AMERICAN RE HEALTHCARE
A Division of American Re-Insurance Company
NewsLetter
April 2006

Medicare Part D: An Update

While enrollment in the new Medicare Prescription Drug Plan continues to grow, the first reports have surfaced of insurers changing their initial list of approved drugs. And CMS is restricting the number of different types of plans insurers can offer in 2007.
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First Inhaled Insulin Treatment: FDA Approved

On January 27, 2006, the FDA granted approval to Exubera®, the first inhaled version of insulin for the treatment of adult diabetics - an innovation that many diabetes specialists say will encourage more diabetics to take the life-sustaining drug. Jointly developed by Nektar Therapeutics and Pfizer, the drug will be launched during the second half of 2006, and is expected to reach sales of over $1 billion in about five years. [See page 3]

Treating Chronic Illness: Challenging and Costly in Patients with Depression

Depression and chronic illness are a common combination. It is reported that people with one or more chronic conditions must live with numerous lifestyle restrictions and follow complex treatment regimens. Even under the best of circumstances, self-care tasks can be daunting and confusing. Depression makes treatment even more difficult and costly.
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Coming Down the Pipeline: New Medical Technologies

Our newest feature, here we identify three medical technology advances that are expected to have significant cost increases in the near future. Based on your feedback, we anticipate this will be a regular feature.
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- American Re-Insurance Company has completed a strategic investment in Health Dialog, a company created to address unwarranted variation in healthcare. "We believe that the capabilities of Health Dialog are unique and have the potential to create some new types of risk-bearing products," said Bob Trainer, President, American Re HealthCare.

- Medical malpractice litigation and the "defensive" measures doctors take to avoid it combine to account for 10% of the cost of health insurance, according to a new study done by PricewaterhouseCoopers.

The report, sponsored by America's Health Insurance Plans, estimated 2% of the cost of private health insurance could be attributed directly to the cost of malpractice.

- The *Wall Street Journal* reports Intel is developing prototypes of specialized computers that could help medical professionals as well as consumers who are trying to manage chronic conditions at home. No word yet on when such products might be ready for market.

Medicare Part D: An Update

Insurers Limited to Two Plans in 2007

Medicare Prescription Drug Benefit Insurers will be limited to two plan offerings next year, according to CQ HealthBeat, a new federal healthcare policy website. Insurers were allowed to offer three plans this year. The Centers for Medicare & Medicaid Services (CMS) recently sent out "call letters" to instruct insurers on how to develop plans that will be available in 2007. "In general, we expect that more than two bids from a sponsoring organization would not provide meaningful variation, unless one of the bids is an enhanced alternative plan that provides coverage in the coverage gap," the letter to Prescription Drug Plan (PDP) sponsors said.

In the letter to Medicare Advantage Plans, CMS said MA plan sponsors should eliminate plans "that are substantially duplicative in terms of cost sharing, provider networks and benefit design," including prescription drug coverage. According to the letter, some beneficiaries "are unable to make meaningful distinctions between the various plans offered by a sponsor."

Regional Blue Cross Alters Drug List

In other recent news, the *Philadelphia Inquirer* (4/5) reports that Independence Blue Cross will change its list of preferred pharmaceuticals for Medicare recipients effective June 1. Although the changes affect only a small fraction (22) of the 3,000 drugs approved, some experts say this marks a shift that could alter drug plans across the country. Medicare allows insurers to add or remove drugs from their approved list every month. Medicare recipients can change plans only once a year. The paper notes that this new development is drawing some scrutiny from Congress.

No Shortage of Opinion, Pro and Con

Depending on which day of the week it is, news headlines might proclaim Medicare Part D as either a good deal for seniors or a stunning act of fiscal irresponsibility. It's not surprising that the new prescription drug program draws such attention. Its January 1 kickoff marked the single biggest expansion of Medicare over the last 40 years. Both the *Washington Post* and the *New York Times* have reported that the Medicare Part D benefit will cost the Federal Government anywhere between $400 billion and $1.2 trillion over the coming decade, assuming the current benefit design is continued. Given the magnitude of these numbers, it's reasonable to conclude that there will be significant cost-shifting to the beneficiary and benefit redesign in the coming years.

