ICER's Latest Backtracking Illuminates Inconsistent Policies & Practices

For several years ICER has been providing their version of proprietary value assessments about compounds that hadn't been approved by the FDA, as well as some newly approved medicines. However, despite stating explicit revised protocols, practices, and expectations – and updating them over the past several years - ICER continues to make up their own rules as it goes along.

While the inconsistencies in ICER's assessment processes have sometimes been minor, on January 25th, ICER published a new draft report "Novel Agents to Prevent Chemotherapy-Induced Neutropenia and Other Myelosuppressive Effects," and also announced they were truncating their normal assessment process. Specifically, ICER stated:

"On December 1st, BeyondSpring Pharmaceuticals received a Complete Response Letter [from the FDA] for plinabulin. Therefore, [since the FDA had not approved plinabulin] ICER has cancelled our public meeting, and will conclude this assessment with the revised Evidence Report that will be posted on March 17th."

Although ICER will still accept public comments on the draft report, because there will be no public meeting and no final report, Patients Rising Now will not be providing guidance to advocates for providing comments on ICER's draft report. Instead, we are taking the opportunity to use this situation to illuminate several of the fundamental problems with ICER's assessment process.

Attempts to Predict the Future

ICER's practice of doing assessments before FDA's review in order to provide guidance to insurance companies and attempt to influence both list prices and coverage policies (particularly for Medicaid programs), is an inherent fundamental flaw. The January 25th draft report shines a bright light on this since ICER decided to truncate their entire assessment because the FDA asked the company to conduct an additional clinical trial after deciding that there was not enough data about plinabulin to approve it.

While ICER's process is designed to meet the perceived needs of payers and others, it also assumes that all potential medicines submitted to the FDA will be approved. By doing such pre-approval assessments, ICER is assuming that it knows what the specific approval will look like, including the clinical indications and warnings.

Scant Attention to Patients

One of Patients Rising Now's main areas of focus is that patient perspectives are recognized and adequately incorporated into medical care and policy decisions. ICER's January 25th draft report raises two obvious concerns in that area. First, the Patient and Caregiver Perspectives section is half a page in a 145-page report. And second, the risk of death from febrile neutropenia when

hospitalized is 15.7% for people being treated for extensive small cell lung cancer, and 5.6% for people who have early breast cancer. This data is not mentioned in the Patient Perspectives Section, and only included in tables in the draft report's economic modeling section.

Minimizing Importance of Lives of People with Serious Illnesses

ICER's Long-Term Cost Effectiveness calculations minimize the value the lives of people with serious and life-threatening conditions. The January 25th draft report does this when it notes that it found a very small value for the use of trilaciclib in part because of the "limited life expectancy in the ES-SMLC [Extensive-Stage Small Cell Lung Cancer] population." And then notes that "the long-life expectancy of patients with early breast cancer yielded a greater QALY [Quality Adjusted Life Year] gain than in ES-SCLC." (Patients Rising Now has also discussed how calculations using QALYs discriminates against people with serious illnesses and disabilities.)

Making Up Rules as They Go Along

ICER's practices can be in conflict with their own stated principles, and they avoid analyses of real-world data that could provide useful information for payers, policy-makers, and healthcare delivery systems. Those analyses could also validate (or improve) ICER's own practices. Specifically, in the January 25th draft report this was evident by ICER not doing a budget impact analysis on trilaciclib (Cosela™), "Due to trilaciclib having been approved approximately one year ago."

In contrast, ICER could have explored the real-world data of this approved medicine to show what the actual budget impact had been compare to what ICER's algorithm would have predicted. Such information would be very useful to ICER and others for evaluating the ongoing validity of ICER's methodologies.

An Analysis Plan They Refuse to Follow

Part of ICER's normal value assessment process, is publishing a "Modeling Analysis Plan" that describes how it will conduct its economic evaluation. However, comparing the November 12, 2021 Modeling Analysis Plan document, and the January 25, 2022 draft report reveals this inconsistency:

"If a price is unavailable at [when we post the draft report], we will assume that plinabulin will be priced similarly to the pegfilgrastim based on analyst opinion." [emphasis added] (ICER Modeling Analysis Plan, November 12, 2021, p.19)

"As the manufacturer of plinabulin has received a complete response letter delaying potential approval of the drug, and because no suitable analog is currently FDA-approved, there is not enough confidence to utilize a placeholder price for its budget impact analysis." [emphasis added] (ICER Draft Evidence Report, January 25, 2022, p. 31)

Placeholder Prices & Budget Impact Projections are Bad Fiction

Although ICER declined to include a placeholder price for plinabulin in the January 25th draft report, its entire process for assigning placeholder prices and doing budget impact projections fails to recognize market realities or even learn from history. Specifically, anyone knowledgeable about biopharmaceuticals in the United States understands that prices and total costs change over time – and that even when "list prices" increase, net prices and total costs can decline, and sometimes dramatically. Two examples from recent years demonstrate this phenomenon. First, the net price of the cures for chronic Hepatitis C declined about 50% within a few years. And second, the list price for the controversial new treatment for Alzheimer's disease was reduced by 50% about 6 months after it was approved by the

FDA. (Similar reductions in medicines to treat very high cholesterol levels has also occurred via a combination of lower list and net prices.)

Such dramatic changes – and the inherent uncertainty about FDA approvals, labels, indications and warnings; and actual list and net prices – illustrate the reality of often highly dynamic market forces for prescription drugs. In contrast, ICER choses to model a simplified vision of the future as a fictional static market without competition or changes to prices or total costs.

Conclusion

ICER's decision to not waste any time continuing with its assessment of plinabulin makes sense because it is very uncertain when (or if) the FDA will approve it given that they requested another clinical trial. However, since there is a significant amount of real-world data about trilaciclib, ICER could have continued the assessment to validate its processes, or identify ways that to improve its processes based upon the variation between its static modeling and real-world data. In addition, the company that discovered and produces trilaciclib commissioned its own economic analysis, and ICER could have used their assessment to compare and contrast ICER' economic modeling to what this group did. Unfortunately, ICER did not do that – and explicitly avoided even looking at real world data which could have improved their own budget impact modeling moving forward.

Patients Rising Now is disappointed that the data about plinabulin was deemed insufficient for FDA to approve it since patients with cancers undergoing chemotherapy that can cause myelosuppression clearly would benefit from more and better treatment options. We are also disappointed that ICER did not take advantage of the opportunity to review real world data about trilaciclib to evaluate and improve ICER's own processes and protocols rather than cut-and-run in order to avoid exposing more of its own flaws.