Management of Alzheimer's Disease in Managed Care

Diagnosis and Management of Obesity and Cardio Metabolic Risk Factors

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- Contact numbers (phone and fax), complete mailing address, and e-mail address for designated corresponding author
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- Brief biography of author(s) < 50 words and including academic/corporate affiliations
- Copyright transfer letter

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PROCRIT Usage—Oncology

- PROCRIT is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. PROCRIT is indicated to decrease the need for transfusions in patients who will be receiving concomitant chemotherapy for a minimum of 2 months.
- PROCRIT is not indicated in patients with active malignant disease not receiving chemotherapy. PROCRIT is also not indicated for the treatment of anemia due to other factors such as iron or folate deficiencies, hemolytic or gastrointestinal bleeding, which should be managed appropriately.

Important Safety Information

From the Boxed WARNINGS

- Use the lowest dose of PROCRIT that will gradually increase the hemoglobin (Hb) concentration to the lowest level sufficient to avoid the need for red blood cell (RBC) transfusion.
- PROCRIT and other erythropoiesis-stimulating agents (ESAs) increased the risk for death and for serious cardiovascular and cerebrovascular events, myocardial infarction, stroke, congestive heart failure when administered to target an Hb of greater than 12 g/dL. A rate of hemoglobin rise of greater than 1 g/dL over 2 weeks may also contribute to these risks.
- Cancer patients: Use of ESAs:
  - Shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy when administered to target a Hb of greater than 12 g/dL.
  - Shortened overall survival and increased deaths attributed to disease progression at 6 months in patients with metastatic breast cancer receiving chemotherapy when administered to target a Hb of greater than 12 g/dL.
  - Increased the risk of death when administered to target a Hb of 12 g/dL in patients with active malignant disease receiving neither chemotherapy nor radiation therapy. ESAs are not indicated for this population.
- Patients receiving PROCRIT pre-operatively for reduction of allogeneic RBC transfusions: A higher incidence of deep venous thrombosis was documented in patients receiving PROCRIT who were not receiving prophylactic anticoagulation. Antithrombotic prophylaxis should be strongly considered when PROCRIT is used to reduce allogeneic RBC transfusions.

Contraindications

- PROCRIT is contraindicated in patients with uncontrolled hypertension or with known hypersensitivity to epoetin alfa or mannaminic cell-derived products.

Additional Important Safety Information

- The rate of Hb increase should not exceed 1 g/dL in any two-week period and the Hb concentration should not exceed 12 g/dL.
- If the Hb approaches 12 g/dL or increases by more than 1 g/dL in a two-week period, the dose should be reduced by 25%. Withhold the dose of PROCRIT if the Hb exceeds 12 g/dL until the Hb falls below 11 g/dL.
- Monitor Hb regularly during therapy, weekly until Hb becomes stable.
- Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with PROCRIT; predominately in patients with chronic renal failure receiving PROCRIT by subcutaneous administration. If any patient develops a sudden loss of response to PROCRIT, accompanied by severe anemia and low reticulocyte counts, the possibility of anti-erythropoietin antibody-associated anemia is suspected, withhold PROCRIT and other erythropoietic products. Contact ORTHO BIOTECH (1-888-253-8961 or 1-888-227-5624) to perform assays for binding and neutralizing antibodies. If erythropoietin antibody-mediated anemia is confirmed, PROCRIT should be permanently discontinued and patients should not be switched to other erythropoietic products.
- The safety and efficacy of PROCRIT therapy have not been established in patients with a known history of a severe disorder or underlying hematologic disease (eg, sickle cell anemia, myelodysplastic syndromes, or hypocellular anemia).
- In some female patients, menstruation has resumed following PROCRIT therapy; the possibility of pregnancy should be discussed and the need for contraception evaluated.
- Prior to and regularly during PROCRIT therapy monitor iron status; transferrin saturation should be >20% and ferritin should be >100 ng/mL. During therapy absolute or functional iron deficiency may develop and all patients will eventually require supplemental iron to adequately support erythropoiesis stimulated by PROCRIT.
- Treatment of patients with greatly elevated serum erythropoietin levels (eg, >200 mU/mL) is not recommended.
- During PROCRIT therapy, blood pressure should be monitored carefully and aggressively managed, particularly in patients with an underlying history of hypertension or cardiovascular disease.
- Seizures in PROCRIT-treated patients have been reported in the context of a significant increase in hemoglobin from baseline; increases in blood pressure were not always observed; and patients may have had other underlying central nervous system pathology.
- The most commonly reported side effects (>10%) for PROCRIT in clinical trials were pyrexia, diarrhea, nausea, vomiting, edema, asthenia, fatigue, shortness of breath, paresthesia, and upper respiratory infection.

Please see adjacent page for Brief Summary of Prescribing Information, including Boxed WARNINGS.
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IN TERMS OF COST, ALZHEIMER’S DISEASE (AD) is the third leading cause of illness in the United States. The prevalence of AD is predicted to increase from 4 million patients in 2000 to 14.3 million in 2050 (Exhibit 1). The costs and burden on society are going to increase dramatically with the increasing prevalence.

One source of excessive cost in the early stages of this disease is a general failure to diagnose cognitive impairment early. Because of delayed diagnosis, AD is not diagnosed in the mild stage when it is probably most treatable. This results in increased costs of diagnosis, functional impairment and accidents, poor control of medical comorbidities, and caregiver burden. Increasing medication costs through the use of cognitive enhancers, psychotropics, and antidepressants are another reason AD is a costly disease. In the later stages, the main costs are related to institutionalization and hospitalization.

There are several barriers to early diagnosis of this disease. There is fear of reporting and denial by the patient and caregivers. This results in a two-year delay in diagnosis, which may result in missing the window of treating those patients who have early disease. Another barrier is the lack of physicians with training in geriatrics and treatment of dementia. A lack of physician expertise in brief psychometrics leads to the failure to recognize early AD in a significant number of cases. Other barriers are the time required to diagnosis the disease and the lack of adequate reimbursement for this process. There also are myths that the diagnosis can only be made upon death and that once diagnosed, nothing can be done.

In general, the severity of AD is denoted on a mild, moderate, and severe scale. These stages are based on an objective cognitive assessment such as the Folstein mini-mental status exam (MMSE). Mild is generally considered a 20 to 25 score out of 30 total. Although the MMSE is not the most sensitive exam in terms of diagnosing a dementia, it is very useful for tracking the progression of the disease. A score between 10 and 20 is generally considered moderate; less than 10 is considered severe. Disease severity impacts costs—the more severe the disease, the more costly (Exhibit 2).

The main goal in treating AD is to maintain a level of function that allows some independent living. Generally, once a patient scores below 15 on a MMSE and has difficulties with activities of daily living like dressing and grooming, institutionalization occurs. Maintaining the highest level of function possible tends to prevent the adverse outcomes of this disease—falls, infections, and exacerbations of other chronic illnesses that increase costs.

A number of studies have demonstrated that patients...
with dementia have higher utilization of most health care services and have higher health care costs. Most of the increased costs are related to home care, skilled nursing facilities, and hospitals (Exhibit 3). Not only are the direct treatments of Alzheimer’s more costly, but when treatment of co-morbidities is added, the costs increase significantly (Exhibit 4). The same population of patients who have AD also have heart failure, diabetes, and chronic lung disease. It is harder to manage those illnesses in patients with dementia because of their difficulties in adhering to lifestyle and medication regimens.

Unfortunately, the evidence to date indicates most managed care organizations have not targeted Alzheimer’s disease or other dementias for disease management programs or any kind of organized approach to management. This is most likely because primarily, Medicaid covers the costs for many of these patients, especially once institutionalized. Before the end stages, patients do accumulate medical costs from hospitalizations, office visits, and medications for which the managed care organization would be responsible. Alzheimer’s disease may not be identified as a cost driver for many managed care organizations. Costs include medical costs, caregiver hours and other costs incurred in the assisted living/nursing home care setting.
organizations because of flaws in the coding and reimbursement systems which lead practitioners to code visits for dementia patients under higher paying codes such as diabetes, hypertension, or heart failure which the patient may also have.

There are opportunities for managed care to begin targeting the cost of AD care. Slowing or preventing the decline in cognitive function may save costs (see Exhibit 5).6 From a study by Ernst and colleagues, prevention of a 2-point decline in the score of a moderately to severely demented home-dwelling patients with a MMSE score of 7 at baseline would save about $3700 annually, and a 2-point increase in an MMSE score, rather than a 2-point decline, would save about $7100.6

Cholinesterase inhibiters are used in AD to attempt to preserve cognition and function, and avoid behavioral complications of the disease. The three cholinesterase inhibiters, donepezil (Aricept®), galantamine (Razadyne®), and rivastigmine (Exelon®), are approved for use in mild to moderate AD and are similar in efficacy. Exhibit 6 outlines some benefits of pharmacologic therapy.