For insurance companies, this expansion represents a huge opportunity to grow profitably in the immediate future…if they can communicate the complexity of the benefit design to the elderly. To receive benefits, eligible Medicare participants must enroll in a one-of-many private Part D plans offered in their area. The basic benefit design is very complex and has its own jargon such as "donut hole" and "TrOOP." To add to the confusion, plans are allowed to offer a variation of benefits as long as they are deemed "actuarially equivalent" to the basic plan. Premiums charged to the enrollee can vary as well. There are tools available, though, on the Centers for Medicare & Medicaid Services' (CMS) website to help the elderly navigate and pick a plan that most meets their needs.

The latest enrollment figures are promising. CMS reports that as of March 23, 2006, more than 27 million Medicare beneficiaries have enrolled for prescription drug coverage. Beneficiaries are signing up at a rate of 380,000 each week and the Administration is closing in on its goal of 29.3 million in 2006. With a deadline of May 15 looming, it is expected that enrollment will continue to ramp-up. For members joining after May 15, the premiums are likely to be higher, permanently.

Implementation of the Part D benefit has had a number of problems. About 26 states and the District of Columbia have stepped in to pay for drugs for patients also enrolled in Medicaid. These so called "dual eligibles" were supposed to be automatically switched over to the new benefit, but some did not show up on Medicare rolls computer systems, leaving many without a drug benefit.

As mentioned earlier, numerous private Part D plans are offered throughout the country, each with a potentially different benefit scheme and premium charge to the enrollee. *Business Week* reports that Humana has been particularly aggressive with pricing. Its average premium is less than $10 Per Member, Per

Month (PMPM) whereas the overall average is around $32 PMPM. Their strategy appears to be to enroll as many beneficiaries as possible and then migrate them to a Humana-run Medicare Advantage plan.

Time will tell whether this is a brilliant strategy or the road to ruin. Aetna and Cigna's strategy is to limit assignment of dual eligibles.

It's anticipated that the current landscape of Medicare and Part D plans will change over time. Soon, healthcare companies offering Part D plans will be at full risk for the cost of drug benefits. This will occur after a phase-in period of three years during which CMS shares the risk with the plans. When the dust settles, it will be interesting to see who remains and which type of strategy pays off.

First Inhaled Insulin Treatment: FDA Approved

Diabetes affects more than 17 million people in the United States and roughly four million diabetics rely on daily injections of insulin to manage their disease. The need for daily repeat injections is a major drawback for diabetics. Drug manufacturer Pfizer reports that it interferes with daily activities and can lead to patients developing needle phobia. Although special self-injection pens, which are easier to use and deliver an accurate dose of insulin, are available, they do not remove the need for regular injections. And injections are still considered the most efficient and reliable way to deliver insulin to the bloodstream at present.

Various alternatives to injectable insulin have been investigated:

- Insulin patches
- Insulin pumps
- Oral formulations
- Inhaled (pulmonary) insulin

Of all the alternative delivery routes, pulmonary delivery of insulin looks the most promising. Apart from the benefit of needleless administration, inhaled insulin enters the bloodstream more rapidly than by subcutaneous injection. This is likely to be especially beneficial when administering insulin just before meals and may aid treatment compliance.

Several companies have been working to develop a noninvasive, inhaled form of insulin that could offer all patients with diabetes an alternative to injections, resulting in better compliance and improved disease management. The challenge has been to develop an efficient and reproducible deep-lung delivery system that would deliver insulin to the body and be easy to use.

PULMONARY DELIVERY OF INUSLIN

The concept of delivering insulin directly to the lungs (pulmonary insulin) was first advanced in 1925. However, the technical hurdles were high. Most insulin sprayed or inhaled through the mouth tends to become deposited in the pharynx and never reaches the lungs.

Exubera is a rapid-acting, fine dry-powder insulin that overcomes these problems. It is dispensed as "blister packs" of dry powder that are administered using a special inhalation device. Each blister pack delivers insulin powder producing a response that is equivalent to 2-9 units of injected insulin. The time course of response produced by Exubera is similar to regular or NPH insulin.

CLINICAL TRIALS ENCOURAGING

More than 3,500 patients have participated in clinical trials of Exubera worldwide, some for as long as seven years. Results from Phase III clinical trials suggest that Exubera may be as effective as injected insulin and superior to oral agents in lowering blood glucose in patients with diabetes. After 3 months of treatment with Exubera, 83% of patients achieved clinically significant improvements in glucose control versus 58% of patients using traditional oral medications.

