

WELCOME NEW MEMBERS

The City of Everett, Washington

Grant Thornton LLP

Kenan Advantage Group, Inc.

Owens State Community College

*Through strategic alliance with
FrontPath Health Coalition*

Synalloy Corporation

*Through strategic alliance with
HealthCare 21 Business Coalition*

HEALTHSCOPE

A Quarterly Publication of
Employers Health Coalition of Ohio, Inc.

2 A Letter from Chris

4 The Upcoming Flu Season

6 HITECH Breach Notification

8 Increased Growth of
Specialty Drugs



October 14*11:00 am - Noon***Exploring Medical Tourism**

WEBINAR

October 16*8:00 am - 10:00 am***Preparing for Pandemic Flu***What employers should be considering now to plan for the impending situation*

The University Center (Kent State Stark)

October 27*8:00 am - 4:00 pm***REFORM- Symposium on Health Care Reform**

Hilton Columbus - Easton Town Center

November 3*8:00 am - 9:30 am***Evaluating the Cost of Health Care in Stark & Surrounding Counties:***One Consultant's Perspective*

Employer Members Only

Glenmoor Country Club

November 17*5:30 pm - 8:00 pm***Living Life with Diabetes***Featuring Will Cross*

Glenmoor Country Club

December 8*8:00 am - 10:00 am***Annual Meeting of Board of Directors & Members**

Glenmoor Country Club

Mark Your Calendar and Keep an Eye on Our Website for Additional Future Events!

www.ehpc.com**Welcome to the Fall 2009 edition of HealthScope.**

Dear Members and Friends,

Two major health topics currently lead the U.S. public agenda; health reform and H1N1 or swine flu. We have tackled both issues for the month of October beginning with a return engagement with Dr. Stuart Weiss, an internationally recognized expert in pandemic, disaster and business continuity planning. Dr. Weiss facilitated a one-day workshop in fall 2007 for us that entailed over 100 participants. And that workshop was prior to the H1N1 outbreak. Members

outside of the Akron/Canton area will be able to join via webinar.

Also, we have collaborated with Schottenstein, Zox & Dunn and the Health Policy Institute of Ohio to bring you REFORM, a one-day symposium on health care policy reform. In addition to keynotes from Director Mary Jo Hudson of the Ohio Department of Insurance and Jeff Biehl, president of AccessHealth Columbus, three stakeholder panels will include physician/hospital executives, insurance industry executives and employers. I have the privilege of moderating the employer panel which includes the following EHCO member representatives: Greg Paradiso, director, compensation & benefits at P.H. Glatfelter Company; John Popa, president & CEO, Marlite, Inc.; and Rick Schwieterman, CFO at Online Computer Library Center, Inc. Rounding out the employer panel will be Dennis Hicks, director of compensation & benefits at Chiquita Brands International, Inc.

Finally, I want to take the opportunity to welcome five new members:

- Headquartered in Spartanburg, South Carolina, **Synalloy Corporation** has been in business since 1945 and employs over 440 people with operations in South Carolina, North Carolina, Tennessee, and Georgia. The Company is a diverse manufacturer comprised of two major operating segments: metals and chemicals.
- With campuses in Toledo and Findlay, **Owens State Community College (OSCC)**, with over 600 employees, was once a technical college. Converted to a comprehensive community college in 1994, OSCC still retains its technical and career programs and serves more than 45,000 students annually.
- Headquartered in Jackson Township (Canton), Ohio, **Kenan Advantage Group (KAG)**, with over 5,000 employees, is North America's largest bulk transportation and logistics provider to the petroleum and specialty products industries. KAG operates approximately 100 terminals and 98 satellite locations. Its customers include many of the major oil companies, truck stop chains, convenience stores, hypermarkets, aviation fuel marketers and other national/regional petroleum marketers. It is the only independent fuels delivery carrier with a nationwide network, having operations in 38 states and the ability to deliver within all 48 states of the continental United States and Canada.
- **Grant Thornton LLP** is the U.S. member firm of Grant Thornton International Ltd, one of the six global accounting, tax and advisory organizations. Through member firms in more than 100 countries, the firm has 51 offices in the United States, including Cleveland, Ohio and employs over 5,000 US employees.
- **The City of Everett, Washington** has a population over 101,000, is the county seat of Snohomish County, Washington and employs over 1,051 individuals in many classifications. Located about 25 miles north of Seattle, Everett is a Pacific-Rim city situated on Port Gardner Bay.

I look forward to seeing you at one of our upcoming education events.

Sincerely,

Christopher V. Goff, Esq.

CEO & General Counsel

MEDICAL COSTS EXPECTED TO RISE 9% IN 2010

BY CORY SMITH, RHIA



The state of the economy has many employers concerned about trends for medical and pharmacy costs for the rest of 2009 and into 2010. The following is a projection from top PBMs and consulting firms on what employers might be able to expect.

Medical costs are expected to rise 9% in 2010, according to the latest Price Waterhouse Coopers medical trend analysis. While this trend is lower than in previous years, it is still higher than the rate of inflation and wage increases.

	2008	2009	2010
Medical Cost Trend	9.9%	9.2%	9.0%

The traditional and overall drug trends are increasing at a slower rate than overall medical cost trends. According to most PBMs, this can be largely attributed to an increase in generic dispensing rates over the last several years.

The volume of specialty drugs is low but their price is disproportionately high when compared to traditional drug costs. Therefore, this makes specialty drugs a large driver of overall pharmacy trends. According to most sources, specialty drugs made up about 0.5% of their total

dispensed prescriptions, but accounted for 10.9% of the total spend.

There is some variance in opinions on pharmacy cost trend projections for 2010 amongst several Pharmacy Benefit Managers, but most trend projections still fall within a similar range of 6 percent - 10.5 percent.

Findley Davies reported in its 2009 Health Care Trend Survey, a survey of health benefit underwriters on the future of medical and pharmacy trends, that the combined Medical/Rx trend has risen to 12% for 2009. This is after remaining steady at 11% for both 2007 and 2008. However, more concerning is the response of many underwriters to the question, "How will annual health trend

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SYMPOSIUM ON HEALTH CARE REFORM 2009

Employers Health, in collaboration with the Health Policy Institute of Ohio and Schottenstein Zox & Dunn, Co., LPA, is hosting a symposium to address the impact of federal and state health care policy reform efforts among key Ohio stakeholders in the health care industry. In addition to obtaining an overview of the current status of health care policy reform, attendees will benefit from the views and opinions of Ohio policymakers

and leaders in the provider, payor and employer communities on health care reform through informative panel discussions and interactive question and answer sessions.

REFORM BELOW

Key questions to be addressed include:

- What is the current status and substance of the federal government's health policy reform efforts?
- What is the status and substance of any Ohio health policy reform initiatives?
- How will adopted (or proposed) reform legislation impact the provider, payor and employer communities?
- What are these stakeholders' key concerns about health care reform?
- What opportunities does health care reform present for these stakeholders?

REGISTRATION

Register online at:
www.SZD.com, click Resources,
then Events

There is no fee to attend. However, reservations are necessary. Space is limited to three people from each organization.

Continental breakfast and lunch will be provided.

Registration deadline: October 16, 2009

Hilton Columbus - Easton Town Center
3900 Chagrin Drive
Columbus, Ohio 43219

For directions, go to
www.hiltoncolumbus.com

For a list of accommodations in the area, see www.SZD.com registration page for more information.



WHAT YOU SHOULD KNOW THE UPCOMING FLU SEASON

BY BRUCE SHERMAN, MD, FCCP, FACOEM

The recent pandemic caused by the H1N1 influenza virus has generated a great deal of press during the past few months. Seemingly coming from nowhere, this virus has affected likely millions of individuals. While the virus has achieved pandemic status, according to the World Health Organization, this is because of the global impact that the virus has had, and not because of severity concerns – at least, not yet.

While some companies have formulated comprehensive pandemic planning strategies as part of their business continuity efforts, others have done little, if anything to prepare. It's tempting to adopt an "I'll worry about it when the time comes" approach; but the resultant business impact of a sustained period of high absence rates (some estimates have the figure as high as 40%), potentially limited parts supplier production, and a lack of a business continuity strategy have the potential to result in significant, if not devastating business consequences.

Seasonal flu vs. pandemic (H1N1) flu

Based on its level of contagiousness, the vast majority of the influenza cases reported recently appear to have been caused by the H1N1 flu. The seasonal flu remains a threat, and will likely make its way into the northern hemisphere this fall and winter.

No one knows how prevalent or how great the health impact the seasonal flu will be relative to the H1N1 flu, and that's why all health organizations are encouraging individuals to be vaccinated against both viruses.

Vaccines

There will be two vaccines available this fall – the seasonal flu vaccine, and the H1N1 vaccine, which is anticipated to be available sometime during October.

There appears to be sufficient seasonal flu vaccine, but only about 45 million doses of H1N1 vaccine will be ready in October, with about 20 million doses available each month thereafter. The CDC is recommending that the following groups, because of their risk of severe complications from H1N1 infection, receive the vaccine first:

- pregnant women
- people who live with or care for children younger than 6 months of age
- health care and emergency medical services personnel with direct patient contact
- those 6 months through 24 years of age, particularly those who have chronic medical conditions, placing them at higher risk of complications from influenza

Once the above groups have been immunized, the next group to be immunized includes persons aged 25 through 64 years who have chronic medical conditions. Next should include all others aged 25 through 64 years.



The final group should include those aged 65 and older. The H1N1 disease in this population has been mild, likely due to prior exposure to similar strains, resulting in partial immunity.

At this point, it's not yet clear which healthcare providers will be receiving supplies of the H1N1 vaccine, and when. Encourage employees and their family members to check with their local healthcare providers for more information.


Antivirals

The H1N1 virus remains largely sensitive to the two currently available antiviral medications, oseltamivir (Tamiflu) and zanamivir (Relenza). These medications have the greatest effect on illness severity and duration of symptoms when taken within the first 24 hours following symptom onset. Some employers have chosen to stockpile these medications in anticipation of widespread infection, while the majority has chosen to utilize the current medical system. As of now, there is no major concern for a shortage of antivirals.

What can employers do now?

