Why Is Access To New Medications So Complicated?

By Chuck Dinerstein, MD, MBA — December 4, 2018

Supply and demand, what could be more straightforward. As demand increases so does supply; more demand than supply – higher prices; more supply than demand – lower prices. A lot of our worry about prescription medications is about price, but it may be worthwhile to look at how supply and demand curves are affected by vested interests in the marketplace.

Researchers look at how new pharmaceuticals diffused following their FDA approval. By diffused I am referring to how payers, Medicare, and insurance companies, place new medications on their formularies, the first step in supply following the FDA’s determination that the medicines are safe and effective. Medicare will issue a “nationwide coverage determination” (NCD) that indicates it will provide payments for a new drug and insurance companies usually follow the CMS lead. For medical technologies used in the hospital or medical offices, FDA approval and CMS approval are linked resulting in little if any delay in an NCD; but for drugs, we take at home, subject to Part D coverage that is not the case.

Using FDA and Medicare datasets, the researchers looked at the diffusion of drugs into Part D formularies from 2006 to 2012, 144 drugs in all. Few drugs were immediately (within the first year of FDA approval) incorporated in every formulary; although for the optimists 90% of prescriptions were covered by at least one plan (out of between 2,500 and 3,000 Part D plans available) – 60% of plans covered the drugs immediately, about 80% by year 3. But as always, some groups of drugs fared better than others.

- CMS-protected class drugs are those deemed to be as close to essential drug required on all Part D formularies [1], and their adoption was 93% in the first year.
- Priority review drugs – resulting in “significant improvements in …safety or effectiveness … compared to standard applications” 75% approved in the first year.
• Accelerated approval drugs – drugs for unmet needs that use “surrogate” endpoints in their studies [2] 91% approved in the first year.

So at first glance, with a few minor hiccups new, novel pharmaceuticals are available to most of us fairly quickly. Of course, it is the second glance that tells a far different tale. Only 4% of these drugs, the antivirals used in treating HIV, were available without restrictions 3 years following initial FDA approval. What could those restrictions be?

**Prior authorization and Step Therapy**

While CMS can drive pharmaceuticals onto Part D formularies, it leaves it to the insurance companies to follow “existing best practices” in the access they allow to their beneficiaries. And let us say right away, that given the wide variety of access rules used, that there is, in reality, no “existing best practice” it is got to be a term lawyers invented because it can be so widely interpreted.

The most common means of controlling access familiar to patients is tiering, where certain drugs are placed in tiers requiring greater out of pocket expenses. Prior authorization requires the physician to provide a rationale, most often in writing, for why they are prescribing this rather than another drug. And yes, an insurance company’s oversight is unwarranted meddling in the eyes of physicians. For many patients, prior authorization is a behind the scenes issue, the doctor takes care of it. But to give you a sense of the cost, Cleveland Clinic [2], which will complete roughly 900,000 prior authorizations this year puts their cost at $9.7 million.

Step therapy is another way of limiting access requiring a patient to start with the most cost-effective treatment and only change to more costly alternatives when they have “failed” treatment. And while I think that makes some clinical sense if the steps are defined by clinicians rather than accountants, it still remains a significant means of controlling your access and their costs. And by the way, what does failing treatment mean – that the medicine doesn’t work or that the side effects make it difficult to swallow so to speak?

In three more days, the opportunity to change health plans for Medicare recipients ends for the upcoming year. The researchers clearly show that access to new therapies is uneven, varying with many factors and further hampered by insurance companies tiering, prior authorizations and step therapy. The fact that information about access to medications, the supply side of the equation, is so obscure makes the annual “search” for a better plan impossible. Wouldn’t it be nice to see an app where you plug in your prescriptions, and you see your projected costs for the next year? The insurance companies have the data and the actuaries to make those determinations for themselves, when will someone speak for us?

[1] Drugs used in organ transplants, depression, psychosis, epilepsy, cancer, and HIV.
[2] Surrogate endpoints are used when true outcomes are too difficult to measure. For example, cholesterol medications lower cholesterol but for the clinical endpoint of fewer heart attacks, lower cholesterol is the surrogate endpoint, and therefore cholesterol-lowering medications are approved to reduce heart attacks, or at least their risk.

Source: Coverage of Novel Therapeutic Agents by Medicare Prescription Drug Plans Following FDA approval  Journal of Managed Care & Specialty Pharmacy DOI: