



The newest generation of drugs: Who can afford them?

Costs of expensive biotech "specialty" drugs may overwhelm an increasing number of patients and employers, and raise questions about the meaning of "insurance."

Seattle Times, 8/17/08

Sally Garcia, a 53-year-old lawyer disabled by multiple sclerosis, was torn. A new-generation medication, Copaxone, was really working for her. After two decades of being in and out of hospitals, Garcia was taking steps to work again. Her wallet, though, was in severe distress. Under her Medicare prescription plan, **Garcia's share of the expensive drug was \$330 per month.** All together, medications were taking a third of her disability payments — her only income — and she couldn't swing it.

Copaxone, Enbrel, Remicade: For some patients, such new-generation drugs, often called "biologicals" or "bioengineered" when they are created by genetically modified living cells, have performed magic. In some cases, they work when other drugs have failed, or for diseases that previously had no drug treatments at all. But they cost a lot — often \$2,000 to \$3,000 per month. And in a double whammy, some insured patients who previously paid a fixed amount — likely \$30 to \$50 even for the most expensive, brand-name drugs — are suddenly finding the rules have changed. For these new drugs, an increasing number of patients must pay a percentage of the tab, generally 25 to 30 percent. For many of those patients, that can mean a bill of \$600 to \$900 a month for a drug that they may need for many years.

The rising bill for such complex drugs threatens to financially overwhelm patients and employers, and — if current trends continue — to unravel the very philosophy of health insurance. "The idea of insurance is to protect people from catastrophic costs," says Gary Claxton, director of the Healthcare Marketplace Project for the Kaiser Family Foundation. "At some point, people aren't going to consider themselves insured if they're at risk for a huge amount out-of-pocket just because they have one disease rather than another."

Usage expected to soar

Today, such drugs are prescribed relatively rarely. But their use is expected to explode. **In 2007, the tab for bioengineered and "specialty" drugs was nearly \$59 billion. Industry analysts predict it will reach \$98 billion by 2011.** "The reality is that this is where the pharmaceutical industry is focusing their research," says Jim Carlson, Group Health Cooperative's pharmacy director.

The pharmaceutical industry long has been accused of price gouging and producing "new" drugs that aren't better than cheaper ones already on the market, and it has been criticized for its direct-to-patient advertising. In response, the industry points to long periods of expensive research and development that often end without new products. Healthy profits attract investors to fund new research, it argues, and advertising helps patients make informed choices.

The emergence of bioengineered drugs has dramatically magnified these disputes. Most are produced through complicated, delicate procedures that are difficult to replicate. Unlike a typical oral pill, the new bioengineered drugs have no simple chemical "recipe" that can be easily followed by another company. In fact, the federal **Food and Drug Administration has no process yet for creating a generic version, in this world often called a "bio-similar."**

Most often given as injections for diseases such as advanced breast cancer, rheumatoid arthritis or MS, bioengineered drugs can be lifesavers. "The costs might be out of the ballpark, but in the past, without that drug, the person might not be living or not living any type of quality of life," says SuAnn Stone, director of pharmacy services for Regence BlueShield, one of Washington's largest insurers.

For patients and employers, the costs can be huge, particularly since many are targeted at chronic diseases that can require long-term treatment. Typical bioengineered drug treatments for rheumatoid arthritis now run about \$16,000 a year, says Dr. Philip Mease, director of rheumatology research for Swedish Medical Center. At **Premiera Blue Cross, another large local insurer, such unique "specialty" drugs account for 1 percent of pharmacy claims, but 15 percent of the costs.** Because such specialty drugs are so expensive, most Medicare "Part D" prescription-drug plans and a small but increasing number of private insurance plans have isolated them — either by type or by price — into a separate category that requires patients to pay more. Usually, the patient is asked to pick up a percentage of the cost, rather than a fixed co-payment.

Patients with chronic illnesses, who could need the drug for years, are getting hit hardest by the change, says Dan Mendelson, president of Avalere Health, a national health-policy analysis firm. "It gets to the fundamental question of 'What is insurance?'" he said. As advances in medicine become ever more costly, insurance that requires heavy cost-sharing from patients for pricey drugs is likely a "microcosm of medicine's future," predicts a commentary in a recent *New England Journal of Medicine*. The authors warn: "At some point in our lives, we may all join that small pool of users of high-cost care."

Ethical dilemma

Traci Ohlsen, a nurse, had rheumatoid arthritis as a child, but the crippling disease was in remission for years. Seven years ago, it came back hard, attacking her back, hips, neck and hands, and producing debilitating fatigue. She tried several biotech drugs but couldn't tolerate the side effects. Finally, she tried Orencia, given by intravenous infusion in a doctor's office. Her doctor prescribed three infusions, at \$4,500 each. After two, she

began feeling well enough to return to part-time work. But Ohlsen, 44, of Renton, recently put off the third infusion when her insurer balked. She realized she might already owe \$9,000, she said, and didn't want to add to the tab. "If I end up having to pay for those last two infusions ... I would have to file for bankruptcy," she said.

As costly drugs become more commonly prescribed, employers, who buy most private health insurance, are watching warily. "They want to keep employees and be good employers, but there is a lot of pressure on the cost of health care right now," said Group Health Cooperative spokesman Michael Foley.