Even if your organization has no formal pandemic plan, there are a number of steps you can take now in anticipation of the upcoming flu season:

1. Make sure that employees are well informed about ways to minimize their risk of contracting the flu. These include:
 - a. Social distancing
 - b. Frequent hand washing or use of company-provided alcohol-based hand gels
 - c. Proper sneeze and cough hygiene, with appropriate disposal of used tissues
2. Ensure that employees who are ill or develop flu symptoms stay home until 24 hours after their fever has resolved (in the absence of fever-reducing medications).
3. Ensure that your organization has clear policies/guidance regarding illness absence and pay strategies related to H1N1 for employees who are ill or are staying home to care for ill family members. This is particularly important if you want to do your best to keep H1N1 out of the workplace.
4. In the event of a major local outbreak of H1N1, consider implementing additional strategies to minimize large group gatherings (including limiting face-to-face meetings, broadening lunch hours for cafeteria use, and spreading out work shift times). Ensure that frequently touched surfaces, including door knobs, bathroom doors, and stair/escalator/elevator surfaces are disinfected regularly.

The Centers for Disease Control has developed comprehensive employer resources, which can be found at www.flu.gov and www.cdc.gov/h1n1flu/business/guidance. EHPCO can also provide you with additional resource support – contact Bruce Sherman, MD, at bsherman@ehpc.com. 

H1N1 Vaccine Q & A

Q: Who should receive the H1N1 Vaccine?

A: CDC's Advisory Committee on Immunization Practices has recommended that certain groups of the population receive the 2009 H1N1 vaccine when it first becomes available. These target groups include pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people ages of 25 through 64 years of age who are at higher risk for 2009 H1N1 because of chronic health disorders or compromised immune systems.

Initially the vaccine will be available in only limited quantities. In this setting, the following groups should receive the vaccine before others: pregnant women, people who live with or care for children younger than 6 months of age, health care and emergency medical services personnel with direct patient contact, children 6 months through 4 years of age, and children 5 through 18 years of age who have chronic medical conditions.

Once the demand for the vaccine for these target groups has been met at the local level, programs and providers should begin vaccinating everyone from ages 25 through 64 years. Current studies indicate the risk for infection among persons age 65 or older is less than the risk for younger age groups. Therefore, as vaccine supply and demand for vaccines among younger age groups is being met, programs and providers should offer vaccinations to people over the age of 65.

Q: When will the H1N1 Vaccine be available?

A: The vaccine is expected to be available in early-mid October. Shipments will begin to identified community providers at that time.

Q: Where will the Vaccine be available?

A: Every state is developing a vaccine delivery plan. Vaccine will be available in a combination of settings such as vaccination clinics organized by local health departments, healthcare provider offices, schools, and other private settings, such as pharmacies, retail clinics and workplaces. Individuals should check with their personal physicians to see when the vaccine will be available.

Q: Will there be enough vaccine for everybody?

A: Yes. The CDC has projected that enough vaccine will be produced to meet the demand, though the vaccine will be made available on a gradual basis. Some people in the lowest priority group for vaccination may have to wait until sometime during 2010 to receive their vaccine. It is likely that a number of these individuals may be infected with H1N1 before having an opportunity to be vaccinated.

Q: Should I get both a regular flu shot & the H1N1 shot?

A: Yes. Both the regular (seasonal) flu and the H1N1 flu are expected to cause illness this season. According to the CDC, both the seasonal flu and 2009 H1N1 vaccines can safely be administered on the same day. However, the seasonal vaccine will be available earlier than the H1N1 vaccine. The usual seasonal influenza viruses are still expected to cause illness this fall and winter. Individuals are encouraged to get their seasonal flu vaccine as soon as it is available.

Q: Is it true that the H1N1 vaccine is a series of shots?

A: Not necessarily. Recent data indicate that the current vaccine generates enough of an immune reaction so that only a single dose may be required for adults – a final determination on this issue should be forthcoming shortly from the CDC. For children, however, two doses may still be required. Parents should discuss this with their pediatric healthcare clinicians.

Q: Will the 2009 H1N1 influenza vaccines be safe?

A: The H1N1 influenza vaccine is expected to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans have received seasonal flu vaccines. The most common side effects following flu vaccinations are mild, such as soreness, redness, tenderness or swelling where the shot was given. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will be closely monitoring for any signs that the vaccine is causing unexpected adverse events and will work with state and local health officials to investigate any unusual events.

Q: Are there other ways to prevent the spread of illness?

A: Take everyday actions to stay healthy.

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it. Alternatively, cough or sneeze into your bent elbow to minimize the release of aerosol droplets that can spread infection.
- Wash your hands often with soap and water, especially after you cough or sneeze. Alcohol-based hands cleaners are also effective.
- Avoid touching your eyes, nose or mouth. Germs spread that way.
- Stay home if you get sick. CDC recommends that you stay home from work or school and limit contact with others to keep from infecting them.

For additional information, visit the CDC website, at www.cdc.gov/h1n1flu or call Bruce Sherman, MD at 216-337-4457. (Adapted from www.cdc.gov/h1n1flu.)



Interim Final Rule Issued

HITECH Breach Notification

BY DAVID ULDRICKS, JD, LLM

HHS issued regulations requiring health care providers, health plans, and other entities covered by the Health Insurance Portability and Accountability Act (HIPAA) to notify individuals when their health information is breached.

These “breach notification” regulations implement provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, passed as part of American Recovery and Reinvestment Act of 2009 (ARRA).

The regulations, developed by the Office for Civil Rights after close consultation with the Federal Trade Commission (FTC), require health care providers and other HIPAA covered entities to promptly notify affected individuals upon the discovery of a breach, as well as the HHS Secretary and the media in cases where a breach affects more than 500 individuals. Breaches affecting fewer than 500 individuals will be reported to the HHS Secretary on an annual basis. The regulations also require business associates of covered entities to notify the covered entity of the discovery of breaches at or by the business associate. The FTC has issued companion breach notification regulations that apply to vendors of personal health records and certain others not covered by HIPAA.

