VIA ELECTRONIC SUBMISSION
January 21, 2021

Acting Secretary Liz Richter
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Attention: CMS-5528-IFC, Mail Stop C4-26-05
Baltimore, MD 21244

RE: CMS-5528-IFC; Most Favored Nation Model

Dear Acting Secretary Richter:

The International Myeloma Foundation writes in regards to the Centers for Medicare & Medicaid Services’ (CMS’) Interim Final Rule with Comment Period (IFC) entitled “Most Favored Nation Model” (MFN) in Medicare Part B. We have serious concerns surrounding this proposal and how it could impact myeloma patients and their access to care. While we share many of the concerns already expressed by the cancer advocacy community and have signed on to other coalition led correspondence with the agency regarding this issue, we believe it is also important for CMS to understand how this proposal could specifically impact patients with multiple myeloma.

Founded in 1990, the International Myeloma Foundation (IMF) is the oldest and largest myeloma specific patient advocacy organization in the world. With more than 525,000 members in 140 countries, the IMF 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 the second most common form of blood cancer and it most frequently impacts individuals between the ages of 65 and 74 and our patient population will be heavily impacted this proposal or any additional proposed changes to Medicare Part B. There is not a cure for myeloma and while many treatments exist to manage the disease, access to innovative therapies have helped increase the quality and length of life of myeloma patients.

We first wish to address the estimation provided in the IFC document surrounding patients who will lose access to their care or be forced to obtain drugs through 340B providers. We are disturbed by the figures in Table 11 estimating that approximately .9% of patients could be forced to forego care within the first year with that number increasing to 19% by 2023. While this alone is disturbing, the table also highlights
additional disruptions in care. This is sure to create financial hardships for patients and create poor health outcomes for those forced to forgo care. We hope our comment letter will provide the agency with an awareness of how the proposal would harm myeloma patients as well as the difficult position providers will be placed in as a result of implementation.

There are many reasons why losing access to therapies will be detrimental to myeloma patients, but we first wish to share with you some information regarding some basics about how myeloma is treated and our patient population. As you may know, myeloma is a heterogeneous cancer. The treatment and progression of the disease differs from person to person. While there are many examples of how myeloma differs between individuals, one of the most basic examples of the heterogeneity of the disease we want to highlight is the many different types and subtypes of myeloma. Indeed, the genetic and molecular abnormalities in this disease are highly diverse and result in a wide range of presentations and outcomes for patients. Furthermore, a patient’s age and other illnesses or comorbidities heavily influence the choice of therapy. This, therefore, requires each patient to have an individualized treatment plan. We have concerns about how the reduction in access driven by this proposal could attempt to force a uniform approach to treating myeloma despite the many different types and subgroups that exist and how differently the disease can present from person to person.

Another important fact to consider about myeloma is that many of the innovative therapies that have increased survivorship in myeloma are given to patients as combination therapies. Disturbing or decreasing access to even one therapy could severely disrupt how this cancer is treated and cause patients to needlessly face disease progression and adversely impact the increases that have occurred in survivorship over the last decade. This is another important factor that conveys why we believe this model is inappropriate and dangerous to cancer people living with cancer.

While we understand that this model is designed to impact the 50 drugs that account for 75 percent of Medicare Part B expenditures, we believe the large number of myeloma drugs (used both for disease treatment and symptom management) on this list would cause our patient population and providers to face a disproportionate impact of the burdens associated with the model. This list includes two different proteasome inhibitor drugs as well as two different monoclonal antibody drugs. These drugs all play a major role in the treatment of myeloma and many are used to treat patients who have relapsed on other treatments. Our organization has produced a handbook detailing the various treatment options and which individuals would benefit from them. Table 10 in this document illustrates just how problematic losing access to these drugs would be and give an idea of how the patients who lose access may have limited or no other options.3

Another important factor to consider is the fact that many myeloma patients already face access issues when their drugs are covered under Medicare Part D. Hindering their access to Part B therapies will only exacerbate the issues the patients we serve are facing. Due to how Medicare Part D is designed many patients who would benefit from orally administered drugs face high

---

out of pocket costs. Myeloma providers are already in a place that while they know which therapies will best benefit their patients, they must make decisions based on not what drug will provide a patient with the best chances of progression free survival, but what the patient’s insurer will provide coverage for. Creating new constraints that will further harm access to the therapies myeloma patients need is reprehensible.

Additionally, we specifically wish to address one item you raise for discussion in the IFC document regarding CAR T-cell therapies. You state “We note that we are also considering as a potential addition to the model design whether certain drugs, such as certain gene and cell therapies (for example, chimeric antigen receptor T-cell (CAR-T) products) and drugs approved by FDA after the start of the MFN Model that are indicated for and used to treat rare diseases or conditions, should be excluded from the MFN Model for all performance years, or for several years after the drug is first sold in the U.S.” We question the appropriateness of this action.

At the present time, CAR T-cell therapy is not approved for an indication within the treatment of myeloma. With that said, the technology could be very promising in the future treatment of myeloma and there are likely to be approvals within the next few months. We have been closely monitoring reimbursement policies and how they have impacted patients with other forms of cancer with current drug approvals. In our previous correspondence with the agency, we share your support for ensuring future therapies are accessible to patients and we were pleased with the creation of the new CAR T-cell therapy MS-DRG. We believe the creation of the MS-DRG was an encouraging step to ensure patients are able to access these treatments in the future. We also shared our concern that inadequate reimbursement policies for CAR T-cell therapies will adversely impact patient access. We request CMS to ensure reimbursement for CAR T-cell therapies to remain reasonable and not to deviate away from the newly created MS-DRG. By doing so, reimbursement will stay at a level that ensures providers are able to provide these therapies and patients will be able to access this life saving technology.

Lastly, we were also dismayed by the decision to move forward with the proposal as an interim final rule. This is a monumental decision which should require the input of stakeholders. We have serious concerns about how the MFN model will impact the quality of care that myeloma patients would receive and the delivery system as a whole. We wholeheartedly believe this proposal should be withdrawn and the voices of patients and providers should be taken into serious consideration.

We appreciate the opportunity to engage with you on this topic and respectfully urge CMS to withdraw this harmful proposal. If you wish to discuss how this proposal will impact myeloma patients in more detail, please contact Robin Roland Levy at RLevy@myeloma.org.

Sincerely,

Robin Roland Levy
Senior Director
Public Policy and Advocacy