

## Specialty Pharmaceuticals: Policy Options to Promote Access and Affordability

**S**pecialty pharmaceuticals pose a policy challenge that is emblematic of much of American healthcare: the need to balance access to expensive therapies with the need to maintain affordable health coverage. The cost of specialty pharmaceuticals has been growing 20% annually, and growth is expected to continue as more expensive treatments are introduced. As tiered pharmaceutical benefits have evolved, specialty drugs have increasingly been placed into Tier 4 status with coinsurance rates of 25% - 33%, making them unaffordable for many patients. The policy dilemma centers on finding ways to ensure that patients have access to appropriate therapies, while limiting unnecessary or marginally beneficial utilization in a complex distribution system with multiple stakeholders and suboptimal information.

In July 2008, a group convened by the Health Industry Forum identified four key challenges for specialty pharmaceuticals: 1) overlapping benefit structures that hinder effective medical management; 2) physician financial incentives that may bias therapeutic choice; 3) evidence gaps that hinder rational coverage and payment policy; and 4) untenable patient financial burdens created by Tier 4 coinsurance. In October 2008, it held a follow-up meeting to outline policy considerations and potential solutions. Dan Mendelson, President of Avalere Health, began the meeting by proposing guiding principals to help evaluate policy alternatives. The policy options discussed during the October meeting are summarized below.

### Specialty Pharmaceuticals: Principals for Policy Development

1. Provide timely access to medications in an appropriate setting.
2. Maintain neutral incentives across products, settings, and benefits to match drug treatment to optimal setting of care through:
  - a. Neutral prescribing incentives across medications and modes of delivery
  - b. Appropriate compensation for medical management
  - c. Equivalent patient cost sharing between benefits
  - d. Consistent use of utilization controls between benefits
3. Encourage innovative drug formulation and delivery systems.
4. Ensure reasonable cost containment.

Source: Adapted from Avalere Health 10-2-2008

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*Integrated programs are needed to support better coordination across medical and pharmacy benefits, and ensure timely appropriate treatment.*

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The existence of separate medical and pharmaceutical benefits within most health coverage programs creates challenges for managing specialty pharmaceuticals that may affect cost, beneficiary equity, and quality of care. This is clear in the Medicare program where

beneficiaries who do not have additional private or Medicaid coverage and need specialty pharmaceuticals face 20% coinsurance for drugs provided under Medicare Part B, and even higher, 25% - 33%, coinsurance for Tier 4 specialty drugs under Medicare Part D. Beneficiary coinsurance can be as high as 100% for beneficiaries in the Part D “coverage gap.” Rather than utilize less costly oral medications that require high Part D coinsurance, providers may attempt to get patients necessary medications by prescribing more costly alternatives covered under Part B where the coverage gap does not exist. In addition, the separation of medical and pharmaceutical benefits complicates care coordination for beneficiaries with complex medical needs. One option to address these challenges would be creating a consolidated specialty pharmaceutical benefit that would eliminate differential coinsurance, and end differential provider reimbursement based on site of service. A consolidated benefit could set up utilization management protocols to ensure appropriate use. It could also provide a framework to devise new payment methodologies for drug administration, medical management, and treatment planning.

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***Eliminating “buy and bill” for physician-administered drugs would reduce problematic financial incentives, but implementation would be extremely challenging.***

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Under “buy and bill” reimbursement, physicians purchase drugs and bill insurers for drug costs plus a markup. There is significant variability in markup depending on the drug prescribed, and physicians often have financial incentives to choose more costly medications. Some specialists like oncologists earn substantial portions of their income through “buy and bill”. Eliminating or scaling back “buy and bill” would have a negative effect on physician margins, which could save money, but could also affect quality if physicians respond by reducing patient support services. Furthermore, payers do not want to reduce margins to the point where specialty drug administration shifts from physician offices’ into more costly hospital settings. To address concerns about potential impacts on quality and access, changes to “buy and bill” would have to be accompanied by enhanced professional fees for administration and patient management. Another option for maintaining sufficient margins and encouraging physicians to maintain current levels of patient services would be to establish a monthly patient management fee for each course of therapy. Determining the terms and amounts for these type of episode payments would be technically challenging. Although a payment methodology with neutral financial incentives would be preferable in many ways to “buy and bill”, establishing a new system that supports a high level of patient service and keeps drug administration in community settings is a complex proposition.