For purposes of the regulations, a “breach” is the acquisition, access, use or disclosure of unsecured Protected Health Information (PHI) in a manner not permitted by the HIPAA privacy regulations which compromises the security or privacy of the PHI. HITECH provides exceptions to this definition to encompass disclosures where the recipient of the information would not reasonably have been able to retain the information, certain unintentional acquisition, access, or use of information by employees or persons acting under the authority of a covered entity or business associate, as well as certain inadvertent disclosures among persons similarly authorized to access protected health information as a business associate or covered entity.

The Act defines “unsecured protected health information” as “protected health information that is not secured through the use of a technology or methodology specified by the Secretary in guidance” and provides that the guidance specify the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. Covered entities and business associates that implement the specified technologies and methodologies with respect to protected health information are not required to provide notifications in the event of a breach of such information— that is, the information is not considered “unsecured” in such cases.

The security or privacy of the PHI is “compromised” when the inappropriate acquisition, access, use or disclosure pose a significant risk of financial, reputational or other harm to the individual. A breach is “discovered” when the breach is known to the covered entity or its business associate, the breach is known to any employee or agent of the covered entity or business associate, other than the individual who committed the breach, or the covered entity, business associate, employee or agent should have known about the breach.

The HHS interim final regulations are effective September 23, 2009, and include a 60-day public comment period. To review the Interim Final Regulations online, go to: <http://edocket.access.gpo.gov/2009/pdf/E9-20169.pdf>

To offer public comment on the Interim Final Regulations, submit your comments, identified by RIN 0991-AB56, by any of the following methods:

* Federal eRulemaking Portal:
<http://www.regulations.gov>.

* Regular, Express, or Overnight Mail (Submit one original and two copies) U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HITECH Breach Notification, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW. Washington, DC 20201. ☺

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factors change over the next 3-5 years? A majority of the underwriters feel the trend rates will increase, as shown below:

Trend rates will moderately decrease	14.3%
Trend rates will stay about the same	21.4%
Trend rates will moderately increase	50.0%
Trend rates will significantly increase	14.3%

The state of the current economy has both positive and negative effects on medical and drug trends. It has increased preference and utilization of generic drugs. However, many employers are worried workers who have not lost their jobs, but are fearful of losing them, will use more services while they are still covered.

As mentioned above, trends are either remaining relatively steady or even decreasing for both medical and pharmacy costs. Nevertheless, these trends are still outpacing both inflation and increases in labor costs. According to The Segal Group, the good news is that many plan sponsors are seeing actual trend rates which are less than the projected. They

theorize that these companies most likely practice “aggressive cost management” in order to produce these better than expected trend rates.

The legislation proposed by the Obama administration, if and when passed, will have an impact on medical and pharmacy trends. However, the content of the legislation will determine whether the effect will be positive or negative. Either way, the effects will not be seen until 2011 or later.

For additional trend reports and resources, contact Cory Smith at csmith@ehpco.com or 614.336.2883. ☺

	CVS Caremark		Express Scripts		Medco		Walgreens	
	2009	2010	2009	2010	2009	2010	2009	2010
Traditional	5.5%-8.5%	6.5%-9.5%	2.2%	2.8%	N/A	N/A	N/A	N/A
Specialty	12.0%-22.0%	14.0%-24.0%	15.2%	17.7%	N/A	N/A	N/A	N/A
Overall	6.5%-9.5%	7.5%-10.5%	N/A	N/A	6%-9%	6%-9%	5.0%-6.5%	4.0%-6.0%

Traditional drug, specialty drug, and overall pharmacy trend projections for 2009 and 2010.

Thank You to 2009 Contributor Members

Employers Health would like to thank its Contributor Members for 2009. Employers Health members benefit from the support that these Contributors provide the Coalition, and it is our hope that their support is noticed by our members when seeking solutions that each provide. Thank you to the following Contributor Members for your support in 2009:

- Abbott Laboratories
- Akron Children's Hospital
- Anthem Blue Cross & Blue Shield
- Aultman Health Foundation
- Bayer HealthCare Pharmaceuticals
- Bellevue Hospital
- Boehringer Ingelheim Pharmaceuticals
- Business Benefits of Ohio
- CBIZ Benefits & Insurance Services of Ohio
- Cleveland Clinic
- Compensation Prog. of Ohio, Inc.
- Enterprise Group Planning
- Findley Davies
- Leonard Insurance Services
- Medical Mutual of Ohio
- Mercy Medical Center
- Mike Sessor Agency
- Ohio Health Choice
- Ritzman Pharmacies
- Roche Laboratories, Inc.
- Sepracor, Inc.
- St Vincent Charity Hospital
- SummaCare Health Plans
- The Segal Co.
- Towers Perrin
- United Healthcare
- Wyeth Pharmaceuticals

Contributor membership is \$1,000 per year. If your organization is interested in becoming a contributor member, please contact Mike Stull at mstull@ehpco.com

Increased Growth of Specialty Drugs



BY CHARITY RAUSCH, RPH



Employers are confronting a challenge in the form of expensive specialty drugs that are being prescribed for a growing list of health conditions. Unlike traditional medications, most specialty drugs do not have generic equivalents or substitutes that offer opportunities to manage drug costs.

What is a specialty drug?