An economic study of donepezil examined the

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An economic study of donepezil examined the
medical costs of 70 AD patients for one year before and one year after starting this agent. Although medication costs increased significantly, overall costs decreased dramatically. In this study, the most cost effective use was in those patients who stayed on the medication for two years or more. Starting the medication early, when the patient has mild illness, results in the biggest cost savings. Starting medications once patients have progressed to a moderate or severe stage usually does not have as significant an impact. Two other economic studies have shown that persistent donepezil use results in reductions in overall costs.

Caregiver burden from AD is estimated to cost U.S. businesses $30 to 60 billion per year. Excessive caregiver burden is a risk factor for hospitalization and institutionalization of the patient, and results in increased costs. From a societal standpoint, if medications can relieve the burden on caregivers, costs of managing this illness will be reduced. In one study, caregivers of patients on donepezil had significantly lower levels of difficulty in providing care and fewer costs. In another study, galantamine significantly reduced the amount of time spent by caregivers assisting patients with activities of daily living.

Another beneficial aspect of cholinesterase inhibitors is their ability to impact the behavioral problems of Alzheimer’s disease. As Alzheimer’s disease progresses, patients start to experience significant psychiatric problems. The most troubling to caregivers are hallucinations, delusions, paranoia, and inappropriate sexual behavior. The traditional way to manage these problems has been either psychotherapy or behavioral therapy, which is very labor intensive and difficult to implement outside of an institutional

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**Exhibit 5: Cost savings as a Result of Preventing Cognitive Decline**

<table>
<thead>
<tr>
<th>Baseline MMSE Score</th>
<th>Estimated savings from prevention of decline in MMSE score per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$356</td>
</tr>
<tr>
<td>2</td>
<td>$765</td>
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<td>5</td>
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</tr>
<tr>
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<tr>
<td>2</td>
<td>$2,494</td>
</tr>
<tr>
<td>5</td>
<td>$7,407</td>
</tr>
</tbody>
</table>

**Exhibit 6: Anti-Dementia Therapy: Domains of Efficacy and Effectiveness**

- Cognition
- Function
- Behavior
- Clinical Improvement
- Reduce caregiver burden
- Reduce Risk of Hospitalization
- Delay SNF placement
- Pharmacoeconomic benefit
setting. Antipsychotic agents such as haloperidol and newer generation agents also have been frequently used, but these agents have significant adverse effects with long-term use. None of the antipsychotic agents have an FDA indication for the management of behavioral problems in dementia. Additionally, the newer antipsychotic agents appear to increase mortality when used over a long period of time in this patient population. At least one study has demonstrated that rivastigmine reduces behavior problems such as agitation, anxiety, and disinhibition.\textsuperscript{13}

The biggest potential cost and quality benefit of cholinesterase inhibitors is a delay in skilled nursing facility placement. Some studies have shown significant delays in the institutionalization of patients taking cholinesterase inhibitors versus those not taking these agents (Exhibit 7).\textsuperscript{14}

Currently, there is only one agent, memantine (Namenda\textsuperscript{®}), that is FDA approved for moderate to severe AD. This agent works differently than the cholinesterase inhibitors. In a short term, pharmacoconomics study, those patients who were treated with memantine had reductions in their overall medical and caregiver costs.\textsuperscript{15}

A disease management approach to dementia would be beneficial for a managed care organization because Alzheimer’s disease results in significant total costs of care at the middle and late stages, affects a rapidly growing population, and causes a high rate of preventable complications.\textsuperscript{16,17} Preventable complications include falls, infections, aspiration, and issues with urinary incontinence. Alzheimer’s disease is also an appropriate target for disease management programs because there are issues with appropriate coding, treatment is relatively easy but there is wide practice variation, and there is a high rate of patient nonadherence, which can be altered by education.\textsuperscript{16,17} Additionally, a high rate of referrals for specialty consultation occurs because many primary care providers feel inadequate about caring for these patients.\textsuperscript{16,17} Appropriately educated primary care doctors, without a lot of specialty consultation, can provide much of the care for these patients. Consensus for defining quality care, practice guidelines, and dementia specific outcome measures are also possible with this disease. Lastly, there are opportunities for better coordination of community services, particularly those not covered by Medicare.

There are many opportunities to improve the care of Alzheimer’s disease patients within the managed

\textbf{Exhibit 8: Opportunities to Improve Alzheimer’s Disease Quality of Care}
- Improve early diagnosis
- More effective use of AD therapeutics
- Enhance coordination of care
- Improve management of comorbidities and complications
- Caregiver education and support
- Counseling on prevention

Exhibit 7: Donepezil Use Delays Nursing Home Placement

\begin{itemize}
  \item A (patients taking AchEIs)
  \item B (patients not taking AchEIs)
\end{itemize}

\text{AchEIs = acetylcholinesterase inhibitors}

\text{SNF = skilled nursing facility}
Dementia care management has been shown to produce positive outcomes. Patients and caregivers receiving care consultation, education, and counseling had fewer emergency room visits and hospitalizations.\textsuperscript{18,19} In another example, telephonic care management counseling for AD caregivers delayed time to nursing home placement by almost one year.\textsuperscript{20}

Conclusion

Emerging pharmacotherapy data indicates potential savings in health care costs associated with early intervention and treatment, and the potential cost effectiveness of cholinesterase inhibitors. Managed care organizations have a greater opportunity to implement a disease management model for Alzheimer’s disease than other health care delivery systems.\textsuperscript{JMCM}

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References

1. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2000.
DURING THE LAST TWO GENERATIONS of the 20th century and the first few years of the 21st century, the prevalence incidence of obesity has been increasing. Rates of other classical risk factors for cardiovascular disease—hypertension, smoking, and high cholesterol—are improving, which is good news.\(^1\) Death rates from stroke, cardiovascular disease, and cancer have been going down in the general population. The exception is in patients with diabetes, where deaths from cardiovascular disease are going up (Exhibit 1).\(^2\) About 80 percent of patients with diabetes die from cardiovascular disease. Cardiovascular deaths in patients with diabetes and the prevalence of obesity parallel each other (Exhibits 2 and 3).\(^3,4\) The United States has a huge public health problem in front of us and, at the moment, the health care community is grappling with trying to reverse the obesity trend.

Classical risk factors for cardiovascular disease are elevated low-density lipoprotein cholesterol (LDL-C), elevated blood glucose, elevated blood pressure, and smoking (Exhibit 4). Over the past few years, several other risk factors including abdominal adiposity, inflammatory markers, elevated triglycerides, and low high-density lipoprotein cholesterol (HDL-C) have been identified. All of these risk factors contribute to cardiometabolic risk and the development of CVD. Many of them also contribute to the development of type 2 diabetes.

Type 2 diabetes develops when two defects are present—insulin deficiency and insulin resistance. Obesity does not cause diabetes but it leads to insulin resistance. Type 2 diabetes develops when there is a relative or absolute deficiency of insulin. Many obese individuals do not have diabetes. Every woman in the third trimester of pregnancy is fundamentally as insulin resistant as a 300-pound type 2 diabetic; but not all women who are pregnant become diabetic because the beta cells can sense the insulin resistance and can increase insulin secretion to compensate.

According to National Health Survey (NHANES) data, glucose control in patients with Type 2 disease is not optimal. The number of individuals who had good glucose control (A1C below seven percent) actually declined from 1988 to 2000.\(^5\) This worsening of control may have come from the advent of the powerful insulin sensitzers (metformin and thiazolidinediones) in the 1990s. There was a rush to treat insulin resistance. The fundamental defect of insulin deficiency was neglected. Sulfonylurea and
early insulin use went down during this period of time and consequently the number of people with good glucose control also went down. In recent years, the adoption of early insulin use has lead to a 10 percent increase in people with good glucose control. Also in recent years, the number of people with better blood pressure control and total cholesterol has improved. Unfortunately, the number of individuals who have their three important cardiometabolic risk factors (glucose, cholesterol, and blood pressure) under control is only seven percent.

Readily accessible, highly palatable food and an increase in the number of meals eaten outside of the home are two of the factors contributing to the obesity epidemic. In the 1970s, 70 to 80 percent of meals were cooked at home and now only 20 to 30 percent of meals are cooked at home.

Because people are eating more and more often, patients with type 2 diabetes spend a lot of time in the postprandial state (Exhibit 5). To achieve blood glucose control and lower cardiometabolic risk, methods for controlling postprandial glucose in addition to fasting glucose have to be considered.

There are at least nine studies from around the world linking elevated postprandial glucose with cardiovascular mortality. Elevated postprandial glucose causes high triglycerides. It has been linked directly with microvascular disease. It also elevates oxidized LDL-C, inflammatory markers, and oxidative stress, and activates coagulation. The Decode Study demonstrated that the risk for cardiovascular mortality begins to increase in the pre-diabetic state and continues to increase as the patient progresses to diabetes.

The mechanism by which postprandial hyperglycemia increases cardiometabolic risk is under study. Elevated glucose values after a meal appear to promote damage to the blood vessel walls. Endothelial function and oxygen derived free radical
levels both correlate with postprandial glucose values. Triglycerides also cause endothelial dysfunction. Unfortunately, patients with type 2 have the combined effects of elevated postprandial triglycerides and glucose causing a significant reduction in endothelial function and magnifying the risk for cardiovascular disease.