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***Drug payment policy must promote the development of credible evidence of effectiveness, and also reward value.***

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Under the current system, health plans face pressure from manufacturers, physicians, and patients to cover expensive new drugs even when their value is not proven. The high cost of specialty pharmaceuticals is associated with the cost of innovation and the significant financial risks of drug development. Although payers are generally supportive of promising new therapies, they are increasingly resistant to paying high rates for products with uncertain effectiveness. One option to address this impasse would be to establish new models that link payment to the strength of evidence. Under such a system, drugs would be reimbursed at an incrementally higher rate as the value of the product is demonstrated in clinical practice and post-market trials. Manufacturers have suggested that they would be more interested in such a model if there was an opportunity for a longer period of exclusivity in exchange for an agreement to accept lower prices in the early stages of evidence

development. If designed correctly, such a model could reduce uncertainty by creating an initial revenue stream for manufacturers despite limited evidence, while assuring payers of a process for developing additional evidence to support rational payment and coverage policy.

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*Pharmacy benefits should be consistent with principals of insurance, and protect patients against catastrophic expenses.*

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The current Tier 4 benefit design is a cruel lottery where beneficiaries face significant costs if they are unfortunate enough to be diagnosed with a disease that requires ongoing specialty drug treatment. Patients, physicians, payers, and pharmaceutical firms would all prefer to do away with Tier 4 coinsurance; however, this will not occur in a free market because the first health plan to eliminate Tier 4 will face a deluge of expensive new enrollees. Therefore, a more comprehensive solution is required. One option would be to ban systematically Tier 4 benefit design, or to set mandatory maximum patient out-of-pocket limits. Doing so would require amending each state's health care laws, since insurance is regulated by individual states, not by the federal government. A total ban on Tier 4 coinsurance would spread the cost of these products to all members in the plan making the drugs accessible for those who need it. However, at a time when health plans are attempting to design benefit packages that employers can afford, mandated coverage for specialty pharmaceuticals will likely result in reduced coverage for other services.

An alternative would be a federally-supported reinsurance program for high cost beneficiaries whose expenses exceed a certain threshold. Such a program could focus on specialty pharmaceuticals, in particular, or high cost beneficiaries generally. If all insurers are required to participate, catastrophic costs would be shared more broadly across the market. This would also make it much easier for patients with high cost conditions to change plans. Publicly funded reinsurance could be very costly depending on its design. It would require strong incentives for insurers to continue managing complex patients once they hit the reinsurance threshold, as well as protections against gaming. Tier 4 banning and reinsurance policy options address patient access barriers; however, neither would reduce the cost of specialty drugs.

The policy dilemmas posed by specialty pharmaceuticals reflect broader challenges in the US health care system. Middle class Americans are increasingly less able to bear the rising costs of health care coverage that are driven upward partly by a growing array of often fantastic new technologies and services. As in other areas of medicine, developing policy options for broadly improving the effectiveness, appropriateness, and affordability of specialty pharmaceuticals care requires navigating a complex web of benefit structures and financial arrangements involving multiple stakeholders. The policy changes discussed in this paper affecting benefit structure, physician payment, drug pricing, and beneficiary coinsurance are all interrelated. It would be difficult to address any single area separately, and achieve optimal results. A more integrated set of policy solutions is needed. These policy changes are likely to yield winners and losers. Given the complexity of issues, and diversity of stakeholders, guiding principals like those presented at the beginning of this paper are important for moving the discussion forward, and developing balanced solutions that recognize social priorities.

*This policy brief was prepared by Palmira Santos and Rob Mechanic of Brandeis University. This policy brief draws heavily from presentations at the October 2, 2008 forum by: Dan Mendelson and Lauren Barnes of Avalere Health; Lee Blansett of MattsonJack DaVinci; Sharon Levine, MD, of The Permanente Medical Group; and Donald Moran of the Moran Company. For presentations and a detailed proceedings go to [www.healthindustryforum.org](http://www.healthindustryforum.org).*

***The Health Industry Forum** is based at Brandeis University, chaired by Professor Stuart Altman and directed by Robert Mechanic. The Forum brings together public policy experts and senior executives from leading healthcare organizations to address challenging health policy issues. The Forum conducts independent, objective policy analysis and provides neutral venues where stakeholders work together to develop practical, actionable strategies to improve the quality and value of the US healthcare system.*

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