Specialty drugs are developed from human proteins and DNA research, using biotechnology engineering and research techniques, such as monoclonal antibody and recombinant DNA technologies. Specialty drugs are targeted to treat disease at the cellular level.

Specialty drugs offer new treatments and cures for previously untreatable or hard to manage conditions, such as multiple sclerosis, blood disorders (e.g., hemophilia), rheumatoid arthritis, and many forms of cancers. When these drugs successfully treat plan participants

who have these conditions, they improve quality of life, potentially lower employers' medical and disability plan costs. This treatment of these drugs can enable employees to return to or stay at work.

Why are they so expensive?

Specialty drugs are expensive to produce, store and administer, and manufacturers pass their costs on to payers and group health plan participants. On average, employer costs for specialty drugs run \$18,000 per patient per year, compared to \$550 for traditional medications. Also, unlike traditional medications, specialty drugs are usually administered via injection by a nurse, adding to the overall cost.

Specialty drugs have less of a chance to have generic alternatives approved by the FDA. Biologics are genetically engineered proteins and are more difficult to manufacture. The FDA does not currently have a regulatory framework to quickly approve biologic generics, although this is expected to change in the next few years. Even when generics are created, they too can be expensive; sometimes the difference in price is only 30 percent, compared to non-specialty generics, which

are typically 60 to 90 percent less than their brand-name counterparts. However, there is still a huge savings opportunity for generic biologics as many specialty drugs currently on the market have already lost patent protection.

How to manage specialty drug?

Offering benefits for specialty products comes at a high price for the employer. The average per-prescription cost of specialty drugs is approximately \$1,500 monthly per drug, although the monthly cost can range from about \$1,000 to more than \$20,000, depending on the drug. Typically, these patients also use an average of 12 additional different drugs per year, compared with an average of five prescription drugs per year used by non-specialty drug patients. Annual specialty drug trend for 2005 was 17 percent, compared with an average of 6 percent to 8 percent for traditional drugs. In 2006, specialty drug trend climbed to 21 percent, compared with 6 percent for non-specialty drugs.

The pipeline of specialty drugs under development is robust and continues to grow. More than 400 specialty drugs and vaccines are currently in development, with many expected to enter the U.S. marketplace in the next several years. With so many drugs in development, the annual specialty drug trend is anticipated to soon reach 25 percent or higher.


Steps an employer can take to reduce specialty costs:

- Utilize a care management program to reduce costs. This type of program will ensure the drug is being properly dispensed for the appropriate condition and dosage, educate patient on usage and side effects, and improve adherence to achieve maximum therapeutic benefit.
- Compare, contrast and benchmark the pricing terms under your health plan versus your PBM contracts. While health plans may inconsistently apply discounting rules to claims, PBMs generally apply negotiated discounts at the NDC level to every claim.
- Decide what level of benefit you can provide. Look at your copayment or coinsurance-based on your formulary and design your program to meet budgeted cost targets. In addition, you should evaluate the advantages and disadvantages of specialty pharmacy distribution channels compared to retail pharmacy channels.
- Limiting supplies to 30 days per co-pay can reduce waste due to changes in dosing or side effects. Using specialty pharmacies helps to control the distribution of specialty drugs to

provide high-touch clinical management of the patient, including counseling and training on the use of the medication, as well as better pricing and enhanced reporting.

References

V. J. Willey, M. F. Pollack, W. M. Lednar, W. N. Yang, C. Kennedy, and G. Lawless. Costs Of Severely Ill Members And Specialty Medication Use In A Commercially Insured Population. *Health Aff.* May 1, 2008; 27(3): 824 - 834.

D. P. Goldman, G. F. Joyce, and Y. Zheng. Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health. *JAMA*, July 4, 2007; 298(1): 61 - 69. 

Employers Health Staff Participate in Local and National Presentations & Programs

Bruce Sherman


- Integration of On-Site Medical Clinics with the Patient-Centered Medical Home. Congress on On-Site Employee Health Clinics. Las Vegas, NV, 2009.
- Consensus Workshop and Presentation of Findings – Quantifying Return on Investment for Worksite Healthcare Services. Maximizing ROI of On-Site Employee Health Clinics. Chicago, IL, 2009.
- The Medical Home & Its Application to Onsite Clinics. Midwest Business Group on Health. Chicago, IL, 2009.
- Appointed to Board of Advisors – Center for Health Value Innovation.

Mike Stull

- PBM 201, FrontPath Health Coalition, July, 2009.
- Health Benefits Trends & Strategies , Akron Area SHRM, September, 2009.

David Uldricks

- Appointed to Payment Reform Task Force that is serving under the Health Care Coverage and Quality Council - convened by executive order of Governor Strickland.



In moderate to severe Alzheimer's disease

Recognize the value of treatment with NAMENDA

NAMENDA delivers proven efficacy and may reduce total healthcare costs¹⁻⁵

Patients with Alzheimer's disease are complex and present unique challenges to managed care organizations

The proven efficacy of NAMENDA can help you meet these challenges

Comorbid conditions, such as congestive heart failure and diabetes, are more common and more expensive to manage in patients with Alzheimer's disease⁶

NAMENDA treatment benefits in cognition and function could reduce the costs of comorbid conditions^{1-3,6}

Behavioral issues are a major contributor to increased costs in Alzheimer's disease⁷

NAMENDA improves behavior and delays the onset of behavioral symptoms in combination with an acetylcholinesterase inhibitor (AChEI)^{1,4}

Patients with Alzheimer's disease who received NAMENDA demonstrated reduced total healthcare costs⁵

The value of treatment with NAMENDA

- Unique mechanism of action—in a class of its own⁸⁻¹³
- Efficacy in cognition and function, alone or in combination with an AChEI^{1,3}
- Efficacy in behavior in combination with an AChEI^{1,4}
- Proven safety and tolerability may lead to therapy persistence^{5,8,14}

Namenda
memantine HCl



Extending memory and function

NAMENDA® (memantine HCl) is indicated for the treatment of moderate to severe Alzheimer's disease.

