

Is All “Skin in the Game” Fair Game? The Problem With “Non-Preferred” Generics

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The new blockbuster drug sofosbuvir (Sovaldi) is offering hope to many patients with hepatitis C, but treatment is expensive and many insurers are demanding that patients shoulder a large portion of the cost. The demand that patients pay a larger share of their drug costs, however, is not limited to expensive new medicines. In fact, many patients are now facing substantially higher co-pays for various generic drugs that their insurers have designated “non-preferred,” often including those recommended as first-line treatment in evidence-based guidelines for hypertension, diabetes, epilepsy, schizophrenia, migraine headache, osteoporosis, Parkinson’s disease, and human immunodeficiency virus (HIV). We are concerned about this relatively recent development.

For many years, most insurers had formularies that consisted of only 3 tiers: Tier 1 was for generic drugs (lowest co-pay), Tier 2 was for branded drugs that were designated “preferred” (higher co-pay), and Tier 3 was for “non-preferred” branded drugs (highest co-pay). Generic drugs were automatically placed in Tier 1, thereby ensuring that patients had access to medically appropriate therapies at the lowest possible cost. In these 3-tier plans, all generic drugs were de facto “preferred.” Now, however, a number of insurers have split their all-generics tier into a bottom tier consisting of “preferred” generics, and a second tier consisting of “non-preferred” generics, paralleling the similar split that one typically finds with branded products. Co-pays for generic drugs in the “non-preferred” tier are characteristically much higher than those for drugs in the first tier.

To better understand coverage policies in plans with 2 tiers for generic drugs, we identified several such offerings, including both commercial plans and those under the Medicare Part D program, via an informal search of the Internet. For 6 such plans, we examined coverage policies for 10 widely used drugs—all generically available—that are recommended as first-line treatment in current evidence-based guidelines (Table).

While 2 of the plans provide access on a “preferred” basis to all of the medicines we considered, 1 or more of the drugs are “non-preferred” in all of the remaining plans. Metformin, for example, is a “non-preferred” drug in 1 plan, despite being a first-line treatment for type 2 diabetes mellitus. Two plans have no “preferred” generic anticonvulsant drugs; 3 plans have no “preferred” generic antipsychotic medicines; levodopa is designated a “non-preferred” agent in 3 plans; 4 plans have no “preferred” generic triptans (for migraine headache); and all generic antiretrovirals are Tier 2 agents in 4 plans. When there are no “preferred” generics from which clinicians and patients with particular diseases can choose, it may be argued that the diseases themselves effectively are “non-preferred.”

We think it is apparent that designation of these generic drugs as “non-preferred” was based on cost considerations alone; indeed, a number of insurers unabashedly refer to their second tiers as consisting of “higher-cost generic drugs.” It also is difficult to imagine what criteria other than cost could have led to the exclusion of highly effective and widely used generic drugs from the “preferred” tier. If cost was indeed the reason for designating these medications “non-preferred,” it would be inconsistent with all accepted principles and standards of formulary design and management, including guidelines jointly endorsed in 2000 by 7 professional groups, representing physicians, pharmacists, business, and other constituencies.¹

It is sometimes argued that patients should have “skin in the game” to motivate them to become more prudent consumers. One must ask, however, what sort of consumer behavior is encouraged when *all* generic medicines for particular diseases are “non-preferred” and subject to higher co-pays. The answer is informed, we believe, by a 2007 *JAMA* study of cost sharing by researchers at RAND, which was based on a review of 132 published studies. The authors report that “(i)ncreased cost sharing is associated with lower rates of drug treatment,

Take-Away Points

Many patients are now encountering much higher co-pays for generic drugs that have been designated “non-preferred” by their insurers, including those recommended as first-line treatment in evidence-based guidelines. For some diseases, in fact, many insurers have no “preferred” generic medicines, effectively rendering the diseases themselves “non-preferred.” Designation of clinically important generic medicines as “non-preferred” without ensuring that patients have access to therapeutically equivalent “preferred” drugs runs counter to established principles of formulary design, may increase other healthcare costs, and ultimately may undermine emerging payment reform initiatives.

