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PAYING TILL IT HURTS Chronic Illnesses

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Part 7: Type 1 Diabetes

Even Small Medical Advances Can Mean Big Jumps in Bills

By ELISABETH ROSENTHAL APRIL 5, 2014

MEMPHIS — Catherine Hayley is saving up for an important purchase: an updated version of the tiny digital pump at her waist that delivers lifesaving insulin under her skin.

Such devices, which tailor insulin dosing more precisely to the body's needs, have transformed the lives of people with Type 1 diabetes like Ms. Hayley. But as diabetics live longer, healthier lives and worries fade about dreaded complications like heart attacks, kidney failure, amputations and blindness, they have been replaced by another preoccupation: soaring treatment costs.

"It looks like a beeper," said Ms. Hayley, a 36-year-old manager here for an environmental services company, referring to the vintage 2007 pump on the waistband of her jeans. "It's made of plastic and runs on triple-A batteries, but it's the most expensive thing I own, aside from my house."

A new model, along with related treatment supplies, prices out at tens of thousands of dollars for this year and will cost her about \$5,000, even with top-notch insurance. "It's great," Ms. Hayley said, "but it all adds up."

Traditionally, insurers lost money by covering people with chronic illnesses, because they often ended up hospitalized with myriad complications as their diseases progressed. Today, the routine care costs of many chronic illnesses eclipse that of acute care because new treatments that keep patients well have become a multibillion-dollar business opportunity for device and drug makers and medical providers.

The high price of new treatments for diabetes, rheumatoid arthritis, colitis

and other chronic diseases contribute mightily to the United States' \$2.7 trillion annual health care bill.

More than 1.5 million Americans have Type 1 diabetes and cannot survive without frequent insulin doses, so they are utterly dependent on a small number of producers of supplies and drugs, which have great leeway to set prices. (Patients with the far more common Type 2 diabetes — linked to obesity — still produce insulin and can improve with lifestyle changes and weight loss, or on oral medicines.)

That captive audience of Type 1 diabetics has spawned lines of high-priced gadgets and disposable accouterments, borrowing business models from technology companies like Apple: Each pump and monitor requires the separate purchase of an array of items that are often brand and model specific.

A steady stream of new models and updates often offer dubious improvement: colored pumps; talking, bilingual meters; sensors reporting minute-by-minute sugar readouts. Ms. Hayley's new pump will cost \$7,350 (she will pay \$2,500 under the terms of her insurance). But she will also need to pay her part for supplies, including \$100 monitor probes that must be replaced every week, disposable tubing that she must change every three days and 10 or so test strips every day.

That does not even include insulin, which has been produced with genetic engineering and protected by patents, so that a medicine that cost a few dollars when Ms. Hayley was a child now often sells for more than \$200 a vial, meaning some patients must pay more than \$4,000 a year. Other refinements have benefited a minority of patients but raised prices for all. There are no generics in the United States.

Companies that produce the treatments say the higher costs reflect medical advances and the need to recoup money spent on research. But David Kliff, a financial analyst who is editor of Diabetic Investor, an independent newsletter on the industry, points out: "Diabetes is not just a disease state; it's a huge business, too."

Those companies spend millions of dollars recruiting patients at health fairs, through physicians' offices and with aggressive advertising — often urging them to get devices and treatments that are not necessary, doctors say. "They may be better in some abstract sense, but the clinical relevance is minor," said Dr. Joel

Zonszein, director of the Clinical Diabetes Center at Montefiore Medical Center.

“People don’t need a meter that talks to them,” he added. “There’s an incredible waste of money.”

Even patients with insurance often feel squeezed by large out-of-pocket costs, and many describe holding old pumps together with duct tape, rationing their test strips and skimping on insulin. Dr. Jeffrey B. Gordon, a family practitioner in San Diego, said he had patients with failing kidneys and others who had ended up in emergency rooms because they could not afford their maintenance care.

“From a guy on the front lines, the improvements have been miraculous,” he said. “But the acquisition cost is very high, and the pricing dictates what treatment you get.”

Complication rates from diabetes in the United States are generally higher than in other developed countries. That is true even though the United States spends more per patient and per capita treating diabetes than elsewhere, said Ping Zhang, an economist at the Centers for Disease Control and Prevention.

The high costs are taking their toll on public coffers, since 62 percent of that treatment money comes from government insurers. The cumulative outlays for treating Type 1 and Type 2 diabetes reached nearly \$200 billion in 2012, or about 7 percent of America’s health care bill.

