Rochester Regional Health Information Organization

The Rochester Regional Health Information Organization (RHIO) has received a $4.4 million grant as part of the New York State Health Information Technology (HIT) initiative.

The Rochester RHIO, led by a collaborative group of representatives from businesses, insurance plans and health care systems, will develop a community-wide platform for the collection, analysis and dissemination of health care information through a high-security electronic network. The goals of the RHIO are to encourage increased use of electronic medical records, prevent duplication of services, reduce medical errors and provide important public health statistics reporting capabilities.

“Developing a RHIO is a major step forward in improving the efficiency and the effectiveness of health care in Rochester,” said Martin Hickey, MD, senior vice-president of Health Care Affairs for Excellus BlueCross BlueShield. “Having access to the latest information available helps doctors make faster and better diagnoses. Patients don’t have to undergo duplicative tests, scans and imagining. And in the end, employers would see their increases in health care cost mitigated through improved efficiency.”

The Rochester RHIO is one of 26 regional health care networks throughout the state to receive the grant funding. Statewide, the HIT grant awards total $52.9 million.

Over time, RHIOs throughout the state, and eventually throughout the country, are expected to develop and evolve into a nationally-standardized and integrated health information network.

Stay tuned for more details about the RHIO as they become available.
Talk to your patients about generic drugs. They’re safe, effective and affordable.

Prenatal Billing Reminder
Please remember to bill using the units field whenever applicable. Recently, we have received a number of bills that have been incorrectly submitted for procedure codes 59425 (Antepartum care only; 4-6 visits) and 59426 (7 or more visits – prenatal). Without the necessary information regarding the number of visits in the units field, it is difficult to accurately assess copayment responsibilities for your patients. Please be sure to include complete information when submitting bills for these services.

Confidentiality Reminder
Excellus BCBS would like to ask that provider staff regularly review standards for confidentiality in practitioner offices and health-related facilities. The Health Insurance Portability and Accountability Act (HIPAA) stresses the importance of confidentiality relating to personal health information. Any information regarding an individual’s identity or health status must be protected from unauthorized access.

Please stress the importance of using any information obtained through the Excellus BCBS Web site or QuickLink inquiry system for business purposes only. Accessing information about friends or relatives for personal reasons is in direct violation of HIPAA regulations – whether or not authorization has been given to obtain the information.

We appreciate your efforts to help protect the privacy of our members, your patients, as the health care industry continues its evolution toward increased use of electronic information systems.

Timely Filing Limit for Facility and Ancillary Claims
We are focusing on opportunities to make our business processes more consistent for our participating providers. As part of this effort, we have reviewed the timely filing limits coded into each claims system and determined that there were differences in how we processed claims across the Health Plan. Therefore, moving forward, you will begin to see the timely filing processing handled in a uniform manner according to the timely filing limits of your provider contract. As most claims are currently filed well within your timely filing agreement, we anticipate that our changes will have minimal impact.

Claims Processing for Childhood Vaccines
In response to a recent mandate from the New York State Insurance Department, we will now process claims and apply benefits for childhood vaccines as recommended by the Advisory Council on Immunization Practices (ACIP) and published in the Morbidity and Mortality Weekly Report (MMWR).

Prior to the Insurance Department’s mandate, we waited for the official recommendation of the American Academy of Pediatrics (AAP) before announcing our coverage decision.

Currently, the rotavirus vaccine, Rotateq™, is impacted by this mandate. In the May issue of this newsletter, we indicated that the Rotateq vaccine would not be covered until the AAP made its official recommendation. However, because the Rotateq vaccine has been recommended by the ACIP, claims for this vaccine will be processed for auto-payment following publication of the ACIP’s recommendation in the MMWR.
Sterilization/Hysterectomy Claims for FHP, Blue Choice Option Members

This is just a reminder that sterilization and hysterectomy claims for members with Family Health Plus or Blue Choice Option require a signed consent form. Claims related to these procedures must be accompanied by form LDSS-3113 Acknowledgement of Receipt of Hysterectomy Information or LDSS-3134 Sterilization Consent Form signed by the patient and the attending physician at least 30 days but not more than 180 days prior to the procedure.

Claims that are not accompanied by the consent form will be denied.

Physicians, nurse practitioners and midwives may request copies of these forms by completing the Request for Forms or Publications that is included in this newsletter. It should be mailed or faxed directly to the New York State Department of Health using the contact information provided on the form.

Medicare Advantage Reviews

The Medicare Division will be conducting an ICD-9-CM coding validation review of claims submitted by physicians who participate in Medicare Advantage plans. The plans include Medicare Blue Choice (formally known as Medicare + Choice), Medicare Blue PPO and Blue Choice Senior.

Reviews will involve either a request for medical record documentation or an onsite visit. The code review will help demonstrate compliance with CMS regulations and educate providers and their staff on the Medicare Risk Adjustment Model. The model relies on ICD-9-CM diagnosis codes to prospectively reflect the health status of Medicare Advantage beneficiaries. Reviewers will focus on complete and accurate diagnosis reporting according to the official ICD-9-CM coding guidelines. Our credentialed medical coding specialists are available to answer any questions you may have. Your cooperation is greatly appreciated during this review process.

