



December 18, 2020

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-5528-IFC, P.O. Box 8013
Baltimore, MD 21244-8013

Re: Most Favored Nation (MFN) Model (CMS-5528-IFC)

Dear Administrator Verma:

I am writing to you on behalf of Susan G. Komen (Komen) in response to the interim final rule with comment period implementing the Most Favored Nation (MFN) Model (MFN rule). Komen is the world's leading nonprofit breast cancer organization representing the millions of women and men who have been diagnosed with breast cancer. Komen has an unmatched, comprehensive 360-degree approach to fighting this disease across all fronts—we advocate for patients, drive research breakthroughs, improve access to high quality care, offer direct patient support and empower people with trustworthy information. Komen is committed to supporting those affected by breast cancer today, while tirelessly searching for tomorrow's cures. We advocate on behalf of the estimated 279,100 women and men in the United States who will be diagnosed with breast cancer and the more than 42,690 who will die from the disease in 2020 alone.

Komen appreciates the opportunity to provide feedback on the MFN rule. Komen supports federal policy changes that reduce drug costs, especially the high patient cost-sharing required for many cancer treatments. However, reliable and timely access to high-quality drugs is a critical part of treating breast cancer. **We are very concerned about the potential consequences of the policies included in the MFN rule and we urge CMS to halt its implementation until the impact on access to treatment and care for breast cancer patients and survivors are better understood and mitigated.**

Patients with breast cancer are treated with some combination of surgery, radiation therapy, and/or drug therapy. Drug therapy for breast cancer includes three main categories of drugs: chemotherapy, hormone therapy, and targeted therapy (a cornerstone of precision medicine). In addition to their primary therapies, breast cancer patients also rely on a variety of therapies to help treat or mitigate side effects and/or co-morbidities. These therapies can include brand name, biologics, generic and/or biosimilar drugs. Treatment is tailored to the biology or type of breast cancer, stage of breast cancer and the patient's overall health and preferences.

Breast cancer patients and survivors need unfettered access to these treatments and the providers that they depend on for care. **The MFN rule states clearly that some Medicare beneficiaries will lose access to their treatments, estimating that a "portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit."** In fact, CMS estimates that 9 percent of Medicare beneficiaries will simply forgo access to treatment in the first year, increasing to 19 percent by 2023. Given that more than 75 percent of the "year one" MFN drugs are used to treat cancer and blood disorders, the MFN

model will disrupt treatment and innovations in breast cancer care. Among the drugs that patients may “forgo access” to are some of the most cutting-edge treatments that have had dramatic results in stopping the progression of cancer. While we appreciate that CMS intends to specifically analyze the impact of this new policy on cancer patients, **it is not clear how it will mitigate these disruptions once the model is implemented.**

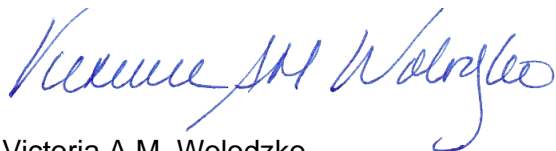
Moreover, the rule will harm the oncology providers on whom breast cancer patients and survivors depend. Oncology providers will suffer significant financial losses if manufacturers do not lower their prices to be below the MFN reimbursement level -- and there is no requirement that they do so. While the CMS and HHS actuaries had a difficult time modeling the effects of the MFN rule since it is without precedent, they were able to estimate the impact of the add-on fee changing to a flat fee rather than the current +6 percent. Table 8 of the rule indicates that change alone will lead to an average reduction of 13 percent in reimbursement for medical oncology providers. This does not take into account the losses that providers will suffer if manufacturers do not lower their reimbursement levels to be lower than the MFN price. In fact, CMS estimates that as many as 900 practices each year could suffer such significant losses that they would be eligible for a financial hardship exemption. However, CMS also notes that the **hardship exemption qualification may be so difficult to reach that practices will have likely already been forced to close their doors.** This will jeopardize not only access to treatment but oncology care in general, especially for smaller and rural practices, leaving breast cancer patients in these areas without local providers.

In addition to our concerns around the impact on implementation for drugs included in year one, we also do not want to see CAR T therapies included in the model. Today, CAR T is an important new therapeutic option for patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) and B-cell acute lymphoblastic leukemia (ALL). We recognize a robust pipeline of new autologous CAR T cell therapies, including for solid tumors, and anticipate that CAR T may be available for breast cancer patients in the future.

Again, Komen thanks CMS for the opportunity to provide comments. Breast cancer patients deserve access to the full range of treatment options for their cancers and their providers deserve fair reimbursement levels. **Accordingly, we ask that you stop implementation of the MFN rule until you can ensure that breast cancer patients and survivors are not harmed. If this is not possible, we ask that you withdraw the rule.**

If you have any questions, or we may be of further assistance, please do not hesitate to reach out to Molly Guthrie, Director of Public Policy and Advocacy, at mguthrie@komen.org.

Sincerely,



Victoria A.M. Wolodzko
Senior Vice President, Mission
Susan G. Komen