NOTE OF CAUTION

While Exubera appears effective, concerns have been raised about the safety of inhaled preparations and whether Exubera will compromise lung capacity or damage lung tissue in long-term use. In the clinical trials, the frequency and nature of adverse events were similar in the Exubera and control groups. However, mild to moderate cough occurred more frequently in Exubera-treated patients, which disappeared with increased exposure. A small, non-progressive difference in pulmonary function tests, but without

clinical manifestation, was also observed between a limited group of Exubera and control patients. Additional studies are being conducted to address this safety concern and determine Exubera's long-term pulmonary safety profile.

INHALED INSULIN NOT FOR EVERYONE

Ingenix, a healthcare information and research company, reports that although Exubera is considered a "rapid acting" form of insulin, it is not equivalent to insulin-lispro (Humalog) – one of the most popular forms of insulin in the United States and favored by many physicians that treat diabetics.

Since the blister packs produce a standard metered dose, Exubera lacks the flexibility that injections provide. It may not be appropriate for diabetics who require highly accurate dosing to achieve glucose control.

The duration of its response – generally 4-5 hours – makes it unsuitable for use overnight. As a result, diabetics will have to use injections of ultralente or basal insulin at bedtime to tide them over until morning.

Exubera is expressly contraindicated for individuals with even modest impairments of lung function – such as smokers. It may also be inappropriate for some Type II diabetics with emerging insulin-resistance.

Finally, using Exubera does not eliminate other aspects of insulin regimens that diabetics find unappealing: daily finger-stick testing, weight-gain and lifestyle modification.

WHAT ABOUT COST?

Ingenix reports that Exubera's costs are expected to add materially to Pharmacy Benefit expenses for direct management of diabetes. Cost per dose and cost per day's supply will be materially higher. In addition to unique additional costs required to manufacture Exubera, the amount of insulin that must be delivered to the lungs to achieve an equivalent response is substantially greater than the amount delivered by injection. Also, the inhalation device is expected to be more expensive than other inhalers - even other powder/blister pack systems, and it is expected to be significantly more expensive than syringes or pen injection systems. Current estimates indicate that the cost of one day's supply of Exubera will average at least 175% of standard insulin injections.

The expectation is that the effects of significantly improved patient compliance will offset these direct costs. Increased compliance and better glucose control should lead to a lower frequency of advanced diabetes and its high-morbidity complications such as coronary disease, renal failure, etc.

Several other companies are also developing inhaled insulin and "needleless" insulin products, though no other applications are pending at the FDA. Eli Lilly and partner, Alkermes, have a late-stage product in development, as does European drugmaker Novo Nordisk with Aradigm. Valencia, California-based Mannkind, meanwhile, has a product in Phase III clinical trials.

Treating Chronic Illness: Challenging and Costly in Patients with Depression

by Victor Villagra, M.D.

Depression and chronic illness are a common combination. People with one or more chronic conditions such as diabetes, congestive heart failure or coronary heart disease often face a number of physical limitations – blindness, shortness of breath, chronic fatigue – as a result of years of cumulative organ damage caused by their various conditions. At the same time, these patients must live with numerous lifestyle restrictions and follow complex treatment regimens to avert further deterioration of their health. Even under the best of circumstances, self-care tasks can be daunting and confusing. Co-morbidity can complicate matters further as patients grapple with health advice from numerous physicians, nurses and literature. For example, we know that 20% of Medicare beneficiaries have five or more chronic conditions, see 14 different doctors, fill 57 prescriptions and incur an average of seven hospital days every year. It is logical to conclude that these conditions should create a fertile ground for the development of co-morbid depression, and in fact, between 25 and 40 percent of patients with underlying chronic illnesses become clinically depressed. The combination creates special challenges for clinicians, caregivers and patients alike.

How does depression develop among patients with chronic conditions?

Depression may emerge after an unexpected catastrophic and disabling health event such as a heart attack or a stroke. Approximately 20% of people experience depression after such events. Given this known correlation and a heightened level of awareness on the part of clinicians, one may assume that making a diagnosis early in the course of care should be relatively straightforward. In reality, depression that occurs even while the patient is still in the hospital with an acute myocardial infarct is all too often missed. An important factor is the lack of a systematic approach to detecting depression as it unfolds.

