February 22, 2022

Submitted electronically to: publiccomments@icer-review.org

Steven D. Pearson, MD
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Draft Evidence Report for Chemotherapy-Induced Neutropenia

Dear Dr. Pearson:

On behalf of the Institute for Patient Access, I thank you for the opportunity to provide comments regarding ICER's draft evidence report on plinabulin and trilaciclib for chemotherapy-induced neutropenia. This letter also includes comments about the unusual process ICER has followed for this review.

About the Institute for Patient Access

The Institute for Patient Access (IfPA) is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. To further that mission, IfPA produces educational materials and programming designed to promote informed discussion about patient-centered care. IfPA was established in 2012 by the leadership of the Alliance for Patient Access, a national network of health care providers committed to shaping a patient-centered health care system. IfPA is a 501(c)(3) public charity nonprofit organization.

Evidence Report and Review Process Comments

ICER has announced its intent to issue a final evidence report in this review without first holding a public hearing, a highly unusual decision. It is disappointing to see ICER moving forward in this manner after denying patients and advocacy organizations the public opportunity to participate in the only open component of ICER's assessment process.

Review of Treatments Prior to FDA Approval

Trilaciclib and plinabulin are two novel treatments for cancer patients facing neutropenia caused by cancer treatment with cytotoxic chemotherapy. These two agents use different

mechanisms of action, yet both serve to combat and decrease the incidence of neutropenia.

Trilaciclib was approved by the U.S. Food and Drug Administration in February 2021 and is currently available for patient use. Plinabulin has not yet been approved by the FDA. Rather, the federal agency requested that the manufacturer complete an additional trial prior to reconsideration.

IfPA has previously raised concerns about ICER's habit of prematurely initiating reviews. The FDA's approval should be complete before ICER initiates a value assessment. Federal officials review all available data before making a determination about the safety and efficacy of new treatments. It is their job to decide whether a breakthrough medication should be approved for use. In some cases, as with plinabulin, federal officials may determine that more data is needed. Decisions like these render ICER's assumptions and calculations incomplete. This can be avoided in the future by reviewing only federally approved drugs and devices.

Process Irregularities

Rather than suspend or pause this review due to the unforeseen circumstance surrounding plinabulin, ICER instead announced it will fast track and finalize the review with process changes.

While altering a well-documented process midway through is cause for concern, the cancellation of the only public meeting is particularly alarming. The public meeting would have given the cancer community an opportunity to hear and see the process unfold. It would have also provided a platform for stakeholders to express their experiences and raise concerns directly to reviewers.

With a disease like cancer, it is unrealistic to expect a panel or review board to include all stakeholders. However, the opportunity to participate in a public meeting, which allows patients, providers and other invested parties to provide their unique viewpoints, can be valuable for reviewers. This importance is elevated when dealing with diseases like cancer, where clear disparities and inequities exist. Due to the removal of the public meeting, those who want to offer comments – about the review or the unseemly process changes – are left with submitting a written comment as their only option.

Patients, especially those from the communities who are most affected by cancer, should be offered more opportunities, not fewer, to comment on processes that could affect their long-term access to new treatments. The data is clear that the current standard of care for the side effects of chemotherapy, including neutropenia, is not sufficient. Over 60,000

patients are hospitalized, at a cost of more than $2.7 billion, and more than 4,000 die of febrile neutropenia annually.[1, 2]

The new drugs assessed in this ICER review could provide an opportunity for cancer patients to expand their treatment options. Plinabulin is the first drug submitted for FDA approval that would address neutropenia during the first week of chemotherapy, providing an innovative option to the current G-CSF standard of care.[3] While the value of increasing treatment options is difficult to quantify, it must not be dismissed. Neither should patients. They deserve the opportunity to publicly share their concerns about the seriousness of chemotherapy side effects as well as their optimism about the potential lifesaving benefits of a new medication.

ICER's reports, once finalized, live in the public domain and are used by many groups. Among those most interested in ICER's findings are health insurers, both public and commercial. It is no secret that ICER's reviews are referenced as evidence to justify utilization management techniques like prior authorization or to place medications on unaffordable specialty tiers. These barriers serve to limit patients access to novel treatments.

To diminish patients' participation in a process that could eventually be used against them is, simply stated, wrong.

Conclusion

Removing the most direct opportunity for patients to contribute to this review flies in the face of ICER's pledge to incorporate more patient input. ICER's review, despite its shortcomings, has the potential to impact cancer patients' access to novel treatments. For these reasons, IfPA urges ICER to consider these concerns as it moves forward with finalizing the evidence report.

If IfPA can provide further information or aid the Institute for Clinical and Economic Review in any way, please contact IfPA at 202-951-7097.

Sincerely,

Michelle M. D. Winokur, DrPH
Executive Director
Institute for Patient Access

---

[1] https://www.cdc.gov/cancer/dcpc/research/articles/neutropenia.htm

[2] https://www.cdc.gov/cancer/dcpc/research/articles/neutropenia.htm#:~:text=The%20total%20cost%20for%20adults,for%20children%20(%241.6%20billion).

[3] https://beyondspringpharma.com/pipeline/plinabulin/