Until the early 2000’s, insulin had an incorrect reputation as an atherosclerotic risk factor by itself. Retrospective or cross sectional studies found patients who had insulin resistance had elevated insulin levels and developed cardiovascular disease. It is not the insulin, but the insulin resistance causing the cardiovascular disease. In a study of basal insulin glargine, blood glucose and endothelial function dramatically improved with this therapy. Another study found that insulin analogs such as lispro insulin actually increase cardiac blood flow postprandially more than regular insulin and better than a placebo.

The insulin analogs not only improve glycemic control but also cause less hypoglycemia than insulin.

The criteria for diagnosis of metabolic syndrome are given in Exhibit 6. One in four adults in the United States have diabetes or metabolic syndrome. About 21 million people have diabetes. This figure is increasing by 15 percent per year. Forty-four million people have pre-diabetes and 64 million have metabolic syndrome.

The most prevalent component of the metabolic syndrome is abdominal obesity followed by the low HDL-C and hypertension. Metabolic syndrome does not equal type 2 diabetes but it is a strong risk factor for diabetes and cardiovascular disease. A patient with metabolic syndrome and diabetes has amplified cardiovascular risk.

In a large study of a public health data base, individuals who had never smoked had increases in risk for cardiovascular disease starting after their weight reached a body mass index (BMI) of 26. Risk dramatically goes up with a BMI greater than 40 (Exhibit 7).

In the Nurse’s Health study, women with diabetes at baseline had a fivefold risk for heart attack or stroke. The clock begins ticking for developing cardiovascular disease when glucose begins to rise, even before the diagnosis of diabetes (Exhibit 8).

Multiple risk factors within one person will significantly increase the risk of myocardial infarction (MI). For example, smoking leads to an odds ratio of 2.87 for having an MI. Smoking, diabetes, hypertension, and obesity combined result in an odds ratio of 21.

Many of the problems with metabolic syndrome come from excessive fat in the abdomen (inter-abdominal adiposity). Thinking about fat deposits has evolved over the years. Previously, the adipocyte was considered an inert storage medium for excess energy. Now it is known that fat metabolism adipocytes are an endocrine organ, which produce inflammatory cytokines and hormones. Compared
with other fat deposits in the body, interabdominal fat makes much more of the inflammatory cytokines that are negative and increases insulin resistance and cardiovascular disease (Exhibit 9). The hormones secreted by interabdominal fat include leptin, angiotensin, resistin, and adiponectin. Leptin is a very important hormone in regulating energy balance and partitioning carbohydrates and fat. Typical obesity is a state of leptin resistance. Although important in rodent models, resistin's importance to weight maintenance in humans is controversial. It does increase insulin resistance.

Various cytokines are secreted by interabdominal fat. Tumor necrosis factor alpha (TNF-α) has been linked with insulin resistance. Exercise physiology studies find that exercise leads to large increases in IL-6. High levels of IL-6 in obesity may be the body trying to compensate for insulin resistance.

A beneficial product of subcutaneous tissue is adiponectin. It is a very powerful insulin sensitizer, which also decreases vascular inflammation. Adiponectin has mechanisms similar to the oral insulin sensitizers metformin and thiazolidinediones. Adiponectin has been shown to have positive effects on the liver, muscle, endothelium, and maybe even the brain.

Inflammation as marked by increasing levels of fibrinogen, C reactive protein (CRP), and PAI-1 is a contributing mechanism to the development of diabetes. Levels of these inflammatory cytokines are seen with increasing levels of abdominal obesity.

Waist circumference, a marker of interabdominal fat, correlates with increased insulin resistance, blood pressure, and thus risk of diabetes and heart disease. Measuring waist circumference is an easy and inexpensive way to get a general idea of the amount of visceral fat present in a patient.

Putting this all together, excess interabdominal adipocytes release inflammatory cytokines which result in impaired thrombolyis, glucose intolerance, hypertension, dyslipidemia, endothelial dysfunction, and inflammation (Exhibit 10). The end result of excess interabdominal fat is a vicious cycle of myocardial infarction and thrombotic stroke.
Cardiometabolic risk can be decreased with physical activity and weight loss. A 10 percent loss of body weight will decrease total cholesterol, LDL-C, and triglycerides. It will also increase HDL-C. Weight loss also reduces inflammatory biomarkers such as TNF-α. In the Diabetes Prevention Program study, 150 minutes of cumulative exercise per week and a seven percent weight loss reduced the progression to type 2 diabetes by 58 percent. Lifestyle changes were compared to metformin therapy, which reduced diabetes risk by 31 percent. Lifestyle changes also reduce the risk of metabolic syndrome by 41 percent.

The practical problem is getting overweight patients to lose weight and keep it off. The current approaches to treating obesity include diet, exercise, behavioral therapies, short-term pharmacotherapy, and surgery. With most diets, patients lose weight but regain the same amount or more once they stop dieting. Dansinger and colleagues compared four major diets, Atkins, Zone, Weight Watchers, and Ornish. Each lead to modest weight loss of 4.5 to 7 pounds over a year with a 1 to 1.5 inch decrease in waist circumference. The problem for most patients is trying to maintain one of these diets especially since some of these diets require severe changes.

Orlistat, sibutramine, and phentermine are approved drugs for treating obesity. Randomized controlled trials with these agents demonstrate modest weight loss as long as the patient continues the agent. Weight regain occurs once the medication is stopped. Orlistat, which recently became available over the counter at a lower dosage, is a pancreatic lipase inhibitor. Thus, it reduces fat absorption. The primary adverse effects of this agent are related to excess fat in the lower gastrointestinal tract. Sibutramine is a mixed serotonin, norepinephrine, and dopamine reuptake inhibitor. The most common side effects of sibutramine are elevated blood pressure and heart rate.

Currently available pharmacotherapy for treating obesity is not ideal. Other agents are under study for weight loss, which will possibly be more effective with fewer adverse effects. Agents targeting the endocannabinoid system example are one. The endocannabinoid system is a physiologic entity that is activated by pleasurable behavior and is classically activated by repeated intake of desirable food. Cannabinoid receptors spread throughout the brain are important in appetite and motivation to eat. These receptors also are in adipose tissue, skeletal muscle, liver, gastrointestinal tract, pancreas, adrenal medulla, and sympa-

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**Exhibit 8: The Ticking Clock: CV Risk Before Glucose**

Nurses’ Health Study; 20-year follow-up of 117,629 women

<table>
<thead>
<tr>
<th>Relative risk of MI or stroke</th>
<th>No diabetes throughout study</th>
<th>Risk of event prior to diabetes diagnosis</th>
<th>Risk of event after diabetes diagnosis</th>
<th>Diabetes at baseline</th>
</tr>
</thead>
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<tr>
<td>1.0</td>
<td>2.8</td>
<td>3.7</td>
<td>5.0</td>
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</tr>
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</table>

**Exhibit 9: Adipose Tissue as an Endocrine Organ**

Traditional View

Fat is an inert storage depot

Fatty Acids → Glucose

Emerging View

Fat is a secretory endocrine

Fatty Acids → Glycerol

Leptin, fatty acids, adiponectin, TNF-α, PAI-1, cytokines

Muscle → Liver → Pancreas → Vasculature

PAI-1 = plasminogen activator inhibitor-1
TNF-α = tumor necrosis factor alpha

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thetic nervous system. When the endocannabinoid system is activated in obesity, increased insulin resistance, low HDL-C, increased triglycerides, low glucose uptake, and reduced adiponectin occur. It appears that an activated endocannabinoid system is another cardiometabolic risk factor.

**Conclusion**

The prevalence of obesity and diabetes is increasing dramatically. Metabolic syndrome is a precursor to cardiovascular disease and diabetes, and also is increasing dramatically. Obesity is the major risk factor for diabetes, cardiovascular disease, and the driving force behind the metabolic syndrome. Weight reduction and exercise are the cornerstones for reducing cardiometabolic risk. Pharmacotherapy at the moment has limited success.

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**References**

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On the Road to Personalized Health Care: Translating Promise into Practice

From The Editor

Eric Faulkner, MPH, is editor-in-chief of the Genomics Biotech Institute special section of the Journal of Managed Care Medicine; director of the Genomics Biotech Institute of the National Association of Managed Care Physicians; and director of US Market Access and Reimbursement, RTI Health Solutions

ON SEPTEMBER 19, 2007, Health and Human Services (HHS) Secretary Michael Leavitt unveiled the forward-looking report entitled Personalized Health Care: Opportunities, Pathways, Resources. This report is described as an “early reconnoitering” for how HHS envisions harnessing the convergence of our rapidly expanding biomedical knowledge base and interoperable health information systems to enable truly personalized health care.

While the concept of personalized medicine generally involves use of patient genetic information in selecting the right drug, for the right patient, at the right time and dose, personalized health care is a broader concept. Personalized health care would leverage the best available information from a variety of sources in a focused and actionable manner so that physicians and patients can make health care decisions with “greater precision, confidence and individualization.”

