed from the Express Scripts 2020 National Preferred Formulary Exclusions List and that future lists take into consideration the lack of true alternatives to a personalized treatment regimen. A lack of grandfathering in of current treatments, as well as the inability to access excluded treatments through an appeal or exceptions process is particularly troubling, especially considering the mid-year switch.

Please contact Raymond Wezik at rwezik@myeloma.org or Kristen Santiago at ksantiago@lungevity.org with questions or to provide more information.

Respectfully,

Alliance for Patient Access

American Urological Association

CancerCare

GO2 Foundation for Lung Cancer

International Myeloma Foundation

LUNgevity

Ovarian Cancer Research Alliance

Susan G. Komen