Expenditures could well double by 2030, according to estimates by the C.D.C., in large part because the number of Americans found to have diabetes has been increasing more than 50 percent every 10 years. Most of the increase is attributable to Type 2 diabetes patients, whom manufacturers are encouraging to try insulin treatment and glucose monitoring, even though that is rarely medically required. Also, the Affordable Care Act requires health insurers to cover people with chronic disease, meaning they will have better access to treatments.

“This is not just a health care crisis,” said Mr. Kliff, the newsletter editor, who has Type 1 diabetes. “It’s an economic crisis as well.”

Maintaining Control

Catherine Hayley was born in 1977, the year before the first synthetic human

insulin was made using new gene-splicing technology. Her diabetes was diagnosed when she was 9, about the time this new generation of genetically engineered insulin was brought to market. One of her earliest memories is practicing insulin injections on an orange.

The development of insulin therapy in the 1920s was one of the great medical triumphs of the 20th century, on a par with the discovery of antibiotics. Before then, Type 1 diabetics often died within a year and were on such restrictive diets that they sometimes succumbed to starvation.

Diabetes is an autoimmune disease in which the pancreas stops producing the hormone insulin. Without it, sugars build up in the blood, producing symptoms like blurry vision, exhaustion and frequent urination and leading to a severe accumulation of acids that can be rapidly fatal. Even when treated with insulin shots, moderately high sugar levels over the long term can damage the eyes, heart, kidneys and nerves. But if too much insulin is given, blood sugar can plummet, leading to unconsciousness and seizures. Because digestive enzymes degrade insulin, it cannot be swallowed, and must be injected.

When Ms. Hayley's diabetes was diagnosed, maintaining that balance involved testing a drop of blood on a paper strip that would change color to indicate — within a wide range — the patient's glucose level. Patients would typically give themselves a shot of insulin morning and night in response to the results.

"What I ate was all very regimented, and it had to be at the same time each day," she recalled. At school every day at 10 a.m., she pulled out a snack of a precisely weighed chunk of cheese and rice cakes.

The treatment tools were initially cheap: simple syringes and pig insulin, which is almost identical to that made by the human body. But that all changed after a landmark study in 1992 showed that patients did better if they maintained very tight control — keeping their blood sugar within a nearly normal range by checking it frequently and taking multiple insulin shots a day. Around the same time the business of American medicine was changing, too, with direct-to-consumer advertising, proprietary treatments and designer insulin in development.

When Ms. Hayley left Memphis for Colorado College in 1996, she was using a tiny meter through which she could get more precise measures of her blood sugar

level, a penlike injector containing insulin with an adjustable dose, and human insulin made with gene-splicing technology. All were covered by patents.

She did not switch to a pump until 2006 when, after years of waiting tables and studying in graduate school, she got her first job with insurance benefits. “It controls my blood sugar better,” she said, on her way to a dinner that included sharing a once-forbidden fruit cobbler. “I’m really able to live how I want. However, the price has increased dramatically.”

The tiny squirts from her pump are delivered more precisely by patented systems with microchip sensors and Bluetooth capability, with technical support by company representatives in endocrinologists’ offices. When Ms. Hayley pricks her finger, it is with a customized lancet to go with a customized test strip that fits into a customized meter, which transmits the result wirelessly to her compatible insulin pump, which delivers the appropriate insulin dose. (There is not yet a one-device-does-all that automatically performs the pricking, measuring and dosing.)

While some components, like the meters, are low cost or even free for patients, their supplies are costly. Dr. Spencer Owades, a dentist in suburban Denver with Type 1 diabetes, said he was shocked to discover that his test strips — which cost just pennies to make — were priced at \$1.50 apiece when he ran out and had to buy them at a pharmacy. He usually received them in the mail through his insurer and uses five to 10 a day.

“It’s a printer model,” he said, “where the printer is cheap, but they get you on the cartridges.” He added: “But if you have diabetes, they have you over a barrel.”

Planned Obsolescence

Diabetes experts say a good part of what companies label as innovation amounts to planned obsolescence. Just as Apple customers can no longer buy an iPhone 3 even if they were content with it, diabetics are nudged to keep up with the latest model.

Medtronic is the dominant insulin pump manufacturer, serving 65 percent of American patients and the majority of those worldwide. Though smaller companies sell cheaper pumps, it is hard to make inroads: Once familiar with the

Medtronic system and its extensive support network for troubleshooting problems, patients are reluctant to switch. Doctors are leery of prescribing equipment from a new company that may be out of business in a year; their office computer may not sync with the new software anyway.