Information inputs envisioned for personalized health care appear to be potentially boundless. Inputs are anticipated to include diagnostic data, medical records, anonymized medical databases and registries, patient-reported data, clinical studies, health technology assessments and evidence-based practice guidelines. This myriad of information will be channeled into decision support systems or “smart tools” that inform health decisions and presumably generate better health outcomes. These changes in care delivery may also refocus our current “sickness-based” system to towards disease prediction and prevention.

Translating Knowledge into Personalized Health Practice

Despite the promise of personalized health care, this convergence of science, medicine and technology will not occur overnight. While the vanguard of this movement can point to existing examples of personalized health care, the Secretary acknowledges that we are only at the beginning of this journey. In general, it has taken up to 20 years to move a new treatment or intervention from research into clinical practice.

Events such as sequencing the human genome have markedly advanced our scientific knowledge. However, the reality is that a tremendous amount of additional research will be necessary to understand how and in what ways this information can be used in routine clinical practice. Science and clinical discovery simply takes time, even considering the rapid pace of technological innovation.

Likewise, it will be some time before most health care providers have interoperable health information systems that could feasibly support personalized health care as envisioned in the Secretary’s report. It is well accepted that our US health care systems have lagged behind many other industries. Providers must perceive that benefits of adopting such systems outweigh the costs, and this has historically been a hard sell. However, increasing data reporting requirements as a condition of contracting with third-party payers and employers is likely to stimulate more rapid adoption.

As data to support personalized health becomes more accessible, it will be important that this information is presented in a format useful to physicians and patients. More information does not necessarily translate into better decision
making. Many health stakeholders struggle to make sense of the evidence that is currently available. Even when well-established evidence-based guidelines or quality measures define appropriate treatment actions, only around half of patients receive recommended care in routine clinical practice.

Ideally, decision support tools that emerge for personalized health care will package available evidence to isolate the most essential decision inputs that support high quality and efficient care, while maintaining the flexibility to address multiple stakeholder needs. Despite its promise, personalized health care is more likely to evolve as a confluence of incremental gains as we learn and apply new knowledge and systems over time, instead of emerging as a flood of “plug-n-play” advancements.

Other Considerations for Personalized Health Care

It will be important to ensure that the questions one wishes to answer with personalized health information are appropriately aligned with the quality and nature of the information source. For example, while randomized controlled trials (RCTs) often have strong internal validity (i.e., a high degree of certainty that the result is valid for the study population), such studies may not have sufficient external validity (i.e., relevance to the broader patient population). On the other hand, evolving sources of personalized health information (e.g., electronic medical records, patient database and registries) may be reflective of real world outcomes, but have limitations versus controlled trials. Decisions that do not adequately take benefits and limitations of available evidence into account may inadvertently result in barriers to patient access to care or inappropriate care decisions.

Personalized health information may also prove useful for monitoring and influencing health care services provision. For example, electronic medical record data, in addition to informing individual health decisions, may inform pay-for-performance initiatives or useful prove useful for tracking health product utilization. As personalized health care evolves, it is essential that this information improves evidence-based decision making, but not in a manner that inappropriately constrains physician autonomy or biomedical innovation. Due to the complexity and cost of science and technology required to advance personalized health care, the Secretary rightly calls for collaborative solutions between government and the private sector.

No single stakeholder group can advance personalized health care alone (or afford to). As personalized health care develops, payers, providers, patients, and industry must all play a pivotal role.

As data to support personalized health becomes more accessible, it will be important that this information is presented in a format useful to physicians and patients.

References

Hypersensitivity to a drug is a dose-dependent type of drug allergy that develops in a subset of patients who have experienced a previous reaction to the drug. The incidence of hypersensitivity reactions is generally low, but some drugs, such as penicillin and nonsteroidal anti-inflammatory drugs, have a higher risk of causing hypersensitivity reactions.

**Inhibition and Resolution**

Hypersensitivity reactions can be classified into two main categories: immediate and delayed. Immediate hypersensitivity reactions are caused by the rapid release of histamine and other inflammatory mediators from mast cells and basophils. Delayed hypersensitivity reactions occur as a result of the immune system's attempt to eliminate the antigen, which can lead to the development of granulomas or other tissue damage.

**Manifestations of Hypersensitivity**

Hypersensitivity reactions can manifest in various ways, including cutaneous reactions, respiratory symptoms, gastrointestinal symptoms, and systemic reactions. The severity of the reaction can range from mild to life-threatening, and the specific manifestations depend on the type of drug and the individual patient.

**Prevention**

To prevent hypersensitivity reactions, patients should be thoroughly informed about the potential risks and benefits of the drug and should be monitored closely during treatment. If a reaction occurs, the drug should be discontinued, and appropriate medical intervention should be provided.

**Conclusion**

Hypersensitivity reactions are a significant concern in the field of medicine. By understanding the mechanisms and clinical manifestations of these reactions, healthcare providers can take steps to prevent and manage them effectively.
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HIV REMAINS A LEADING CAUSE OF ILLNESS and death in the United States. As of 2004, 944,306 persons have received a diagnosis of acquired immunodeficiency syndrome (AIDS) and more than half a million have died (Exhibit 1). During the past 20 years, the overall prevalence of persons living with HIV/AIDS has steadily increased. This is partly attributed to the advent of modern antiretroviral regimens that have dramatically reduced the death rate from AIDS. However, the fact that prevalence is steadily increasing also can be attributed to a relative lack of success at preventing transmission.

Since 1998, the estimated number of new HIV infections has remained stable at approximately 40,000 a year. It is important to note that since 1994 the annual number of cases among blacks, members of other racial/ethnic minorities, women, and persons exposed through heterosexual contact has increased.

Revised HIV testing guidelines were published in September 2006. The revisions took into consideration the advice of a panel of physicians, many of them emergency medicine physicians, to simplify the process of HIV testing. Previously, there were too many barriers to getting HIV testing done and notifying patients of their results. These recommendations also took into consideration an extensive review of the literature and demonstration projects from across the United States.

The CDC noted several pieces of evidence for revising and expanding the testing recommendations. Many HIV-infected persons access health care but are not tested for HIV until symptomatic. From data over the years, routine HIV screening is easy to do, reliable, and cost effective. Additionally, effective treatment is available. Data also have shown that automatically offering testing and allowing people to choose to not be screened (opt-out method) increases testing rates compared with allowing people to seek testing (opt-in method). Lastly, HIV awareness has proved to be a significant factor in decreasing transmission.

The CDC estimates that more than a million people are infected with HIV in the United States.
Twenty-five percent of these people are unaware that they are HIV-infected. It is estimated that 54 to 75 percent of the new cases that are documented every year in the U.S. are transmitted by people who are unaware of their infection. Thirty-two thousand new infections yearly are attributed to sexual transmission in the United States. This is one of the reasons to make people aware of their HIV disease and, hopefully, change behaviors that decrease transmission of the disease.

The prevalence of high-risk sexual behavior is reduced substantially after people become aware they are HIV positive. An analysis of behavioral data from 11 studies found that once a person knows he or she is HIV positive, they reduce their rate of unprotected intercourse (vaginal or anal) by 53 percent. These data confirm that HIV transmission can be substantially reduced by increasing the percentage of persons who are aware of their seropositive status. If infected persons are not aware of their status, behavior does not change.

In the CDC HIV Behavioral Surveillance survey performed in 2004 to 2005, among men who had sex with other men, 14 percent of men aged 18 to 24 were infected with HIV. Almost 80 percent of these young men who tested positive were unaware they were infected. From this survey, the rate of unrecognized HIV infection was highly dependent on the age of the person (Exhibit 2). The percentage of unaware people decreased steadily by age group through age 49, then increased slightly in older men.

Treatment of AIDS has improved survival rates dramatically, especially since the introduction of highly active antiretroviral therapy (HAART), but progress in obtaining earlier diagnosis has been insufficient. Persons who receive an AIDS diagnosis within 12 months of gaining a diagnosis of HIV infection account for 40 percent of individuals identified as infected. Male injection drug users were most likely to receive a late diagnosis of HIV infection, followed by men acquiring HIV disease through heterosexual contact. A greater percentage of women tend to receive an “early” diagnosis (≥12 months from HIV diagnosis to AIDS diagnosis). Since effective treatment is available, a significant impact on infected patients would occur if diagnosis occurred earlier.

Prevention strategies that incorporate universal HIV screening have been highly successful. The best example of effective screening and prevention in the U.S. has been the significant reduction in prenatal transmission. Since the time that therapy was shown to be effective for preventing mother-to-child transmission and universal screening was recommended, there has been a 95 percent reduction in the number of perinatally-acquired AIDS cases. Another method, screening blood donors for HIV, has nearly eliminated transfusion-associated HIV infection. These successes contrast with a relative lack of progress in preventing sexual transmission of HIV for which screening is not commonly performed.

The new CDC recommendations for HIV testing include routine voluntary screening for all persons...
aged 13 to 64 years of age. Highlights of the revised recommendations can be found in Exhibit 3. The age range is based on surveillance data but does not exclude testing people outside that range. The recommended testing age was lowered because multiple behavioral studies have proved that adolescents are sexually active before many people want to admit. By eighteen years old, between 70 and 80 percent of adolescents have been sexually active and 37 percent did not use condoms during their last sexual act. Persons aged 50 to 64 account for 13 percent of new HIV cases, yet many people in that age group do not think they are at risk for HIV and other sexually transmitted diseases. People over 65 comprise less than 2 percent of new cases. Many providers feel uncomfortable discussing sexual practices or other risk factors for HIV with older patients.

