US ICER's Assessments to Date Indicate Price Cuts Required for 90% of Drugs, but HTA Framework Not Consistently Applied in 37% of Reviews

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Objectives

The US Institute for Clinical and Economic Review (ICER) began assessing innovative drugs in 2014, applying a cost-effectiveness threshold of USD100,000-150,000. While its guidance is not binding, ICER's recommendations are considered by private health insurers and, since 2017, by the Department of Veterans Affairs. Understanding ICER's pricing recommendations and whether in arriving at them ICER consistently applies its assessment framework would be beneficial for pharmaceutical companies when they set US prices.

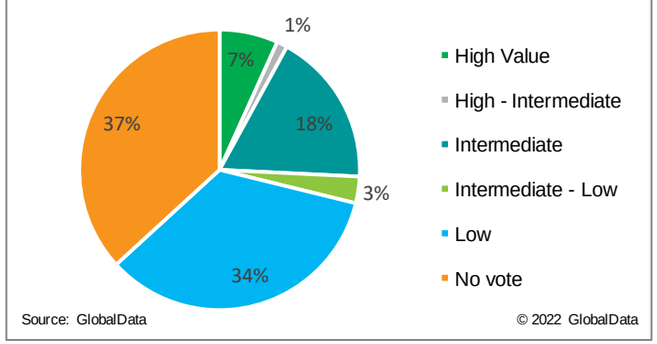
Methods

All ICER's decisions for pharmaceuticals between the inception of assessments in 2014 and the end of August 2021 were reviewed to ascertain the price level recommendations by ICER and also whether the assessment process adhered to ICER's assessment framework.

Results

Over the 2014-2021 period examined, ICER evaluated 170 products/indications (across 48 evidence reports), including 117 active pharmaceutical ingredients (APIs). Not all ICER reviews concluded with a "value" determination. In fact, 37% of products/indications had no clear "value" determination (that is, "No Vote"). Conversely, there were multiple cases of voting by ICER for medicines that should have automatically qualified as low or high value – a practice which deviates from ICER's value assessment framework. Among those assessments with clear value ratings, our research suggests that the largest proportion of value determinations for drugs/indications made by ICER is Low (34%; 56), followed by Intermediate (18%; 29) and High (7%; 11). There were a few products where the panel was equally split between two ratings: High – Intermediate (1%; 2) and Intermediate – Low (3%; 5).

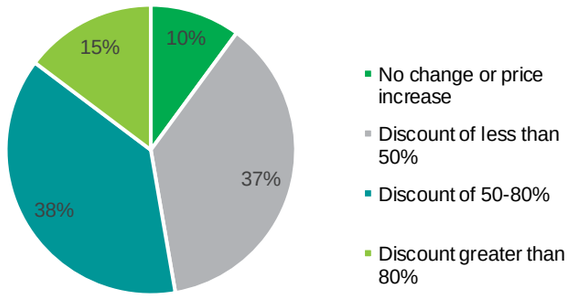
ICER value determinations 2014 - 2021



We separately examined whether ICER judged the products' cost-effectiveness to be within its cost-effectiveness range of USD100,000-150,000 and the discounts required to fall within these benchmarks. In the majority of cases, ICER was using the wholesale acquisition cost (WAC) of the drug, which does not take into account actual net pricing after rebates and discounts.

ICER's assessments resulted in a recommendation to reduce list prices by more than 80% for 15% of reviewed drugs, by 50-80% for 38% of drugs and by less than 50% for 37% of drugs. For only about 10% of the products/indications reviewed ICER recommended no change in price given that the current list price of the product was below the value-based pricing benchmark.

Price change needed to meet cost-effectiveness threshold



Conclusions

The vast majority of ICER's assessments result in recommendations for substantial price cuts to meet the cost-effectiveness threshold. The threshold itself of USD100,000-150,000 has been criticised for being too high, but ICER maintained its level in the January 2020 revision of its assessment framework. While the framework gives some predictability to pharma, it is worrying that it was not consistently applied in 37% of assessments. Conducting assessments as prescribed in the framework should help create a more transparent and predictable HTA process for pharmaceutical companies and for the eventual users of ICER's cost-effectiveness reports.