Medtronic declined to talk about specific prices, but said a core tenet was to make only “a fair profit.” Amanda Sheldon, a spokeswoman, added: “We are committed to reinvesting in research and development of new technologies to improve the lives of people with diabetes, and our current pricing structure ensures that we can bring new products to market.”

For the small meters to test blood sugar, “the technology isn’t very sophisticated — it essentially hasn’t really changed much in the past 25 years,” said Dr. John Pickup, a professor of diabetes and metabolism at King’s College London. “The test strips are based on an electrochemical reaction. The new meters are a bit more sophisticated — they can make charts and things like that. It’s a little bit of added value to the patient. But the companies can charge a lot more money.”

The types of insulin available have evolved as well, as has their price. Synthetic human insulin is safer for patients, who sometimes developed reactions to animal insulin. But it is made by only three companies: Eli Lilly, Sanofi and Novo Nordisk. Manufactured in microbes, each one’s product has minor dissimilarities that reflect the type of cell in which it was made. Since the companies owned the cell lines, it is nearly impossible for other companies to make exact copies or even similar versions that would be cheaper, even once the patents expire. And the pharmaceutical companies defend the patents ferociously.

What’s more, the three companies continued to refine their product, adding chemical groups that made the insulin absorb somewhat more quickly or evenly, for example. They are called insulin analogues, and their benefits are promoted tirelessly to doctors and patients.

“The insulins are tweaked for minor benefits that may help a small number of patients with difficult-to-control diabetes, and result in major price increases for all,” Dr. Pickup said. Because of analogues, he added, Britain’s National Health Service has had to spend 130 percent more on insulin in the past five years.

In the United States, said Dr. Zonszein at Montefiore, the price of Humalog, Lilly’s analogue insulin, was typically two to four times that of its older human

insulin line, called Humulin. “There is not a lot of difference between Humulin and analogues,” he said, but he noted that Humulin was getting “hard to find.” Sanofi Aventis has stopped selling its older product in the United States, and Mr. Kliff, the financial analyst, said other companies were likely to follow suit, effectively forcing patients to use the costlier versions.

Dr. Todd Hobbs, chief medical officer of Novo Nordisk, defended the rising prices of insulin, linking them to medical benefits. “The cost to develop these new insulin products has been enormous, and the cost of the insulin to the consumer in developed countries has risen to enable these and future advancements to occur,” he wrote in an email.

Patients get squeezed between insurers or employers, who are trying to limit their outlays, and the suppliers. The constant shifts in products and prices are a challenge for even the most sophisticated consumers.

Denise Lombard, an insurance broker in Oakland, Calif., whose 16-year-old daughter, Gabrielle Woodland, has diabetes, said many policies contained “not one word about how they are going to cover insulin and supplies.” Gabrielle’s current policy does not cover glucagon, a hormone injection — which retails at \$272.72 a dose — that families of diabetic children are told to stock should they faint because their blood sugar drops too low.

Jonathan Lloyd, a pharmacist in upstate New York, has been frustrated trying to manage the care of his daughter, Erin, 25, who uses a pump with a built-in glucose meter and is teaching in Nicaragua. When Mr. Lloyd went to fill the four prescriptions for her supplies this year, he discovered many of them were no longer covered by his insurer, which had switched to reimburse a different brand of insulin and a different metering system, because the insurer got a better deal.

He now faces a dilemma: His daughter could switch to the new type of meter, which cannot communicate with her pump, which would mean her current meter would sit uselessly on her waist. Or he can pay thousands of dollars to buy supplies for the meter she already has. “It’s so complicated — there are all these hidden costs, and I’m a pharmacist, for crying out loud,” he said.

Meanwhile, as the price of supplies rises, endocrinologists remain among the lowest-paid specialists in American medicine, meaning severe physician shortages in many areas and long waits to see a doctor.

Chronic Diseases

Most other developed countries — with or without national health systems — provide free care and supplies for people with chronic diseases, reasoning that the disease is a natural catastrophe that fells its victims unpredictably. Also, with such policies in place, other countries and health care systems bargain hard with drug and device makers to bring down list prices.

In Germany, where everyone must have private insurance and contribute co-pays, people with diabetes get their care free; the price of pumps and insulin is negotiated by the government. In Britain, each hospital negotiates for pumps for its patients, getting prices that are typically less than half those in the United States, Dr. Pickup said. The vial of insulin analogue that Ms. Hayley gets for \$200 at an American pharmacy is typically bought by British pharmacists for under \$30 and dispensed free.

Some economists say manufacturers extract high prices in the United States to compensate for the fact that national purchasers overseas demand bargains. That may be justified in a world where bringing a new drug to market can cost \$1 billion, they add.