The most important reason for expanded screening for HIV infection is the effectiveness of therapy. There has been a significant decrease of death rates attributed to the implementation of HAART (Exhibit 1). People infected with HIV can live long and productive lives today because of the medications that are available.

Screening should be conducted irrespective of risk factors. In contrast to previous recommendations, consent for testing should be based on an opt-out scheme, and HIV consent should be part of the general consent for care. According to the revised CDC recommendations, specific informed consent to do HIV testing is not required. Many states do still require a separate consent for HIV. Health care providers must carefully consider state and federal laws and regulations related to HIV testing, confidentiality and the principles of informed consent that might limit the implementation of these recommendations.

Based on the limited resources in most health care settings, testing has been limited because of required pretest counseling. Many providers do not feel comfortable with the amount of training they have to complete for this kind of counseling and because of that they are not doing counseling. Pre-screening counseling is no longer required for routine screening, although it should be offered when requested or when patients are at high risk. It is recommended that persons at high risk be screened annually.

HIV screening should be discussed with all adolescents and encouraged for those who are sexually active. Confidentiality laws and legal precedents allow for evaluation and treatment of minors for sexually transmitted disease (STD) without parental knowledge or consent. Not every state has defined HIV infection explicitly as a condition for which testing or treatment may proceed without parental consent.

A substantial number of persons who are HIV infected do not perceive themselves to be at risk or do not disclose their risk. Targeted testing based on risk behaviors fails to identify a significant number of persons who are infected with HIV. The new recommendations call for opt-out instead of opt-in screening. Opt-out screening is preferred because all patients are considered candidates for screening. Opt-out screening does not require the healthcare provider to make an assessment of an individual’s risk of HIV infection. Patients can still decline screening, but the test will be performed unless the patient
specifically refuses to be tested. Rates of HIV screening have been consistently higher in prenatal and STD service settings using opt-out screening.

Opt-out screening replaces the CDC’s previously recommended standard of opt-in testing, where patients must be specifically counseled to receive an HIV test. Opt-in screening may be routinely offered in many settings, but usually takes more staff time to administer. One of the best benefits of using an “Opt-out” approach is that it will decrease the stigma that is associated with HIV testing. When people do not feel singled out because of their behavior, they are more agreeable to being tested.

Routine screening procedures and prevention counseling for HIV should be a part of all primary care providers’ overall well-care strategy. This means engaging each patient in a conversation that includes risk factors, sexual history, and practices of the patient. HIV screening provides opportunities to intervene in patients’ risky behavior. Offering or arranging referral for infected patients to appropriate counseling and risk reduction services can reduce transmission of HIV.

Screening also is recommended for emergency departments, inpatient services, and urgent care settings, as well as locations where HIV testing has traditionally been concentrated, such as STD and tuberculosis clinics. These recommendations do not change existing guidelines concerning HIV testing in non-clinical settings such as outreach settings or mobile vans. The CDC recommends routine screening can be discontinued in communities that have a documented prevalence less than 0.1 percent. This type of data is not currently available but should be available once community wide screening is implemented.

For pregnant women, the recommendations are more complex. Universal opt-out screening during each pregnancy is recommended. For those women who are considered to be high risk or who are living in communities of high prevalence, screening should be repeated during the third trimester. It is also recommended that if a woman gets to labor and delivery without knowing what her status is, a rapid test be done so the infant can be treated. Antiretroviral prophylaxis should be initiated within 12 hours of birth on the basis of rapid test results.

The availability of rapid tests has allowed universal screening. The rapid tests allow results to be reported within 30 minutes. Rapid screening has a much higher rate of acceptance among patients. In addition, rapid testing improves the “return” rate of patients to receive the results of the test, compared with the traditional testing system. Rapid tests not only increase patient receipt of test results but also allow increased identifications of infected pregnant women so they can receive effective prophylaxis, increased feasibility of testing in acute care settings such as emergency rooms, and increase the number of venues where testing can be offered.

There are six tests approved for rapid testing. Four of these are approved for point of care testing. When a rapid test is positive, the patient is told this is a preliminary result that will need to be confirmed with a second test, usually a standard laboratory test. HIV-positive test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff.

CDC recommendations for HIV/AIDS surveillance have not changed significantly. Risk factor
assessment to guide public health risk reduction efforts, HIV/AIDS case reporting, and pediatric exposure reporting are all recommended with mandatory reporting required in all states.

Like other sexually transmitted diseases, partner notification is an important component of HIV control. Providers should encourage patients who test positive to notify current and prior sex partners. Local health departments offer confidential partner notification and referral services.

Providers should notify patients they may be approached by local health departments for voluntary interviews regarding partner notification.

There are concerns about the costs of universal screening in the United States. There is no doubt that implementing these new guidelines is going to increase the need for funding. Implementing routine testing will dramatically increase the funding needs of screening programs. Additionally, effective HIV screening programs do not work unless patients are effectively linked to appropriate care and prevention services. Currently, it is estimated that close to 50 percent of HIV positive patients have no health insurance. Identifying more patients will increase demand on public funding to support the cost of care and medications.

Although identifying and moving patients into care will substantially increase costs, getting patients into care early will reduce morbidity, mortality, and per-patient cost of care. The antiretroviral medications work better when used early in the course of the disease. Treating at later stages increases the chance of HIV resistance. Late in the disease, higher numbers of hospital admissions, cancers, and opportunistic infections also drain the budget. In addition, early treatment increases survival. Another cost benefit of early detection of HIV infection is the potential for fewer cases caused by unaware transmission. Additionally, decreasing viral load among the infected with medications may decrease the rate of transmission of HIV in the U.S.

Paltiel and colleagues confirmed that implementing universal screening at a rate of one-time screening or screening every five years was cost effective (Exhibit 4). The model made the assumption that society would consider a cost of $50,000 or less per quality-adjusted life-year gained to be cost-effective. This analysis included the costs of prescreening counseling, which is no longer routinely recommended. The authors concluded that routine rapid HIV testing is recommended and cost-effective when the prevalence of HIV is greater than or equal to 0.2 percent. Other studies have suggested screening to be cost effective on populations with a prevalence of 0.1 percent. The HIV prevalence in the general US population is approximately 0.4 percent.

To be able to provide cost-effective treatment and competent care for HIV infected patients, HIV specialty centers must be adequately staffed and funded. Data suggest patients cared for by HIV specialists have better outcomes. They do better in terms of survival and have lower morbidity. Specialists are usually faster in adopting new guidelines and therapies. They also are somewhat better at addressing adherence issues with this population. Experience in providing HIV care is essential for the management of
the complexities of HIV disease and the appropriate use of HIV therapies. Recommended therapy for this disease changes very frequently. In fact, there are two new classes of medications ready to be approved and there are many implications as to when these agents should be used. An expert panel convened by the Department of Health and Human Services recommends that primary HIV care be provided by clinicians with expertise in the disease. The level of expertise is variably defined as those with at least 20, but preferably at least 50 patients.

Since the treatment of HIV infection is highly variable and changes within the field occur relatively rapidly, ongoing continuing education in HIV therapy also is recommended. The AIDS Education Training Center (AETC) provides educational services nationwide. The AETC web site, www.aids-ed.org, provides an extensive library of online training resources. Funding through the AETC also provides a national HIV consultation service for health-care professionals. This service provides individual case consultation, and is offered free of charge to healthcare professionals.

Conclusion

Routine HIV testing is needed and is cost effective. Rapid tests have significantly improved the feasibility of HIV testing at the point of care. Awareness of HIV status does have a significant implication and will reduce transmission of HIV disease. Early detection is associated with decreased morbidity and mortality, and is cost effective. JMCM

Olga Lugo-Torres, MD, is a supervising physician of the STD/HIV/AIDS Division of the Chicago Department of Public Health.

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ALTHOUGH MULTIPLE SCLEROSIS (MS) IS not the most common neurological disease in young adults, it is the most common neurological disease that causes disability in young adults. It is a chronic illness with no cure, but it does not shorten one’s lifespan.

There are an estimated 350,000 to 500,000 people in North America with MS. About 10,000 new cases are diagnosed annually. The highest prevalence in the U.S. is among Caucasians, and the female-to-male ratio is at least 2-to-1 and possibly higher. The usual age of onset is between 15 and 55. The average age at MS diagnosis is 26.

Because this disease disables young people, the costs of MS to society are enormous. This was estimated at 27 billion dollars about 10 years ago.1

MS is an immune mediated disease in genetically susceptible individuals. It has two aspects, inflammatory and degenerative, which leads to progressive neurological dysfunction with lesions in all areas of the central nervous system, brain, and spinal cord.

Exhibit 1 illustrates the clinical progression of MS. Initially, there is a preclinical phase where changes can be seen on magnetic resonance imaging (MRI) scans. The next stage is a relapsing remitting phase where patients will have an attack and get better. Acute attacks are relapses or episodes with acute neurological dysfunction that last at least 48 hours.