Everyone recognizes the **ethical dilemma: Do you make the sickest pay the most, or do you require everyone to foot the bill? Will costs raise premiums so much that some employers drop drug coverage or even health insurance itself?** Some insurers argue that requiring patients to pay a percentage keeps the patient's share more proportionate to the drug costs, and therefore more fair — and more tolerable to employers. "We're trying to make sure that the benefit is kept affordable for the other 1,000 employees in the company," said Susan Pisano, spokeswoman for America's Health Insurance Plans, an industry group. That group says **doctors sometimes prefer newer drugs even with scant evidence that they work better than older, less-expensive drugs.** "Is a drug that costs 100 times more ... 100 times better?" Pisano asked. "Today, we don't know, because there is no independent entity that makes those comparisons."

Insurers in Washington

In the recent past, most insurance plans covered prescription drugs in three "tiers," requiring flat co-payments ranging from \$5 or \$10 for generics to several times that for brand-name drugs not "preferred" by the insurer. But that appears to be changing, with Medicare Part D plans, the stand-alone prescription drug plans set up by Congress in 2003, leading the way. Now, **86 percent of such plans have a "fourth tier" requiring higher cost-sharing — up to 33 percent — for more expensive drugs,** according to the Kaiser Family Foundation. About 10 percent of commercial plans now have a specialty-drug tier, Mendelson says.

In Washington, two smaller insurers, **Aetna and United Health Group, have created a fourth tier in some plans.** Even without fourth tiers, some plans require high cost-sharing for brand-name drugs, particularly if they aren't "preferred." For example, **Regence BlueShield and Premera Blue Cross** offer plans requiring patients to pay 50 percent of top-tier drugs' costs. About 78,000 of Premera's 1.4 million members statewide have group or individual plans that require them to pay a percentage for some drugs. A minority of those plans limit yearly out-of-pocket expenses to \$10,000. Sometimes injectable biotech drugs are covered under medical benefits because they require doctor visits. That's typically true for the asthma drug Xolair, which can cost \$30,000 a year, and some arthritis biotech drugs.

Insurers say that when there's convincing evidence a drug works better, it's moved to their "preferred" list. But insurers can disagree. For example, Tykerb, for advanced breast cancer, is a preferred drug at Premera but not at Regence. And for patients, the rules can get really confusing. Jeanne Sather, 53, a 10-year cancer survivor in Seattle who lives on Social Security disability payments, recently discovered that her new Medicare Part D plan required her to pay \$1,600 a month for Tykerb. That would leave her \$900 a month to live on. "For me, Tykerb is a fabulous drug," Sather said. "... But obviously, I can't pay this."

Escalating cost-sharing tiers for drugs originally were developed to encourage patients to use lower-cost generics or "therapeutically equivalent" brands, noted Claxton, of the Healthcare Marketplace Project. But, with the development of costly bioengineered drugs, insurers may have found a new use for the tier system. When patients have no less-expensive choice, Avalere's Mendelson argues, cost tiers simply punish patients instead of encouraging thrifty, healthy behavior. "These tiering policies don't accomplish that. They just stick it to the chronically ill."

The future: tough choices

As bioengineered drugs become more widely used, industry observers predict more employers will adopt percentage cost-sharing. At SeaBright Insurance in Seattle, Gene Gerrard, the assistant vice president of human resources, says prescription drugs make up 24 percent of the company's health-care spending. In the future, he says, his employees will have to have "a little more skin in the game," but so far, it's not clear how much. Still, he adds: "We have to recognize that we can only spend so much on health care."

That means tough choices. For example, **the state spends \$25 million a year on lifesaving specialty drugs for 30 patients with hemophilia**, says Dr. Jeffery Thompson, chief medical officer for the state's Medicaid program. "What are the options? Other than turn off the lights and say goodbye?"

In large part, the looming cost issue of specialty drugs has been masked by the increasing use of cheaper generic drugs. But with unique drugs, insurers have little bargaining power, they say. Patients should have access to the best available therapies, said Pisano, the insurance-industry spokeswoman. But, she added: "In some instances, manufacturers are charging exorbitant prices for single-source drugs, and prices keep increasing dramatically."

Dr. Peter McGough, former president of the Washington State Medical Association, and now chief medical officer for UW Medicine's neighborhood clinics, recalls the time decades ago in Seattle when kidney-dialysis treatment was so scarce and expensive, a secret committee was formed to decide which patients got treatment — and which died. As was true then, McGough says, these super-expensive new drugs "are pushing at the question of limited resources." Decisions can't simply be left to insurers and employers, he said, because they require a broad social policy about what's "sustainable, ethical and

equitable." Group Health's Carlson says he reluctantly ponders price controls. "Is 'The sky's the limit' a tolerable national policy?"

Getting help with costs

Many programs exist to help patients with expensive medications, but patients often say they're difficult to negotiate. Sally Garcia, the MS patient, has struggled to pay for Copaxone, "the only drug that worked for me," for five years. Off and on, she's received help, but never for long. Last year, she dashed off an anguished letter to government agencies and every politician she could find. "I ask you, 'How could the wealthiest nation in the world allow their disabled to go without medications specifically designed to promote their quality of life?' " she beseeched them.

For three months, she got help from the National MS Society's local chapter, and she switched plans. Then, out of the blue, she began getting aid from an organization she says she's never heard of and never contacted. She's grateful, but she worries the help will vanish as mysteriously as it arrived. "This is going to go on until the day I die," she predicts. "I'll be this 90-year-old lady fighting for her Copaxone."