A more common situation is that the onset of depression does not follow a catastrophic event but is gradual and almost imperceptible in its early stages. This represents a serious concern because depression may go unrecognized for years, adding its own cumulative effects upon the person's health status. Failure to diagnose depression early is problematic because as depression sets in, patients lose motivation, energy and will to keep up with the numerous demands of self-care required of their chronic conditions. It is not unusual that depression manifests itself not through its classic emotional footprints – "the blues" – but rather as a steady deterioration of one or more indicators of the patient's underlying chronic illnesses.

Depression Renders Treatment Efforts More Challenging and Costly

Depression always makes treatment of the underlying condition considerably more difficult. In the case of cardiac disease, we know that patients have more difficulties maintaining the recommended physical activity level. Depression reduces adherence to self-care regimens including diet and pharmacotherapy, and it impairs patients ability to communicate effectively with providers. Depression also complicates efforts of disease management programs to effectively promote self-care**.**

Similar reports of serious consequences of depression, anxiety and stress on quality of life and difficulties with adherence to treatment are also available for patients with diabetes, arthritis, emphysema, end-stage kidney disease and multiple other conditions.

Besides a poorer disease prognosis, reduced quality of life and functional status, co-morbid depression also results in considerably higher medical costs. Compared with their non-depressed counterparts, estimates of excess utilization among co-morbid depressed patients range between two to four times higher. Excess cost spans the whole spectrum of medical services: diagnostic tests related to the evaluation of ill-defined bodily symptoms (sometimes called "depression equivalents"), hospital length of stay, clinical pathology services and special procedures, to mention a few.

Because of the established influence of depression on coexisting non-psychiatric conditions, treating depression aggressively is necessary to pave the way for a more receptive disposition to the many demands of self-care. This is a commonly used strategy in disease management programs. It is reasonable to assume that well-managed, chronically-ill populations with co-morbid depression enjoy better health outcomes and lower healthcare costs.

In summary, understanding the complex interactions between chronic bodily illnesses and their psychological effects is critical if we wish to improve the quality of life, productivity, longevity and functional status of chronically ill people. To do so, we need to identify depression more readily and treat it aggressively.

Coming Down the Pipeline: New Medical Technologies

The following technologies have been identified this quarter by American Re HealthCare as those that may have significant cost impact in the current and subsequent years:

Implanted Cardioverter Defribillator (ICD) - are implanted, programmed microprocessors that combine detection of lethal cardiac arrhythmias with immediate therapeutic electrical discharge to restore normal cardiac rhythm. A basic ICD lists for approximately $20,000, in addition to surgical and hospital costs associated with the implantation procedure.
Projected PMPM impact: $1.75 (2006), $1.94 (2007), $2.14 (2008)

Hybrid Capture 2™ HPV DNA Pap Smear - is an in-vitro test for detection of 13 high-risk types of human papilloma viruses (HPVs) in cervical specimens. The test is given in conjunction with a Pap test. The test costs approximately $50 to $60, in addition to laboratory fees, which vary due to discount pricing arrangements. Overall, the average retail cost of the test is $261 (kit plus lab fees).
Projected PMPM impact: $0.94 (2006), $1.30 (2007), $1.33 (2008).

Colorectal Cancer Therapies - *Avastin*™ (antivascular endothelial growth factor rhuMAb-VEGF) and Eloxatin™ (diaminocyclohexane platinum agent) for first-line treatment of metastatic colorectal cancer, or in combination with standard first-line therapy. Avastin is a monoclonal antibody specific to vascular endothelial growth factor (VEGF). Avastin costs $15,000 to $20,000 per course of treatment. Treatment costs may average about $4400 per month. Eloxatin is an injectable platinum anti-neoplastic agent presenting a broad spectrum of cytotoxic and antitumor activities. It costs approximately $1900 per 100 mg dose and may cost about $2400 every two weeks.
Combined projected PMPM impact: $0.91 (2006), $0.91 (2007), $0.91 (2008).

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Questions/ Comments

We welcome questions and comments on the newsletter and the topics covered.

To make comments, please contact Claudia Scott, VP Marketing.

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