The relapsing remitting stage is where medications are most effective. In the secondary progressive phase, there is a loss of brain volume and increasing evidence of neuron loss on MRI scans. In the earlier phases, the patient will return back or nearly back to baseline after an attack or relapse. As the disease progresses, the patient accumulates damage.

MRI scanning is very important in diagnosis and in following patients. An MRI scan will demonstrate approximately 90 to 95 percent of white matter lesions in the brain and 50 to 75 percent of lesions in the spinal cord. Cost and availability are limiting factors in repeated MRI scans in the clinical setting.

The National Multiple Sclerosis Society states that initiation of therapy with an immunomodulator is advised as soon as possible after a definitive diagnosis of MS with a relapsing course.2 Therapy may be considered for selected patients with a first attack who are high risk for RRMS.2 Early therapy is intended to slow both the inflammatory and degenerative aspects of the disease. Treating patients early has a better chance to affect and modulate the immune system. The goals of pharmacologic therapy in MS are given in Exhibit 2. Importantly, control of disability is a major goal of therapy.

Immunomodulators that are approved for relapsing remitting multiple sclerosis (RRMS) include glati-
ramer acetate (Copaxone®), interferon beta-1a (Avonex® and Rebif®), interferon beta-1b (Betaseron®), and natalizumab (Tysabri®) (Exhibit 3). Natalizumab was briefly withdrawn from the market because of several cases of progressive multi-focal leukoencephalopathy, which can be fatal. It was recently reintroduced to the market. Mitoxantrone (Novantrone®), a chemotherapeutic agent, and corticosteroids are used as immunosuppressants in relapsing forms of MS. Patients at times will respond to one agent and not to another. All of the FDA-approved immunomodulators reduce the number of relapses.

Among untreated patients, 50 percent will reach a level of disability, requiring assistance with walking, within 15 years (expanded disability status scale [EDSS] score of 6, Exhibit 4). Data shows glatiramer acetate and interferons alter the natural history of this disease. For example, in one glatiramer study, only 8 percent of patients progressed to an EDSS of 6 at 10 years.

Although these medications can decrease disability, they are not without side effects. The major adverse effects of the agents are given in Exhibit 5. Glatiramer acetate causes less significant adverse events, which is very important for patient quality of life. Additionally, glatiramer has a pregnancy category B labeling (safe in animals, no human data) versus C (adverse events in animals) or D (known fetal risk) for the other agents. Since women are diagnosed with MS more often than men, this distinction between the agents is important.

Untreated, almost half of the patients will not fully recover from an acute attack. It is very important to treat acute attacks to prevent or reduce long-term disability. High dose intravenous corticosteroids are the standard treatment. In the past, this treatment would have required a three-to-five-day hospital stay. Now, this treatment is almost exclusively given in the home.

In addition to acute attacks, patients have many different symptoms that also require treatment. Symptoms of MS occur depending on the locations of the demyelinating plaques in the brain (Exhibit 7). For example, plaques in the cerebellum can cause ataxia or tremors. The typical symptoms of MS include fatigue, spasticity, pain, bowel & bladder problems, memory loss, swallowing difficulties, tremors, visual changes, sexual dysfunction, speech disorders, balance and mobility dysfunction, and depression. Treating these symptoms improves the patient’s quality of life. Symptom management includes nonpharmacologic therapies, pharmacologic therapies, and psychological support.

Fatigue is a common symptom that may require lifestyle changes. For example, patients are taught to integrate rest times during their daily activities. Fatigue can be treated with amantadine (Symmetrel®), modafinil (Provigil®), and antidepressants. None of these agents are FDA approved for treating fatigue of multiple sclerosis.

Spasticity affects 60 to 80 percent of patients. Nonpharmacologic interventions to manage spasticity include stretching, bed and chair positioning, and physical therapy. Pharmacologic interventions, in addition to nonpharmacologic measures, are most

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**Exhibit 1: Disease Progression**

- Measure of brain volume
- Relapses and impairment
- MRI burden of disease
- MRI activity

**Exhibit 2: Goals of MS Therapy**

- Affect the neurodegenerative & inflammatory components of MS
- Early intervention: initiate therapy as soon as possible for the best chance of controlling damage
- Reduction of disease activity as measures by relapses, MRI findings, & disability
- Provision of therapy that is well tolerated & safe over time
commonly used. The typical agents include baclofen, tizanidine (Zanaflex®), diazepam, dantrolene (Dantrium®), nerve blocks with various agents, and botulinum toxin (Botox®). Surgical interventions include baclofen pumps and rhizotomy.

Various types of pain occur with multiple sclerosis. Nonpharmacologic management of pain includes appropriate seating support to improve posture, physical therapy, gait training, assistive devices, muscle strengthening, and stretching. When treating pain, many pharmacologic agents are used off label. The most commonly used agents include amitriptyline (Elavil®), nor-triptiline (Pamelor®), carbamazepine (Tegretol®), gabapentin (Neurontin®), phenytoin (Dilantin®), baclofen, tizanidine, and clonazepam (Klonopin®).

More than half of the patients with MS have issues with their bladder or bowels, which are very disabling. Aggressive management of bladder dysfunction is necessary because untreated bladder dysfunction can lead to chronic infections. Bladder dysfunction can be managed with intermittent self-catheterization; medications such as antispasmodics, tricyclic antidepressants, DDAVP (an antidiuretic hormone), and alpha blockers; and, if necessary, indwelling catheters. With bowel dysfunction, constipation and fecal incontinence are the most common problems. Constipation is treated with fiber, fluids, activity, bowel training, laxatives, and dietary modification. Involuntary loss of bowel control can be treated with fiber, anticholinergics, and dietary modification.

Because of brain shrinkage, cognitive issues occur in 45 to 60 percent of patients, but result in significant changes in only 15 percent of patients. Early treatment to minimize the number of acute attacks will prevent this shrinkage. The most common cognitive issues are short-term memory loss or impaired judgment, learning, word finding, or executive functioning. Neuropsychological testing is used to identify and monitor cognitive issues related to MS. A brain defect secondary to the disease needs to be dis-
tunguished from depression. Treatment may include occupational therapy and cognitive retraining. Medications, approved for use in Alzheimer’s disease, occasionally are used but have minimal efficacy.

Depression is common in patients with MS. Like many of the other symptoms of MS, depression contributes to a reduced quality of life. The same antidepressants are used in these patients as in someone without MS.

Sexual dysfunction is an issue that physicians often avoid discussing with the patient. Sexual dysfunction must be addressed because it can disrupt family life and quality of life. Management strategies include medications for impotence (vardenafil [Levitra®], tadafal [Cialis®], sildenafil [Viagra®]), management of other symptoms or medical conditions that may be contributing, adjustment of medications that may be contributing, mechanical assistive devices, and emotional support.

Tremor and unsteadiness are two MS symptoms difficult to treat. Various medications can be tried including carbamazepine, ondansetron (Zofran®), clonazepam, primidone, gabapentin, propranolol, tricyclic antidepressants, and levetiracetam (Keppra®).

Optimizing therapy requires regular clinical assessment of patients. Therapies need to be evaluated for effectiveness and adverse effects. Therapy may need to be changed periodically for several reasons. The medications currently available are not all effective in every patient, and are only partially effective in many cases. Disease progression may not be well controlled in some patients. Additionally, the development of neutralizing antibodies may compromise efficacy of the interferons. Switching or combining therapies is routinely practiced although well-designed study data are limited.

Optimizing therapy also has to include the patient. Patients need to be educated about their disease and its therapies. Adherence with the prescribed therapies needs to be monitored and maintained.

Appropriate care of the patient with MS involves a team approach using many different medical professionals. Vocational counselors can be most helpful in assisting the patient with adjusting their workplace to manage many of the symptoms such as pain and fatigue. Physical therapists work with the patient to manage many of the symptoms. Nutritionists assist patients with maintaining an appropriate diet. Keeping these patients active, productive members of society is an important goal.

Conclusion

MS is a disease of an overactive immune system resulting in inflammation and neurodegeneration. Early treatment of this disease may delay progression. Optimizing nonpharmacologic and pharmacologic therapy requires frequent assessment and a team approach. JMCMD

Howard Zwibel, MD, is a neurologist and medical director at the HealthSouth Doctor’s Hospital Comprehensive Multiple Sclerosis Center in Coral Gables, Fl.

References

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THURSDAY, NOVEMBER 8

**General Session**
7:45 am - 9:00 am
The Future of Healthcare Delivery
Jacque Sokolov, MD, SSH Salutians

**Business Track**
9:05 am - 10:05 am
Making Clinical Integration a Reality
Christi Braun, Esq., Ober, Keller, Grimes & Shriver & Eric Nielson, MD, Canaster Rochester IPA (CRIPA)

10:05 am - 10:30 am
Networking with Exhibitors

10:30 am - 11:30 am
Managed Care Contract Management: The Hospital & Physician Perspective
Deborah Lauer, Shands Healthcare, University of FL Physicians

11:30 am - 12:30 pm
Lunch in Exhibit Hall

12:30 pm - 1:30 pm
Strategies for Maximizing Contract Performance
Terri Weller, ICC Management Consultants, Inc.