NAMENDA is contraindicated in patients with known hypersensitivity to memantine HCl or any excipients used in the formulation. The most common adverse events reported with NAMENDA vs placebo ($\geq 5\%$ and higher than placebo) were dizziness, confusion, headache, and constipation. In patients with severe renal impairment, the dosage should be reduced.

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For more details, please visit www.namenda.com. Please see brief summary of Prescribing Information on the adjacent page.

62-1014307M R2

03/09

Namenda

memantine HCl



Tablets/Oral Solution

Rx Only

Brief Summary of Prescribing Information.

For complete details, please see full Prescribing Information for Namenda.

INDICATIONS AND USAGE

Namenda (memantine hydrochloride) is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

CONTRAINDICATIONS

Namenda (memantine hydrochloride) is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation.

PRECAUTIONS

Information for Patients and Caregivers: Caregivers should be instructed in the recommended administration (twice per day for doses above 5 mg) and dose escalation (minimum interval of one week between dose increases).

Neurological Conditions

Seizures: Namenda has not been systematically evaluated in patients with a seizure disorder. In clinical trials of Namenda, seizures occurred in 0.2% of patients treated with Namenda and 0.5% of patients treated with placebo.

Genitourinary Conditions

Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine.

Special Populations

Hepatic Impairment

Namenda undergoes partial hepatic metabolism, with about 48% of administered dose excreted in urine as unchanged drug or as the sum of parent drug and the N-glucuronide conjugate (74%). No dosage adjustment is needed in patients with mild or moderate hepatic impairment. Namenda should be administered with caution to patients with severe hepatic impairment.

Renal Impairment

No dosage adjustment is needed in patients with mild or moderate renal impairment. A dosage reduction is recommended in patients with severe renal impairment (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION in Full Prescribing Information).

Drug-Drug Interactions

N-methyl-D-aspartate (NMDA) antagonists: The combined use of Namenda with other NMDA antagonists (amantadine, ketamine, and dextromethorphan) has not been systematically evaluated and such use should be approached with caution.

Effects of Namenda on substrates of microsomal enzymes: *In vitro* studies conducted with marker substrates of CYP450 enzymes (CYP1A2, -2A6, -2C9, -2D6, -2E1, -3A4) showed minimal inhibition of these enzymes by memantine. In addition, *in vitro* studies indicate that at concentrations exceeding those associated with efficacy, memantine does not induce the cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2E1, and CYP3A4/5. No pharmacokinetic interactions with drugs metabolized by these enzymes are expected.

Effects of inhibitors and/or substrates of microsomal enzymes on Namenda: Memantine is predominantly renally eliminated, and drugs that are substrates and/or inhibitors of the CYP450 system are not expected to alter the metabolism of memantine.

Acetylcholinesterase (AChE) inhibitors: Coadministration of Namenda with the AChE inhibitor donepezil HCl did not affect the pharmacokinetics of either compound. In a 24-week controlled clinical study in patients with moderate to severe Alzheimer's disease, the adverse event profile observed with a combination of memantine and donepezil was similar to that of donepezil alone.

Drugs eliminated via renal mechanisms: Because memantine is eliminated in part by tubular secretion, coadministration of drugs that use the same renal cationic system, including hydrochlorothiazide (HCTZ), triamterene (TA), metformin, cimetidine, ranitidine, quinidine, and nicotine, could potentially result in altered plasma levels of both agents. However, coadministration of Namenda and HCTZ/TA did not affect the bioavailability of either memantine or TA, and the bioavailability of HCTZ decreased by 20%. In addition, coadministration of memantine with the antihyperglycemic drug Glucovance® (glyburide and metformin HCl) did not affect the pharmacokinetics of memantine, metformin and glyburide. Furthermore, memantine did not modify the serum glucose lowering effect of Glucovance®.

Drugs that make the urine alkaline: The clearance of memantine was reduced by about 80% under alkaline urine conditions at pH 8. Therefore, alterations of urine pH towards the alkaline condition may lead to an accumulation of the drug with a possible increase in adverse effects. Urine pH is altered by diet, drugs (e.g. carbonic anhydrase inhibitors, sodium bicarbonate) and clinical state of the patient (e.g. renal tubular acidosis or severe infections of the urinary tract). Hence, memantine should be used with caution under these conditions.

Carcinogenesis, Mutagenesis and Impairment of Fertility

There was no evidence of carcinogenicity in a 113-week oral study in mice at doses up to 40 mg/kg/day (10 times the maximum recommended human dose [MRHD] on a mg/m² basis). There was also no evidence of carcinogenicity in rats orally dosed at up to 40 mg/kg/day for 71 weeks followed by 20 mg/kg/day (20 and 10 times the MRHD on a mg/m² basis, respectively) through 128 weeks.

