IVI INNOVATION AND VALUE INITIATIVE

VALUE BLUEPRINTS
Research Brief Series

ISSUE BRIEF

Aligning Value Assessment with Treatment in Chronic Disease

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POLICY QUESTION

Do conventional value assessments address the questions most relevant to real-world decisions about treatment pathways for chronic diseases?

KEY TAKEAWAYS

- In chronic diseases characterized by a sequence of different therapies over time, it may be more relevant to consider therapies' value as part of sequential treatment strategies, rather than individually.
- ICER's recent analysis of Janus Kinase (JAK) inhibitors for the treatment of rheumatoid arthritis (RA) serves as an example of how conventional head-to-head cost-effectiveness analyses may not align with decision making in chronic disease.
- To provide insights on the value of treatment sequences, modernized value assessment methods and models are needed that compare the full range of available therapies, and model varying treatment sequences.
- IVI is leading advancements in modeling methods to assess value of sequential treatments with open-source models in RA and other diseases, but broader efforts are needed to build the evidence base for these analyses.

WHY ASSESS VALUE?

The Institute for Clinical and Economic Review (ICER) recently conducted a cost-effectiveness analysis of three Janus Kinase (JAK) inhibitors for treatment of rheumatoid arthritis (RA) and released a Draft Evidence Report on their assessment of these therapies' value.[i] This ICER report is the most recent example of an increased effort to formally quantify the value of health technologies.

New health technologies can bring improvements in efficacy, safety, convenience, or adherence—and sometimes all of the above. The introduction of new medical interventions can also significantly affect health care costs. In a world of rising overall health care spending and constrained resources, this often requires difficult decisions about how to allocate scarce resources. To inform decisions that best serve patients and efficiently manage resources, it is important to consider the value of new technologies—their benefits, risks, and costs—compared to one another and to established standards of care. Cost-effectiveness analysis based on models that simulate health benefits and costs of therapies with evidence from multiple studies is the most commonly used approach to doing so.

As value assessments become an increasingly important part of healthcare decision-making, ICER's analysis prompts a fundamental question: do traditional value assessments like ICER's provide information relevant to real-world decisions?

BACKGROUND

Rheumatoid arthritis is the most common autoimmune inflammatory arthritis in adults and often negatively impacts patients' quality of life and ability to perform daily activities.[ii,iii,iv] RA is a chronic and incurable disease; patients are commonly treated over a period of many years, during which they are likely to cycle through multiple available treatment options as therapies' effectiveness may diminish over time.[v]

Multiple therapies are available to treat RA, including a variety of biologic disease-modifying antirheumatic drugs (DMARDs). JAK inhibitors are the most recent class of biologic DMARDs to be approved in RA, raising questions about their value relative to existing therapeutic options. As a result, ICER conducted a cost-effectiveness analysis of three JAK inhibitors among RA patients for whom conventional DMARD therapy (e.g. methotrexate) had failed. The simulation model used for this analysis reports

outcomes after one year, and patients in the modeled population switch to a "market basket" of therapies after the initial therapy fails.[i]