1:30 pm - 2:30 pm
Collaboration: The Strategic and Business Case for Community-Based Integrated Delivery Systems
Peter Laxton, MIA, Wipfli, LLP

2:30 pm - 3:30 pm
Break and Networking in Exhibit Hall

3:00 pm - 4:00 pm
Partnership With Our PCPs: An MCO Case Study
Angelo Giardino, MD, Texas Children's Health Plan & Janet Readwell, RN, PhD, Texas Children's Hospital

4:00 pm - 5:00 pm
Physician-Directed Quality Improvement: The Foundation of Clinical Integration and P4P
Dennis Saran, MD & Patricia Rall, BIS, MS, Waukesha Franciscan Health Care

**Wednesday, November 7 Pre-Conference**
12:15 pm - 1:15 pm
Driving a Care Using an Electronic Health Record
1:15 pm - 2:15 pm
Implementing a Disease Awareness Program in Your Organization
2:15 pm - 3:15 pm
Outcome Measurement: Intensive Care Management
3:15 pm - 4:00 pm
Medicaid Managed Care
4:00 pm - 5:00 pm
Persistence and Adherence in Pharmacy
5:00 pm - 7:00 pm
Opening Reception in Exhibit Hall

**Health Management Institute Track**
9:05 am - 10:05 am
Evidence on Comparative Effectiveness & Value of New Health Technologies, Iran Shadvy, Agency for Healthcare Research & Quality

10:05 am - 10:30 am
Networking with Exhibitors

10:30 am - 11:30 am
Controversies in Adult Vaccinations
Peers Casadesus, MD, Fogarty International Center, National Institutes of Health

11:30 am - 12:10 pm
Lunch in Exhibit Hall

12:10 pm - 1:30 pm
Managing Comorbidities through Smoking Cessation
Angie Vesseyka, BA, PharmD, Wingate University School of Pharmacy

1:30 pm - 2:10 pm
Asthma: Getting to Guidelines
Dennis Sprangle, MD, Atlanta Allergy Associates
OR
1:30 pm - 2:10 pm
Medical & Economic Impact of Respiratory Syncytial Virus Outbreak: The Role of the Medical Director

2:30 pm - 3:00 pm
Break and Networking in Exhibit Hall

3:00 pm - 4:00 pm
Managing (COPD)
David Tinkelman, MD, National Jewish Medical and Research Center

4:00 pm - 5:00 pm
Cost Analysis and Modeling of HPV Vaccination
Evan Myers, MD, MPH, Duke University Medical Center, Department of Obstetrics & Gynecology

**Physician Continuing Education**
This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the American Association of Integrated Healthcare Delivery Systems, the American Association ofManaged Care Nurses and the National Association ofManaged Care Physicians.

The National Association ofManaged Care Physicians designates this activity for a maximum of 14.5 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.
FALL MANAGED CARE FORUM
Schedule at a Glance

FRIDAY, NOVEMBER 9

General Session
8:00 am - 9:00 am
US Health & Human Services' Personalized Health Initiative
Gregory J. Downing, DO, PhD, U.S. Department of Health and Human Services

Business Track
9:05 am - 10:05 am
Case Study: Reinventing the PHO Via Quality Improvement & P4P
Heidi H. Simpkins, LifeWell Group, & James Watson, P4P Global

10:05 am - 11:30 am
Networking with Exhibitors

10:30 am - 11:30 am
Network Diversity: Now More Important Than Ever
Arthur Klein, Multiplix, Inc.

11:30 pm - 12:30 pm
Lunch and Networking in Exhibit Hall

To receive educational credits you must sign in at the registration desk, and complete and return your CMLeod educational validation and evaluation form.

Health Management Institute Track
9:05 am - 10:05 am
Managing Hyperlipidemia
OR
4:05 am - 5:05 am
Health Management of Diabetic Patient
Richard Snow, DO, MPh, Doctors Hospital/OhioHealth

10:30 am - 11:30 am
Concurrent
Healthcare Transitions: Trends in Quality Outcomes and Performance Measures-Pay for Performance GERD
Kevin Mawson, MD, People's Health

10:30 pm - 11:30 pm
Concurrent
Optimal Treatment Time for Diabetes Wound Care
Jean de Jesus, MD, Baylor Speciality Hospital & Vickie Dirks, LPN, MS, LACAS, Center of Lower Extremity Ambulatory Research (CLETAR)

11:30 pm - 12:30 pm
Lunch and Networking in Exhibit Hall

Genomics Biotech Institute Track
12:30 pm - 1:30 pm
Genomic Diagnostics: Opportunities, Challenges & Current Practice
Pat Duerink, MD, MS, MBAs, Duke University Center for Genome Librics, Law & Policy

1:30 pm - 2:30 pm
Determining Bioequivalency in Similar Bio’pharmaceuticals
Richard Wenzel, PharmD, Diamond Headache Clinic Inpatient Unit

1:30 pm - 2:30 pm
Targeted Therapies in Cancer
Edward Lin, MD, University of Washington School of Medicine

2:45 pm - 3:45 pm
Clinical Consequences of Implementing the ESA National Coverage Determination & Update from Cardio Renal Drug Advisory Committee Review on ESAs in CKD
Craig Jendele, MD, Ortho Biotech

2:45 pm - 3:45 pm
Managing Obesity

3:45 pm - 4:45 pm
New Treatments & Management of the Psoriasis Patient: Cost Vs. Benefits, Robert Kells, MD, State Univ. of NY at Buffalo

3:45 pm - 4:45 pm
Managing Anemia in Chemotherapy Patients

Nursing/Healthcare Executive Continuing Education
The American Association of Managed Care Nurses (AAMCN) has been approved as a provider of continuing education by the Virginia Nurses Association (VNA). VNA is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center’s Commission on Accreditation. A maximum of 15 contact hours will be awarded for nurses who complete this activity.

CMCN
The American Board of Managed Care Nurses has approved this activity for a maximum of 15 contact hours towards CMCN recertification.

CCM
This activity has been approved by the Commission for Case Management Certification for 15 contact hours towards recertification requirements.

CPFRC/CPUSM
This activity can be used for submission of up to 15 contact hours toward recertification for Certified Professional Utilization Review and/or Certified Professional Utilization Management.

CPIH
This activity has been approved by the National Association of Healthcare Quality for up to 11 continuing education hours towards recertification requirements.

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Exhibitor: The SCOOTER Store
Booth: 39

Exhibitor: The Wellington Group
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Exhibitor: Ther-Rx Corporation
Booth: 2
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**Senior Director, Specialty Pharmacy Marketing**

Serving as the subject matter expert for Specialty Pharmacy, you will interface with Management, Brand teams and Account Management in order to develop & support the implementation of segments, therapeutic areas, and/or cross brand strategies and tactics for the Specialty Pharmacy Segment. This will encompass maximizing the performance in the Segment by utilizing customer and market insights to develop strategy and execute marketing tactics; be accountable for the design and implementation of programs that meet the relevant needs of Specialty Pharmacy Customers and that are in alignment with Wyeth's business objectives; and developing a customer-centric strategy that maximizes revenues through better, more meaningful relationships with Specialty pharmacy customers.

Selected candidate will possess a BA degree with 12 years business experience and 7 years managed markets customer marketing and/or US healthcare market experience OR an MBA degree with 10 years and 5 years experience respectively. 3-5 years specialty pharmacy segment marketing or specialty pharmacy industry a must. Extensive knowledge of Specialty Pharmacy including stand alone and PBM/Specialty pharmacy providers, clinical services, pharmacy operations, and specialty pharmacy professional associations essential. Prior ownership for developing and executing marketing strategies and tactics for Specialty pharmacy customers; experience developing marketing strategies and tactics for additional audiences (healthcare provider, consumer, non-healthcare consumers, etc); managed care account management experience; and prior supervisory/management/team lead experience preferred.

We offer an exceptional work environment and competitive compensation and benefits, including child-care subsidies, educational assistance and professional development programs.

For more information and to apply online, please visit: www.wyeth.com/careers

Wyeth

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URAC accredited in Utilization Management and External Review, and NCCOA certified in Utilization Management. Prospective, concurrent or retrospective review. Also 24-72 hour written responses and phone consultations. 700+ physicians in 48 states reviewing medical necessity, appropriate treatment or hospitalization, experimental procedures/drugs/medical devices/organ transplants. Cost effective physical medicine UM service. Per case service available.

Medtronic
Medtronic is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world. During the past year, Medtronic provided medical professionals with products and therapies to improve the lives of nearly six million patients. Today, every five seconds another person, somewhere in the world, is alive or living a fuller life as a result of a Medtronic product or therapy.

Merck & Co.  ● Sponsor
Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. For more information, visit: www.merck.com.

