Editorial

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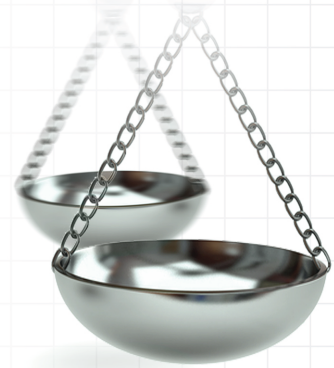

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For what it's worth: the complex area of medicine value assessment

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"By having a narrow perspective, medicines may be undervalued by current HTA analyses."

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Egilman and colleagues recently investigated the therapeutic benefit of the most popular branded pharmaceuticals covered by Medicare in 2020, as determined by health technology assessment (HTA) bodies in Canada, France, and Germany. The authors concluded that many top prescribed drugs have low benefit ratings from these HTA agencies, and this information could be helpful for the future when Medicare are able to negotiate pricing as part of the Inflation Reduction Act.

HTA involves the synthesis of a broad body of clinical, humanistic and economic evidence in order to determine the relative benefit of medicines [1]. The final decision on benefit is determined by the evidence available and also how this evidence is perceived in relation to the values, preferences and constraints of a given HTA body [1]. As such, HTA recommendations vary widely across countries. Some HTA bodies may have concerns with the end points and comparators used in a trial, which may lead them to assign a new treatment as having limited benefit [2]. Indeed, for some of the examples cited by Egilman and colleagues [3], this was the case. Both Apixaban and Palbociclib received low added therapeutic ratings from all HTA bodies reviewed. For Apixaban, one of the reasons given by the French HTA body was that randomised trial comparisons between Apixaban and Rivoroxaban or Dabigatran were lacking [2]. At the time of initiation of the pivotal Apixaban trial, Rivoroxaban or Dabigatran were not approved treatments and therefore this is not an issue of trial design. We now however have a wealth of post-approval studies examining this question with real-world data, with a consistent finding of a safety benefit of Apixaban as compared with other direct oral anticoagulants [4]. For Palbociclib, the low benefit rating was given because progression free survival (PFS) was the primary trial end point, and this is not valued by many HTA agencies, despite a preponderance of data highlighting that PFS, an indicator of of disease control and stabilization is still an important outcome for patients with metastatic cancer, providing positive psychological benefits for themselves and their caregivers knowing that their disease appears under control [5].

HTA agencies focus primarily on the clinical and cost effectiveness of medicines, without fully considering other factors that are important to patients and society, such as the impact on quality of life or the wider societal economic benefits of improved health. By having a narrow perspective, medicines may be undervalued by current HTA analyses. As Egilman *et al.* suggest that their data may be beneficial for pricing negotiations as part of the Inflation Reduction Act, we would caution that this should only be done after understanding the challenges of HTA, making sure the values of the United States are incorporated in any assessment and having a consideration that society should not inappropriately underinvest in scientific advancements that bring patient and societal benefit.

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