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Commentary

Are mAbs different?

A comment on Cohen and Wilson

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Apart from the nifty science behind their development, are monoclonal antibodies (mAbs) different than other new technologies? As highlighted by Cohen and Wilson in their interesting new paper, mAbs are distinctive from most traditional pharmaceuticals in some ways: their relatively high prices; their high costs of development; their mode of administration; the fact that, unlike many other drugs, they offer disease modification not simply symptomatic relief; the frequency of supplemental indications and off-label use—much of it recognized in drug compendia and reimbursable; and the lack of a clear pathway for their generic substitution.

However, like many new and expensive therapies, mAbs present our health care system and our society with fundamental and, by now, familiar challenges. The treatments offer promise to patients and their families, providing relief from suffering and in some cases added life expectancy. Yet their costs create their own hardships. Out-of-pocket spending for the medications is rising. In some cases, patients and their families are incurring large amounts of debt, and even going into bankruptcy because of technologies like mAbs (and, in fairness, because of many other illness-related expenses).

On the key question of whether they are different in terms of delivering better value for money, however, uncertainty prevails, and where evidence exists, the record is mixed. Moreover, as is the case with other expensive technology, as a society the US has only begun to grapple with the choices, tradeoffs and policy solutions surrounding the use of mAbs.

The Cohen and Wilson paper nicely summarizes the emerging clinical and economic landscape for the 22 mAbs approved by the FDA to date and adds to our understanding of the field. It is most useful in highlighting the fact that payers in the US have either given mAbs a free pass towards reimbursement or have turned to blunt instruments in their toolkits to control their utilization.

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Interestingly and perhaps not surprisingly, the authors found that not one of the regional Medicare carriers' local coverage decisions for Part B mAbs has involved denying coverage for on-label indications, nor was step therapy or prior authorization applied to any mAb. Indeed, for on-label indications, Cohen and Wilson found few conditions at all placed on reimbursement. They discovered more denials and restrictions for off-label uses, but wide variation prevails across carriers with citations of different compendia and recommendations for different indications. For the few Part D mAbs, most plans have assigned drugs to the 4th (specialty) tier with co-insurance ranging from 25–75%, but none have implemented step therapies or specific off-label policies.

As Cohen and Wilson note, more sophisticated policies that attempt to link reimbursement to evidence of value do exist. Reimbursement authorities in many countries are using cost-effectiveness analysis to determine whether new technologies—including mAbs—provide good value for money. The US has been a notable holdout in the move to use cost-effectiveness analysis. However, even in the U.S., some plans have begun exploring value-based insurance designs. Moreover, as the authors note, Medicare has begun to implement a policy of "coverage with evidence development," which allows prospective data collection as a condition of coverage for items and services that have some evidence of medical benefit, but for which the evidence is insufficient to support a "reasonable and necessary" determination.

The real question is why more health plans in the US haven't adopted these value-based strategies, particularly with the high-cost mAbs. The answers tend to be several-fold. For one, the strategies are more difficult to execute, requiring data and expertise. For another, there are too few incentives in place for doctors to use them. There is also the prevailing culture, which tends to assume that new technology is preferable to existing standards.

What does the future hold for mAbs? Several scenarios are possible from more patient cost-sharing (which seems likely) to outright price controls (less likely). We are likely to see more information on the comparative effectiveness of therapies, perhaps with a new institute devoted to research in this area.

However, what is really needed is an explicit agenda for value. The real question for mAbs is not how much they cost, but what they deliver in terms of health benefit for the spending. Future policies should include broader application of cost-effectiveness analysis. Apart from processes to gather better information, there is also much

room to improve on flexible coverage strategies. Finally, there is a need for systemic changes in incentives and structural reforms in Medicare, including the eventual end of the Part B and D distinction.

The science behind the mAbs is undeniably exciting. Undeniable, too, is their commercial success as noted with projections for strong growth into the foreseeable future. The policies uncovered by Cohen and Wilson suggest that payers value biologics differently from other areas of health care, but ironically the payers have not yet attempted to actually measure value.