worse adherence among existing users, and more frequent discontinuation of therapy” and that “for certain conditions, the evidence clearly indicates that more cost sharing is associated with increased use of other medical services, such as hospitalizations and emergency department visits.”²

We believe this is the most likely scenario when patients confront substantially higher co-pays for generic medicines that have been designated “non-preferred” and there are no therapeutically equivalent “preferred” drugs from which to choose. Fortunately, such coverage policies have not been universally adopted. In fact, recognizing the impact that high co-pays can have on

adherence with therapy, some insurers now offer drug coverage with low—or even zero—co-pays for generic medicines for diseases such as diabetes, heart failure, high blood pressure, and high cholesterol, consistent with the principles of value-based insurance design.³

When insurers designate clinically important generic medicines “non-preferred” and there are no therapeutically equivalent “preferred” alternatives from which to choose, it cannot be argued that patients are thereby motivated to become more prudent consumers. The existence of clinically sound therapeutic choices is a precondition for any meaningful effort intended to make patients put “skin in the game.” Without choice, such policies are simply punitive and run counter to established principles of formulary design and management. They also may increase utilization and costs elsewhere in the healthcare system, and ultimately may undermine emerging payment reform initiatives designed to reward physicians for attaining disease-specific performance metrics (eg, A1C, blood pressure).

Table. Availability of Guideline-Recommended Medications for Selected Diseases as Tier 1 Drugs in Selected Private Sector Health Plans and Medicare Prescription Drug Plans Having a Formulary Tier for “Non-Preferred” or “More Costly” Generics (Tier 2)

Drug/Therapy	Disease(s)	Guideline	Plan A	Plan B	Plan C	Plan D	Plan E	Plan F
(1) Metformin	Type 2 diabetes	http://www.guideline.gov/content.aspx?id=15202	Yes	Yes	Yes	Yes	Yes	No
(2) Angiotensin II receptor antagonists	Hypertension	http://www.guideline.gov/content.aspx?id=14586#Section420	Yes	Yes	Yes	No	Yes	No
(3) Calcium channel blockers	Hypertension, ^a stable angina	http://www.guideline.gov/content.aspx?id=14586#Section420	Yes	Yes	Yes	Yes	Yes	No
(4) Anticonvulsants	Epilepsy	http://www.iqanda-cme.com/assets/pdf/New%20Onset%20Guidelines.pdf	Yes	Yes	Yes	Yes	No	No
(5) Levodopa	Parkinson's disease	http://www.neurology.org/content/66/7/983.full	Yes	Yes	Yes	No	No	No
(6) Bisphosphonates	Osteoporosis	http://www.guideline.gov/content.aspx?id=38413	Yes	Yes	Yes	Yes	Yes	No
(7) Macrolide antibiotics	Community-acquired pneumonia ^b	https://www.thoracic.org/statements/resources/mtpi/idsaats-cap.pdf	Yes	Yes	Yes	No	No	No
(8) Antiretroviral agents	Human immunodeficiency virus	http://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf	Yes	Yes	No	No	No	No
(9) Triptans	Migraine headache	http://www.guideline.gov/content.aspx?id=36898	Yes	Yes	No	No	No	No
(10) Antipsychotic medications	Schizophrenia	http://www.guideline.gov/content.aspx?id=34115	Yes	Yes	No	Yes	No	No

^aFirst-line therapy in non-Hispanic blacks.

^bFirst-line therapy in previously healthy adults with no risk factors for drug-resistant *S pneumoniae*.

The policy implications are clear—only when there are therapeutically equivalent medicines on formulary that are “preferred” should insurers designate first-line, guideline-recommended therapies “non-preferred” and therefore subject to higher co-pays. Not all “skin in the game” is fair game.

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