Memantine produced no evidence of genotoxic potential when evaluated in the *in vitro* S. typhimurium or E. coli reverse mutation assay, an *in vitro* chromosomal aberration test in human lymphocytes, an *in vivo* cytogenetics assay for chromosome damage in rats, and the *in vivo* mouse micronucleus assay. The results were equivalent in an *in vitro* gene mutation assay using Chinese hamster V79 cells.

No impairment of fertility or reproductive performance was seen in rats administered up to 18 mg/kg/day (9 times the MRHD on a mg/m² basis) orally from 14 days prior to mating through gestation and lactation in females, or for 60 days prior to mating in males.

Pregnancy

Pregnancy Category B: Memantine given orally to pregnant rats and pregnant rabbits during the period of organogenesis was not teratogenic up to the highest doses tested (18 mg/kg/day in rats and 30 mg/kg/day in rabbits, which are 9 and 30 times, respectively, the maximum recommended human dose [MRHD] on a mg/m² basis).

Slight maternal toxicity, decreased pup weights and an increased incidence of non-ossified cervical vertebrae were seen at an oral dose of 18 mg/kg/day in a study in which rats were given oral memantine beginning pre-mating and continuing through the postpartum period. Slight maternal toxicity and decreased pup weights were also seen at this dose in a study in which rats were treated from day 15 of gestation through the post-partum period. The no-effect dose for these effects was 6 mg/kg, which is 3 times the MRHD on a mg/m² basis.

There are no adequate and well-controlled studies of memantine in pregnant women. Memantine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether memantine is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when memantine is administered to a nursing mother.

Pediatric Use

There are no adequate and well-controlled trials documenting the safety and efficacy of memantine in any illness occurring in children.

ADVERSE REACTIONS

The experience described in this section derives from studies in patients with Alzheimer's disease and vascular dementia.

Adverse Events Leading to Discontinuation: In placebo-controlled trials in which dementia patients received doses of Namenda up to 20 mg/day, the likelihood of discontinuation because of an adverse event was the same in the Namenda group as in the placebo group. No individual adverse event was associated with the discontinuation of treatment in 1% or more of Namenda-treated patients and at a rate greater than placebo.

Adverse Events Reported in Controlled Trials: The reported adverse events in Namenda (memantine hydrochloride) trials reflect experience gained under closely monitored conditions in a highly selected patient population. In actual practice or in other clinical trials, these frequency estimates may not apply, as the conditions of use, reporting behavior and the types of patients treated may differ. Table 1 lists treatment-emergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled dementia trials and for which the rate of occurrence was greater for patients treated with Namenda than for those treated with placebo. No adverse event occurred at a frequency of at least 5% and twice the placebo rate.

Table 1: Adverse Events Reported in Controlled Clinical Trials in at Least 2% of Patients Receiving Namenda and at a Higher Frequency than Placebo-treated Patients.

Body System Adverse Event	Placebo (N = 922) %	Namenda (N = 940) %
Body as a Whole		
Fatigue	1	2
Pain	1	3
Cardiovascular System		
Hypertension	2	4
Central and Peripheral Nervous System		
Dizziness	5	7
Headache	3	6
Gastrointestinal System		
Constipation	3	5
Vomiting	2	3
Musculoskeletal System		
Back pain	2	3
Psychiatric Disorders		
Confusion	5	6
Somnolence	2	3
Hallucination	2	3
Respiratory System		
Coughing	3	4
Dyspnea	1	2

Other adverse events occurring with an incidence of at least 2% in Namenda-treated patients but at a greater or equal rate on placebo were agitation, fall, inflated injury, urinary incontinence, diarrhea, bronchitis, insomnia, urinary tract infection, influenza-like symptoms, abnormal gait, depression, upper respiratory tract infection, anxiety, peripheral edema, nausea, anorexia, and arthralgia.

The overall profile of adverse events and the incidence rates for individual adverse events in the subpopulation of patients with moderate to severe Alzheimer's disease were not different from the profile and incidence rates described above for the overall dementia population.

Vital Sign Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, diastolic blood pressure, and weight) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. There were no clinically important changes in vital signs in patients treated with Namenda. A comparison of supine and standing vital sign measures for Namenda and placebo in elderly normal subjects indicated that Namenda treatment is not associated with orthostatic changes.

Laboratory Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Namenda treatment.

ECG Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in ECG parameters associated with Namenda treatment.

Other Adverse Events Observed During Clinical Trials

Namenda has been administered to approximately 1350 patients with dementia, of whom more than 1200 received the maximum recommended dose of 20 mg/day. Patients received Namenda treatment for periods of up to 884 days, with 862 patients receiving at least 24 weeks of treatment and 387 patients receiving 48 weeks or more of treatment.

Treatment emergent signs and symptoms that occurred during 8 controlled clinical trials and 4 open-label trials were recorded as adverse events by the clinical investigators using terminology of their own choosing. To provide an overall estimate of the proportion of individuals having similar types of events, the events were grouped into a smaller number of standardized

categories using WHO terminology, and event frequencies were calculated across all studies.

All adverse events occurring in at least two patients are included, except for those already listed in Table 1, WHO terms too general to be informative, minor symptoms or events unlikely to be drug-caused, e.g., because they are common in the study population. Events are classified by body system and listed using the following definitions: frequent adverse events - those occurring in at least 1/100 patients; infrequent adverse events - those occurring in 1/100 to 1/1000 patients. These adverse events are not necessarily related to Namenda treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies.