MultiPlan, Inc.
MultiPlan is the industry’s oldest and largest independent provider network allowing access to a diverse base of over 2,100 clients and over 40 million lives nationally. An estimated 4,500 acute-care hospitals, 110,000 ancillary care facilities and 550,000 healthcare practitioners participate in the PHCS and/or MultiPlan networks. Founded in 1970, MultiPlan is owned by a group of investors led by The Carlyle Group. Visit us online at www.multiplan.com.

National Medical Reviews, Inc.
National Medical Reviews, Inc. (NMR), URAC accredited IRO, provides dispute resolution for healthcare claims. NMR utilizes Nurse Review Coordinators and a panel of over 1,200 physician reviewers nationwide. Services: Medicare, Internal & External Appeals, ERISA Plans, and PBM. Reviews are accurate, cost-effective, adhere to plan language and compliant with industry regulations.

NDT Labs, a PerkinElmer Co.
NDT LABS, A PerkinElmer Company, is a specialty laboratory that focuses on prenatal screening for birth defects. We provide our services to universities, medical centers, hospitals, other laboratories, and obstetricians throughout the United States and internationally. We also support an extensive research division and our findings are published in many peer-reviewed medical journals.

Newkirk Products
Newkirk is a leading provider of member pre- and post-enrollment, member retention, and provider communications for managed care organizations, third party administrators, and self-funded plans. Our technologically advanced publishing systems and cost-efficient communications will give your organization an edge from enrollment through retention. Convenient online publishing systems enable you to quickly and easily create pre-enrollment communications, Welcome Books with member-specific preventative health information and customized provider directories, and more. For more information, visit www.newkirk.com.

Nexus Healthcare
Nexus Healthcare is an executive search firm dedicated to placing exceptional executives in the healthcare industry nationwide. Our extraordinary client base consists of managed care organizations, health systems, hospitals and physician group practices. As the healthcare industry faces an ever-increasing variety of pressures, the challenge of recruiting, retaining, and developing productive leadership talent within an environment of accountable governance has never been more pressing. Nexus Healthcare understands that each search is a critically important decision and that, ultimately, success is defined by the long-term impact an executive has on the organization. Our innovative approach to executive search allows us to identify key individuals for our clients’ organizational challenges that can best support their strategic objectives. We have access to the highest caliber of managed care talent and have a distinguished track record in placing physician and nurse executives as well as executive operations personnel (CEO, COO, CFO, Director of Managed Care, Network Development, etc.) If you have an available position or have an interest in our placement service, please contact David Mara at (804) 527-1905 or e-mail at dmara@hmampc.org.

OTN Specialty Services
OTN Specialty Services is the nation’s largest independent specialty pharmacy. Each customer is supported by our experienced team of professionals, as well as our specialized nurses and pharmacists. We provide patient care nationwide through our four locations in Texas, Missouri, California, and Massachusetts. Our JCAHO accreditation brings added value to our services, ensuring our organization’s level of performance in key areas, such as patient rights, patient treatment and infection control, are aligned with national standards.

OptumHealth
As one of the nation’s largest health and well-being companies, OptumHealth makes health care easier and better for employers, health plans, public sector entities and the 58 million people with access to its services. The Company’s goal is to optimize health, well-being and financial security, while lowering benefit costs and helping consumers make informed decisions about their health through stand-alone or integrated services. More information about OptumHealth can be found at www.OptumHealth.com.

Ortho Biotech Clinical Affairs
Ortho Biotech Products, LP  ● Sponsor
Ortho Biotech Products, L.P. markets PROCRIT® (Epoetin alfa) used to treat anemia associated with serious medical conditions. The company also markets other biotechnology products. It is based in Bridgewater, New Jersey.

Ortho-McNeil Janssen Pharmaceutical Services

Otsuka America Pharmaceutical, Inc.  ● Sponsor
Otsuka - people creating new products for better health worldwide. Otsuka’s roots date back to 1921 in Tokushima, Japan. In 1964, Otsuka Pharmaceutical Co, Ltd. was established to enhance Otsuka’s pharmaceutical product development. The company has since grown and diversified, investing in enterprises and establishing corporations in 17 countries around the world. These comprise the Otsuka Pharmaceutical Group, a collection of 99 companies employing more than 31,000 people.

In 1985, Otsuka established its first healthcare-related business in Montgomery County, Maryland. As the business grew, it added clinical research to its R&D capabilities, and in 1989, when the commercialization phase for products began, was incorporated as Otsuka America Pharmaceutical, Inc. (OAPI). OAPI’s mission is to market and sell Otsuka-discovered and developed compounds, along with other pharmaceutical products and devices in the U.S. OAPI’s product portfolio is focused primarily on cardiovascular and neuroscience treatments. OAPI is also developing products in other therapeutic areas including gastrointestinal and antiepileptic disease treatments.

Pfizer  ● Sponsor
Phyhealth
Physicians Healthcare Management Group, Inc. (Phyhealth) develops community-based HMOs that are owned and operated in partnership with the participating physicians. Phyhealth Plans are designed to deliver high-quality, patient-centered healthcare by enabling physicians to assume end-to-end management of healthcare for their patients. The Phyhealth model empowers physicians to provide preventive healthcare and proactively manage their patient’s general health by aligning incentives amongst the HMO, physician and the patient.

Professional Services Network, Inc. (PSN)
Professional Services Network, Inc. (PSN) is your resource for temporary and direct hire staffing of qualified nurses and social workers with experience in case management, disease management, utilization review, quality improvement, and HEDIS/chart review. PSN, a 17 year-old, certified Minority Business Enterprise (woman-owned), also provides consulting services in accreditation preparation and program design for hospitals and managed care companies.
Purdue Pharma L.P.
As a privately held pharmaceutical company founded by physicians, Purdue is focused on the needs of patients. We are dedicated to finding, developing, and bringing to market new medicines and related products that promote health and healing.

Rapid Pathogen Screening, Inc.
Rapid Pathogen Screening, Inc. (RPS) develops point-of-care diagnostic devices for ocular diseases. The RPS Adeno Detector™ differentiates viral from bacterial conjunctivitis. It can provide a definitive result in 10 minutes. The RPS Adeno Detector™ can aid health care providers to make an accurate diagnosis, foster patient acceptance of more supportive therapies, identify contagious viral conjunctivitis, and limit spread of disease while simultaneously reducing ocular antibiotic resistance and the cost of unnecessary antibiotics. Reckitt Benckiser Pharmaceuticals
Reckitt Benckiser Pharmaceuticals is at the forefront providing educational resources and treatment options to physicians and patients dealing with the chronic relapsing disease of opioid dependence. Please visit their exhibit where Reckitt Benckiser Managed Care Account Managers will be available to provide scientific information and answer your questions. Reliant Pharmaceuticals
Reliant Pharmaceuticals, Inc. is a pharmaceutical company with integrated sales, marketing and development expertise that markets a portfolio of branded cardiovascular pharmaceutical products. Reliant focuses on marketing promotionally sensitive pharmaceutical products to the high prescrib ing primary care, cardiovascular and specialist physician markets in the United States. Sanofi-aventis
Sanofi-aventis Group, provides pediatric, adult, and travel vaccines for diseases such as diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type b, influenza, rabies, Japanese encephalitis, typhoid fever, yellow fever, and meningococcal disease. To learn more about our products, visit our exhibit. Smith & Nephew, Inc., Orthopaedic Division
Smith & Nephew Orthopaedics offers EXOGEN 4000+, only FDA-approved bone healing device for the non-invasive treatment of fresh fractures and non-unions, SUPARTZ, world’s most prescribed joint fluid therapy for pain reduction in the knee caused by osteoarthritis, BIRMINGHAM HIP RESURFACING system which can end the hip pain of arthritis and degenerative hip disease and help restore eligible patients’ active lifestyle and IDET (Intradiscal Electrothermal Therapy) which offers significant relief from chronic discogenic lower back pain. Solstice Neurosciences, Inc.
Solstice Neurosciences, Inc. is focused on the development, manufacturing, sales and marketing of toxins in multiple therapeutic areas. Solstice’s first product, Myobloc® (Botulinum Toxin Type B) Injectable Solution, represents the only botulinum toxin type B currently available worldwide. TAP Pharmaceutical Products, Inc.
Teva Neuroscience
Teva Neuroscience invites you to visit our booth to discuss COPAXONE® (glatiramer acetate injection), and its use in the treatment of relapsing-remitting multiple sclerosis; AZILECT® a novel, potent, second-generation, selective, irreversible monoamine oxidase type-B (MAO-B) inhibitor that blocks the breakdown of dopamine. AZILECT® has been approved as monotherapy in early Parkinson’s disease and as an adjunct therapy to levodopa in moderate-to-advanced disease. Teva Specialty Pharmaceuticals
Stop by our booth to learn more about Qvar® (beclomethasone dipropionate HFA) & ProAir HFA (albuterol sulfate). Ther-Rx Corporation
Ther-Rx Corporation is a specialty pharmaceutical company focused today on women’s health care. Using proprietary drug-delivery technologies from our parent company, KV Pharmaceutical Company (KV), we create and market products that are easier to take, taste better, act faster, and last longer. By applying our highly advanced technologies in patient-friendly ways, we are working to develop pharmaceuticals that improve health care and well-being.
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