Another Rush to Judgement: The Imaginary Worlds of ICER and Recommendations in Duchenne Muscular Dystrophy

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abstract

Previous commentaries in the Formulary Evaluation section of INNOVATIONS in Pharmacy have pointed to the lack of credibility in modeled claims for cost-effectiveness and associated recommendations for pricing by the Institute for Clinical and Economic Review (ICER). The principal objection to ICER reports has been that their modeled claims fail the standards of normal science: they are best seen as pseudoscience. The purpose of this latest commentary is to consider the recently released ICER report for Duchenne muscular dystrophy (DMD). As ICER has continued in the case of DMD to apply its modeled cost utility framework with consequent recommendations for pricing adjustments, these recommendations also lack credibility. This commentary emphasizes again not only why the ICER methodology fails to meet the standards of normal science but to point to the importance in rare diseases for accelerated approval, while recognizing that evidence generation will continue. While this assessment of the ICER DMD model does not imply any support for this methodology, a key point is the application of quality of life measures which fail to capture the

experience of patients with DMD and, importantly, the interests of both patients and caregivers. While ICER would argue that even with a limited evidence base it is important to address issues of pricing and access for new products, their reports are used as justification for coverage and reimbursement by insurers and health system decision makers without recognition of their lack of scientific merit. This rush to judgement by ICER must raise concerns about potentially adverse formulary decisions that result in access restrictions on new products. If ICER is to make a contribution to the entry of new products in the health market place then it should consider an alternative methodology that generates claims that are empirically evaluable in a timeframe relevant to health decision makers. As it stands, ICER's recommendation should be rejected. This is not a research program that meets accepted scientific standards but one that relies on the willingness of an audience to accept the proposition that evidence is constructed not discovered.

Article Type: Commentary

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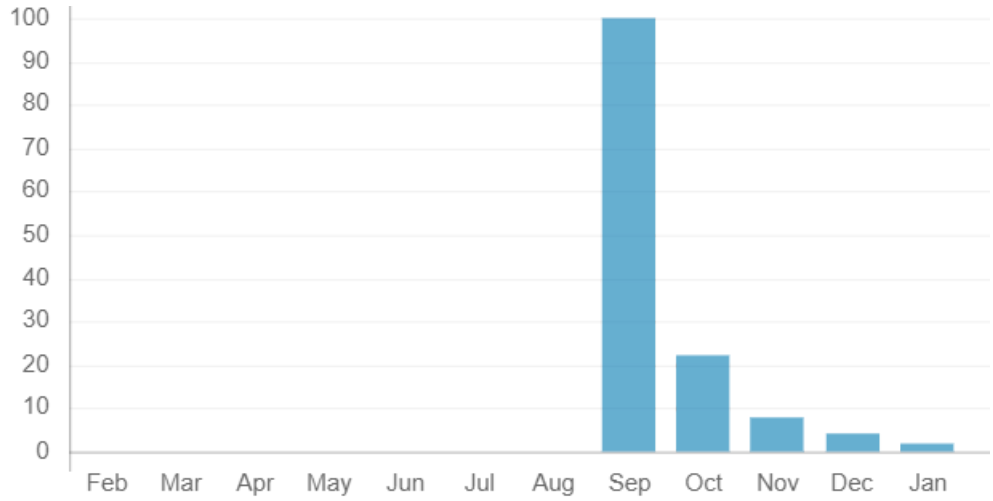

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