Body as a Whole: *Frequent:* syncope. *Infrequent:* hypothermia, allergic reaction.

Cardiovascular System: *Frequent:* cardiac failure. *Infrequent:* angina pectoris, bradycardia, myocardial infarction, thrombophlebitis, atrial fibrillation, hypotension, cardiac arrest, postural hypotension, pulmonary embolism, pulmonary edema.

Central and Peripheral Nervous System: *Frequent:* transient ischemic attack, cerebrovascular accident, vertigo, ataxia, hypokinesia. *Infrequent:* paresthesia, convulsions, extrapyramidal disorder, hypertonia, tremor, aphasia, hypoesthesia, abnormal coordination, hemiplegia, hyperkinesia, involuntary muscle contractions, stupor, cerebral hemorrhage, neuralgia, ptosis, neuropathy.

Gastrointestinal System: *Infrequent:* gastroenteritis, diverticulitis, gastrointestinal hemorrhage, melena, esophageal ulceration.

Hemic and Lymphatic Disorders: *Frequent:* anemia. *Infrequent:* leukopenia.

Metabolic and Nutritional Disorders: *Frequent:* increased alkaline phosphatase, decreased weight. *Infrequent:* dehydration, hyponatremia, aggravated diabetes mellitus.

Psychiatric Disorders: *Frequent:* aggressive reaction. *Infrequent:* delusion, personality disorder, emotional lability, nervousness, sleep disorder, libido increased, psychosis, amnesia, apathy, paranoid reaction, thinking abnormal, crying abnormal, appetite increased, paranoia, delirium, depersonalization, neurosis, suicide attempt.

Respiratory System: *Frequent:* pneumonia. *Infrequent:* apnea, asthma, hemoptysis.

Skin and Appendages: *Frequent:* rash. *Infrequent:* skin ulceration, pruritus, cellulitis, eczema, dermatitis, erythematous rash, alopecia, urticaria.

Special Senses: *Frequent:* cataract, conjunctivitis. *Infrequent:* macula lutea degeneration, decreased visual acuity, decreased hearing, tinnitus, blepharitis, blurred vision, corneal opacity, glaucoma, conjunctival hemorrhage, eye pain, retinal hemorrhage, xerophthalmia, diplopia, abnormal lacrimation, myopia, retinal detachment.

Urinary System: *Frequent:* frequent micturition. *Infrequent:* dysuria, hematuria, urinary retention.

Events Reported Subsequent to the Marketing of Namenda, both US and Ex-US

Although no causal relationship to memantine treatment has been found, the following adverse events have been reported to be temporally associated with memantine treatment and are not described elsewhere in labeling: aspiration pneumonia, asthma, atrioventricular block, bone fracture, carpal tunnel syndrome, cerebral infarction, chest pain, cholelithiasis, claudication, colitis, deep venous thrombosis, depressed level of consciousness (including loss of consciousness and rare reports of coma), dyskinesia, dysphagia, encephalopathy, gastritis, gastroesophageal reflux, grand mal convulsions, intracranial hemorrhage, hepatitis (including increased ALT and AST and hepatic failure), hyperglycemia, hyperlipidemia, hypoglycemia, ileus, increased INR, impotence, lethargy, malaise, myoclonus, neuroleptic malignant syndrome, acute pancreatitis, Parkinsonism, acute renal failure (including increased creatinine and renal insufficiency), prolonged QT interval, restlessness, sepsis, Stevens-Johnson syndrome, suicidal ideation, sudden death, supraventricular tachycardia, tachycardia, tardive dyskinesia, thrombocytopenia, and hallucinations (both visual and auditory).

ANIMAL TOXICOLOGY

Memantine induced neuronal lesions (vacuolation and necrosis) in the multipolar and pyramidal cells in cortical layers III and IV of the posterior cingulate and retrosplenial neocortices in rats, similar to those which are known to occur in rodents administered other NMDA receptor antagonists. Lesions were seen after a single dose of memantine. In a study in which rats were given daily oral doses of memantine for 14 days, the no-effect dose for neuronal necrosis was 6 times the maximum recommended human dose on a mg/m² basis. The potential for induction of central neuronal vacuolation and necrosis by NMDA receptor antagonists in humans is unknown.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: Memantine HCl is not a controlled substance.

Physical and Psychological Dependence: Memantine HCl is a low to moderate affinity uncompetitive NMDA antagonist that did not produce any evidence of drug-seeking behavior or withdrawal symptoms upon discontinuation in 2,504 patients who participated in clinical trials at therapeutic doses. Post marketing data, outside the U.S., retrospectively collected, has provided no evidence of drug abuse or dependence.

OVERDOSAGE

Signs and symptoms associated with memantine overdosage in clinical trials and from worldwide marketing experience include agitation, confusion, ECG changes, loss of consciousness, psychosis, restlessness, slowed movement, somnolence, stupor, unsteady gait, visual hallucinations, vomiting, and weakness. The largest known ingestion of memantine worldwide was 2.0 grams in a patient who took memantine in conjunction with unspecified antidiabetic medications. The patient experienced coma, diplopia, and agitation, but subsequently recovered. Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control center to determine the latest recommendations for the management of an overdose of any drug. As in any cases of overdose, general supportive measures should be utilized, and treatment should be symptomatic. Elimination of memantine can be enhanced by acidification of urine.

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Rev. 04/07

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Marcas Miles, Editor

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