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Rush to Judgement: Imaginary Worlds and Cost-Outcomes Claims for PCSK9 Inhibitors

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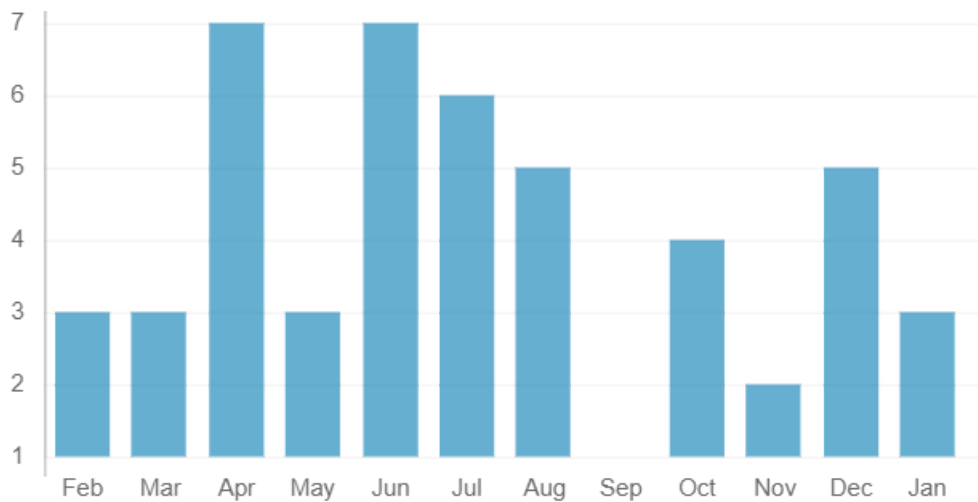
abstract

Pricing by the manufacturers of the two PCSK9 inhibitors recently approved by the FDA, evolocumab and alirocumab, has led to an ongoing debate over the value of these interventions in clinical practice. In the US, the Institute for Clinical and Economic Review (ICER) has been in the forefront of those who have argued that, in the context of notional incremental willingness-to-pay thresholds, manufacturers should reduce drug prices substantially. This conclusion has been echoed in a number of other technology assessments, notably in assessments by the National Institute of Health and Care Excellence (NICE) in the UK. At the same time, other evaluations have reported favorably, arguing that at current US prices, the two products meet willingness-to-pay benchmarks. The purpose of this commentary is not to argue for or against current PCSK9 pricing policies but to point out that the case made for possible price adjustments rest upon technology assessments that fail to meet the standards of normal science. Modeled claims that are properly classified as pseudoscience. The claims made are

non-evaluable. Formulary committees, rather than accepting these claims at face value, should step back and work with manufacturers to develop claims that are targeted, robust, evaluable and replicable in a timeframe where feedback on PCSK9 outcomes are meaningful to health system decision makers.

Type: Commentary

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