



1440 W Taylor St
STE 4299
Chicago, IL 60607

Main: 312.235.4060

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Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Global Benchmark for Efficient Drug Pricing (GLOBE) Model (CMS-5545-P)

Dear Dr. Oz:

On behalf of the Society of Gynecologic Oncology (SGO), thank you for the opportunity to submit these comments on the proposed mandatory GLOBE model to implement a mandatory Most Favored Nation (MFN)-based pricing model under the Medicare Part B inflation rebate program that will be administered by the Centers for Medicare & Medicaid Innovation Center (Innovation Center).

SGO supports CMS's goal of reducing Medicare drug spending through the GLOBE model provided that the Innovation Center includes clear safeguards to protect physician-directed clinical decision making, maintains adequate reimbursement for Part B cancer therapies, and establishes a transparent mechanism to promptly identify and address any disruptions in beneficiary access to medically necessary oncology drugs.

The SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our more than 3,000 members include physicians, advanced practice providers, nurses, and patient advocates who collaborate with the SGO's foundation, the Foundation for Women's Cancer, to increase awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields, all with the ultimate vision of eradicating gynecologic cancers.

Recommended Safeguards to Protect Beneficiary Access and Continuity of Care

Our members share the administration's concerns about the high cost of drugs, particularly those used to treat gynecologic and other cancers. Access to clinically appropriate and medically necessary drugs is essential to ensuring the best possible outcomes for individuals with cancer. Cancer treatment decisions are highly individualized and depend on tumor type, stage, molecular characteristics, prior therapies, and patient comorbidities. Access barriers, including the high cost of these therapies, can delay treatment, force the use of less effective alternatives, and compromise both survival and quality of life. Timely access to recommended chemotherapies, targeted therapies, immunotherapies, and supportive care agents allows clinicians to deliver evidence-based care that reflects the current standard of practice and evolving scientific advances in a rapidly evolving area of medicine. This access should not be impeded by the high cost of drugs.

The SGO applauds the Innovation Center for using this model to explore how to ensure individuals have access to clinically recommended drugs, including cancer therapies, while reducing the cost Medicare pays for them. We appreciate that this model to test MFN-based pricing would lower Medicare beneficiaries' out-of-pocket costs for the drugs included in the model without disrupting physicians' reimbursement for physician-administered Part B drugs. Medicare Part B drug reimbursement supports not only the acquisition of therapies, but also the infrastructure required to safely store, prepare, administer, and monitor high-risk cancer treatments. Reductions in reimbursement would disproportionately affect oncology practices and potentially limit patient access to care close to home, particularly for patients in rural areas.

Protecting Physician-Directed, Evidence-Based Treatment Decisions

The SGO urges CMS to clearly safeguard physician-directed treatment decisions and maintain adequate reimbursement for Part B physician administered cancer therapies as the agency finalizes the GLOBE model. Protecting access to timely, evidence-based cancer therapies must remain a core priority of any payment demonstration affecting oncology care. Should the agency learn that access to any of the included Part B drugs is disrupted at any point during the model, the Innovation Center should have the authority to make any adjustments necessary to maintain beneficiary access to medically necessary therapies.

Specifically, we urge the Innovation Center to monitor the following – disruptions in access and continuity of care and pressure on physicians' clinical decision making – both of which may result if the model disrupts supply of the affected drugs. Access could be disrupted if the model results in changes in supply of the included drugs, reduces the availability of drugs in office-based settings, or disincentivizes the use of certain therapies. Therefore, the SGO recommends that there be a mechanism included in the model for physicians, who are not model participants but may be directly impacted, to report any of these disruptions directly to the Innovation Center. It is imperative for patients with complex or refractory conditions to maintain access to all physician recommended viable treatment options. Physicians should not be forced to switch the treatment regimen for stable patients for non-clinical reasons because the model disrupts supply.

Ensuring Quality of Care Remains Central to Model Evaluation

Additionally, the Innovation Center must ensure the model guards against placing pressure on physicians to make decisions based on pricing rather than evidence. Should the model unintentionally disrupt drug supply, physicians may be forced to favor older, less appropriate therapies because they are less expensive. Newer therapies consistent with clinical guidelines must remain available to Medicare beneficiaries. This is of particular concern where guidelines recommend individualized therapies. Again, physicians should have a mechanism to report these circumstances should they arise, directly to the Innovation Center for the model to be adjusted.

The Innovation Center evaluates a model's success based on its impact on quality of care and Medicare spending. The SGO cautions the agency that there must be strong evidence of benefit when assessing the quality of care received by cancer patients. Cost savings should not come at the expense of patient outcomes and continued innovations in oncology care.



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Thank you for the opportunity to submit these comments. Should you have any questions or require additional information, please contact Carly Gustafson Léon, SGO's Manager of Health Policy and Government Affairs, at carly.leon@sgo.org.

Sincerely,

Karen H. Lu, MD
President, Society of Gynecologic Oncology