

Panel Takes a Deep-Dive on Step Therapy in Oncology

Step (or “fail first”) therapy is hardly a new concept. In oncology, however, increasing utilization of this cost containment approach by payers raises a number of flags.

During the ACCC 45th Annual Meeting & Cancer Center Business Summit in March 2019, a Deep Dive Workshop on Real-World Integration of Immuno-Oncology brought together an expert panel for a focused discussion on step therapy in the context of immunotherapeutics. Panelists explored step therapy from the perspective of different members of the care team, including a patient advocate. Participating in the conversation were Ali McBride, PharmD, MS, BCOP; Jenny Ahlstrom, myeloma patient advocate, founder of Myeloma Crowd; Laura Wood, RN, MSN, OCN; Alexander Spiro, MD, PhD, FACP; and Jennie Crews, MD, MMM, FACP.

Every panelist had experience with some version of payer step therapy edits—either in or outside of oncology. Although step therapy is familiar to clinicians, increased utilization of “fail first” steps as a cost containment measure in oncology is troubling.

Topline concerns raised by the panel include:

- Step edits can conflict with institutional pathways. Many cancer programs have implemented or developed pathways. Step therapy requirements, which vary from payer to payer, can conflict with institutional pathways—disrupting standardization efforts, creating additional administrative and operational challenges.
- Step therapy is counter to patient-centered care delivery. The formulaic nature of step therapy doesn’t allow for the nuances and complexity of treating patients with cancer who have varying goals of care.
- Step therapy can make sense when there is sufficient pharmaco-economic data to support utilization. In most instances, and especially in a less common cancer such as myeloma, there is a lack of this type of data. However, as generic versions of oncology agents become available, step edits may be appropriate (e.g., Gleevec® versus imatinib).

- Step therapy that requires patients to “fail” treatment can leave patients so ill they are unable to access second-line treatment.

- Clinical trials are a critically important response to step therapy constraints. To gain the data needed to support new therapies and to provide patients access, connecting patients to clinical trials is imperative.

As cancer programs and practices seek to standardize treatment through implementation of pathways, in some cases step therapy might actually work against such efforts. “Many institutions have been doing pathway work, using their experts to define what is the best way to treat patients,” said Dr. Crews. “If we’re dictated to on which drugs we can use for different patients depending on who they are insured by, step therapy is going to be very problematic for managing on a pathway.”

Although “cost is the heart of the issue for step therapy,” she said. “In pathway development, cost considerations are in third place, after efficacy and safety.”

Step therapy may also act in opposition to the imperative to better engage patients in their own care. As the multidisciplinary care team aims to understand and align care with the patient’s values and goals, “fail first” therapy can introduce barriers, panelists agreed. “With step therapy, a lot of nuances in terms of choosing a drug that’s right for a patient are being lost,” said Dr. Crews. “We are not all the same. We have different lifestyle desires. Sometimes the drug we choose for patients is based on a toxicity profile that will impact different areas of their life. Sometimes it’s based on patients’ different comorbidities.” Accommodating these individual needs can be difficult when dealing with something as formulaic as step therapy.

Then there is the real-world impact on patients with cancer of having to “fail” a first therapy. “When we say, ‘fail first,’ I don’t know if we’re connecting that to a human being. I don’t want to be the fail first,” said an audience member. “Are we connecting it to human beings that will have to fail and get ill when the treatment isn’t working? Sometimes the fail first can debilitate patients so much that the second treatment in line won’t work as well.”

Panelist Jenny Ahlstrom helped ground the discussion in the real-world multiple myeloma patient experience, “Your disease is so complex by the time you’ve gone through multiple lines of therapy that it is almost impossible to treat. So your first shot at cure and remission in myeloma is your first treatment. If you’re picking suboptimal treatment based on cost at the first line of therapy, you’re out of luck as a patient. You don’t have those options later because they don’t work.”

Clinical trials are a critical piece of the puzzle, clinical research nurse Laura Wood said. “We have clinical trials to build on existing knowledge and to try to improve our decision-making processes. But if patients aren’t referred to answer those key questions, we’re never going to get there; you’re going to be stuck with what the patient’s insurance tells you to do because we haven’t been able to complete the clinical trials that helped expand that knowledge.”

As healthcare costs continue to soar, panelists acknowledged that changes lie ahead. “I think the example we started with was Gleevec®,” said Dr. Spiro. “If generic Gleevec® (imatinib) is \$3,000 a month versus dasatinib, which is \$12,000 per month, it’s going to be an important question for someone to answer. When there is a multiple-fold difference [in price]—we’re not there so far—but it will have to be faced in a year or two.

Letting the data speak is at least part of the answer, Dr. McBride agreed. “I think right now the most important piece of the puzzle is the pharmacoeconomic data as we move forward. We need to partner with pharma to get that pharmacoeconomic data out there, because if we can address these key counterpoints (here’s the cost, it reduces these side effects profiles, CMS utilization of those costs), then we have something.” ■

For more from ACCC on step therapy, please visit the *Perspectives on Step Therapy in Oncology* project at accc-cancer.org/step-therapy.

This project is supported by Amgen.

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The **ACCC Oncology Pharmacy Education Network** advocates on behalf of hematology-oncology pharmacists as vital members of the cancer care team, and is committed to developing educational resources and multidisciplinary connections that advance the field and elevate oncology pharmacy professionals to top-of-license practice.



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