VALUE IN THE CONTEXT OF SEQUENTIAL TREATMENT

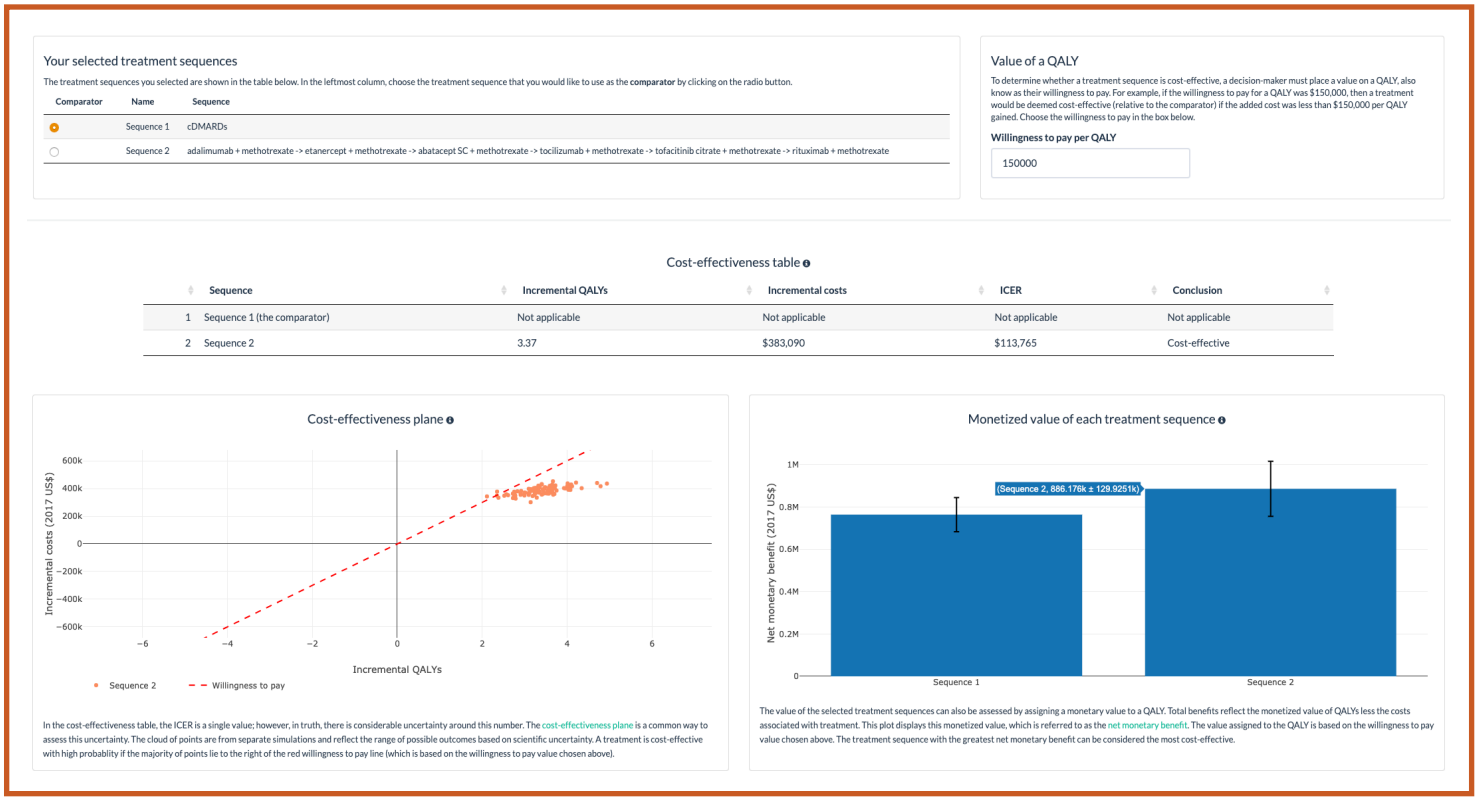
Assessments like ICER's review of JAK inhibitors provide estimates of value for individual therapies. Given the nature of chronic diseases like RA, however, where patients commonly progress through a sequence of therapies over time, would it not be more beneficial for value assessments to provide insights into the most cost-effective treatment sequence strategies?

Assessing value of treatment pathways, rather than individual therapies, requires innovation in methods for modeling and analysis. In particular, to perform such an analysis, simulation models must accommodate both the effects of patients' treatment histories on therapies' performance, and the variation in those outcomes across patients.

Progress is being made toward value assessment models that can provide these insights. The IVI-RA model, which ICER acknowledges as a modeling reference in their recent report, provides an example. Released in 2017, the open-source IVI-RA model simulates outcomes and facilitates value assessment of sequences of biopharmaceutical therapies among patients with moderate to severe RA (Figure 1).[vi] IVI-RA is an individual-patient simulation model, which allows the user to model the outcomes and duration of each treatment in a sequence as a function of important patient-related variables, including treatment history.[1]

Of course, the ability to model the value of treatment strategies as described above is constrained by the availability of data to support such an analysis. In order for value assessment in the context of chronic diseases characterized by sequential treatment like RA to provide truly relevant insights, more robust evidence is needed regarding the impact of prior treatment on the efficacy of the current treatment. Evidence is similarly needed on the efficacy of treatments based on patients' sociodemographic

FIGURE 1. Example Analysis of Sequential Treatment Using IVI-RA Model



Note: This example shows the relative cost-effectiveness of a common sequence of biologic therapies compared to treatment with conventional DMARDs among patients with moderate-to-severe rheumatoid arthritis. Analysis conducted using the IVI-RA Value Tool, accessible at https://www.thevalueinitiative.org/ivi-ra-value-model/.

[1] For full details or to access the IVI-RA model, visit https://www.thevalueinitiative.org/ivi-ra-value-model/.

characteristics, comorbidities, and other clinical factors. Given the obstacles of cost, practicality, and study design involved in gathering this broad base of evidence through randomized control trials, it is important to also consider observational and registry data, despite its known limitations, to estimate heterogeneous treatment effects.

CONCLUSION

Rheumatoid arthritis patients are generally treated over a period of many years, during which they are likely to cycle through available treatment options as therapies' effectiveness diminishes or, in many cases, abruptly ceases. Therefore, the most relevant question to the patient, their clinician and the payer is arguably, "where in the treatment sequence does a given intervention have the most value for this patient, given the evidence available?"

Facing this question, value assessment is more relevant when it aims to identify the most cost-effective sequence given the treatments available, rather than determining whether a certain intervention is cost-effective as a first line therapy for the average patient. Further testing of models and data sources that can support such analyses—such as the IVI-RA model—is needed in order to answer questions like these that matter to all stakeholders about appropriate, cost-effective treatment options.

ABOUT THE INNOVATION AND VALUE INITIATIVE

IVI is a 501(c)(3) nonprofit research organization committed to advancing the science and improving the practice of value assessment in healthcare through collaboration among thought leaders in academia, patient organizations, payers, life science firms, providers, delivery systems and other organizations.

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