“To some extent, Europe is getting a free ride from the U.S.,” said Robert J. Shapiro, an economist and chairman of Sonocom L.L.C., a Washington-based financial advisory firm. “Drugs and equipment makers operate in a global market, and our costs are higher because every other country applies price controls, and we don’t.”

Mr. Kliff, the financial analyst, said some companies were no longer willing to sell in Germany as ever-tougher price negotiations have eaten into their margins. “I’m not saying they can’t make money there — they can,” he said. “But they can’t make the kind of money they make in the U.S.” He added that diabetes treatments remained highly profitable in the United States; insulin, for example, yields profit margins of around 70 percent.

With growing frustration but limited tools, the federal government has taken some tentative steps to fight back. Medicare is not allowed to bargain for insulin

prices. But for the first time last year it instituted competitive bidding for diabetes supplies, cutting reimbursements for test strips, for example, by about 60 percent.

Even when governments negotiate prices and foot the bill, patients may feel the rising price of diabetes care in other ways: While about one-third of Type 1 diabetics use pumps in the United States, that number is under 10 percent in Britain. What is the right number? Since pumps are complicated to operate, young children cannot use them, and some patients prefer syringes that operate like pens because they do not like having pumps attached.

The British government will not dispense these costly items unless a patient's diabetes has proved uncontrollable using other methods, but many doctors feel the devices are underutilized in Britain.

In the United States, each patient with a chronic disease must make the cost-benefit analysis of each new high-priced treatment, weighing symptoms, disposable income and insurance coverage. They are often wrenching decisions.

For Kristen Bailey, 28, of Colorado Springs, who has Crohn's disease, an intestinal disorder, that meant not marrying her fiancée so she could continue to qualify for drug company assistance programs that provide, at no cost, two medicines with list prices of more than \$16,000 a year in the United States.

For Jeffrey Kivi, 51, a chemistry teacher at Stuyvesant High School in New York, it meant recently giving up an intravenous drug that, as an outpatient, he had had infused every six weeks for years to keep his psoriatic arthritis at bay. Before taking that drug, Remicade, Dr. Kivi was on high doses of steroids for debilitating joint pain that left him unable to walk at times.

But when his last three-hour infusion at NYU Langone Medical Center's outpatient clinic generated a bill of \$133,000 — and his insurer paid \$99,593 — Dr. Kivi was so outraged that he decided to risk switching to another drug that he could inject by himself at home. That is true even though his insurer did not require him to make up the difference.

"I cannot, in good conscience, continue to force my insurance company to pay \$100,000 to NYU each time I get a Remicade infusion," Dr. Kivi, who was a drug company researcher for many years, wrote to the hospital. "That's insane."

In a statement, Lisa Greiner, a spokeswoman for the medical center, said Dr. Kivi's charge had been high relative to that of other patients because he had been prescribed a high dose of the drug.

He had moved his care to NYU Langone to follow his longtime doctor, who had moved her practice from a nearby hospital where the same infusion had been billed at \$19,000. The average price that hospitals paid for Dr. Kivi's dose of Remicade late last year was about \$1,200, according to Medicare data.

Changing drugs is not an option for patients with Type 1 diabetes, like Ms. Hayley. They need insulin.

She is resigned to paying her share of the new Medtronic insulin pump. And she is steeling herself for other new costs that will bring. The pumps are designed to work with yet another new device called a continuous glucose monitor — bought separately — that could be lifesaving for some patients with unstable diabetes, because it sounds an alarm and suspends insulin flow if it detects that blood sugar has dropped dangerously low, which can happen during sleep.

This device has two parts: a disposable probe, which is attached to the body and measures the glucose level in the skin, and a transmitter that attaches to the probe to calculate the results and send to the pump. The probes retail for over \$100 and must be changed every six days; the transmitter costs about \$600. (Since such devices are not precise enough to adjust insulin doses — they are meant primarily to detect trends — Ms. Hayley will have to continue pricking her finger for meter measurements as well.)

She does not yet know how well her insurer will cover those. “You want me to be able to afford good treatment,” she said. “Because otherwise I end up disabled.”

Correction: April 13, 2014

An article last Sunday about the rising costs associated with the routine treatment of many chronic illnesses described incorrectly glucagon, a drug that families of diabetic children are advised to keep on hand. It is a hormone injection, not an injection of concentrated sugar water. And a caption with an accompanying chart described incorrectly a picture of medical supplies one patient uses to treat her diabetes. It is an emergency glucagon kit, not an emergency insulin kit.

Follow Ms. Rosenthal on Twitter.

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