INTERNATIONAL MYELOMA FOUNDATION

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June 25, 2020

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

Re: Impact of 2020 National Preferred Formulary Exclusions on Multiple Myeloma Patients

Dear Dr. Miller,

The International Myeloma Foundation writes to express our opposition to the inclusion of two myeloma treatments in the 2020 National Preferred Formulary Exclusion List released by Express Scripts. Due to the nature of myeloma, 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. We request immediate removal of myeloma drugs from the 2020 National Preferred Formulary Exclusion List and that no myeloma drugs be included in future iterations.

Founded in 1990, the International Myeloma Foundation (IMF) has more than 525,000 members in 140 countries, and serves myeloma patients, family members, and the medical community. The IMF provides a wide range of programs in the areas of research, education, support, and advocacy.

Multiple myeloma is an uncurable 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.

Factors that affect treatment include the type of plasma cell neoplasm, the age and general health of the patient, whether there are signs, symptoms, or health problems, such as kidney failure or infection, 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 with the two drugs selected for exclusion, neither has a generic available and the **preferred alternatives are not equivalent**.

Substituting one proteasome inhibitor for another, as recommended on the exclusion list for Ninlaro (ixazomib), 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. To exclude ixazomib reduces the opportunity to obtain other agents. 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. The second drug on the exclusion list, Xpovio (selinexor), is the first in its class and has been recently approved by the FDA for patients who have received at least four prior treatments and their disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody medicine. For many patients who have become resistant to other treatments, this new therapy is the **absolute last resort**.

Underscoring our concern at the lack of consideration for patient access is the way in which these treatments are excluded; abruptly, without concern for those on stable treatment regimens, and with no mechanism to override what amounts to company policy over personalized medicine.

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

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regimen, this places undue stress and burden on them to start a new treatment that may have undesirable results or side effects.

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 them 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.

Finally, it is worth reiterating that 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 manufacturers rather than the list price of the drug. **Patients treatment access should not be used as a negotiating chip between a pharmacy benefit manager and manufacturers.**

For these reasons, the International Myeloma Foundation request immediate removal of myeloma drugs from the 2020 National Preferred Formulary Exclusion List and that no myeloma drugs be included in future versions.

Sincerely,

Robin Roland Levy
Senior Director
Public Policy and Advocacy

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