The Quit For Life™ Program

Quit For Life is a scientifically based and proven program established on 20 years of published research and clinical experience.

This award-winning tobacco cessation program can help your patients quit TODAY.

When your patients enroll in the Quit For Life Program they will receive:
  · One-on-one phone sessions scheduled at their convenience
  · Toll-free access to Quit Coaches seven days a week
  · Medication recommendations, if appropriate
  · Free nicotine replacement products (patch or gum) and delivery to their home, if recommended
  · A “Quit Guide” to help them stay on track between phone sessions

The Quit For Life Program is FREE to all eligible members 18 years or older. Your patients may call 1 (800) 442-8904 to get started, or to determine the best treatment option available to meet their needs.
Freestanding Urgent Care Centers

In addition to the Lifetime Health AfterHours centers (see last month’s newsletter), there are a number of other urgent care centers in the area:

Alton B. Corbit Immediate Care Center
1160 Corporate Drive
Farmington, NY 14425
(585) 924-1510

Greater Rochester Orthopaedic
After Hours Urgent Care Center
Linden Oaks Campus
30 Hagen Drive, Suite 220
Rochester, NY 14625
(585) 295-5300

University Orthopaedic Associates
4901 Lac de Ville Boulevard
Rochester, NY 14618
(585) 275-5321 (days)
(585) 341-9252 (eves)

Livingston Health Services
50 East South Street, Route 20A
Geneseo, NY 14454
(585) 243-9230

Unity Health Walk-in Care Center
89 Genesee Street
Rochester, NY 14611
(585) 368-3050

Eastside Medical Urgent Care Center
2060 Fairport Nine Mile Point Road
Penfield, NY 14526
(585) 388-5280
Medical Policy Update – July 2006

To ensure that the development of corporate medical policies occurs through an open, collaborative process, we encourage our participating practitioners to become actively involved in medical policy development. Each month, draft policies are posted in the Provider section of our Web site (www.excellusbcbs.com) for participating practitioners’ review and comment. Click on For Providers, then Medical Policies. Next, click on Preview & Comment on Draft Policies located at the bottom of the menu on the left side under Medical Policies. The following policies are tentatively scheduled to be available for comment in July 2006:

- Bone Density Testing
- Hyperbaric Oxygen Pressurization
- Immunizations
- Implantable Cardioverter Defibrillator
- Isolated Limb Perfusion
- MAZE Procedures for Atrial Fibrillation
- Posterior Spinal Traction Device-XSTOP® (new)
- Serum Tumor Markers for the Diagnosis and Management of Cancer
- Wireless Capsule Endoscopy

Corporate medical policies are used as a guide. Coverage decisions are made on a case-by-case basis and in accordance with the member's contract. While a technology or service may be medically necessary, payment of benefits is subject to the member's eligibility on the date the service is rendered and the benefit/exclusion provisions in the member's contract. Before rendering care, providers should verify the member's eligibility for the service by calling the Provider Service Department of your local plan.

The following new and updated medical policies have been reviewed and approved by the Corporate Medical Policy Committee, including practitioner representatives from Excellus BlueCross BlueShield, Central New York Region, Central New York Southern Tier Region, Utica Region, and Rochester Region.

Complete detailed policies are available on our Web site at www.excellusbcbs.com. Click on the For Providers menu option, then on View Our Medical Policies. Questions regarding medical policies may be directed to your Provider Relations Representative or to the Provider Service Department of your local health plan.

Medical policies are also located on the Web site for Excellus BlueCross BlueShield members at www.excellusbcbs.com. To access our policies, members need to click on For Members, followed by Health and Wellness, then Research Health Conditions and lastly View our Medical Policies.

Medical policies and protocols apply to commercial and Medicaid products only when a contract benefit for the specific service exists. Excellus BCBS medical policies/protocols only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service. A brief description of CMS coverage has also been provided for Excellus BlueCross BlueShield medical policies at the end of each medical policy if a CMS coverage determination exists. Please refer to the Centers for Medicare & Medicaid Services (CMS) for medical policies pertaining to Medicare contracts. Web sites for review of CMS policies are:

Please note: Although medical policies are effective on the date they are approved by the Medical Policy Committee, updates to the claims processing systems may not occur for up to 90 days.

NEW POLICIES recently approved by Corporate Medical Policy Committee

There were none this reporting period.

CURRENT POLICIES recently updated by Corporate Medical Policy Committee

Endovascular Grafts for Abdominal and Thoracic Aortic Aneurysms

Aneurysms have been investigated as less invasive, catheter-based alternatives to open surgical excision of thoracic and abdominal aortic aneurysms. Endovascular repair of an AAA, using a FDA approved endoprosthesis, is medically appropriate for:

- Patients with aneurysms measuring 5 cm or greater in diameter;
- Women or small individuals, with aneurysms measuring twice the diameter of the normal aorta at the infrarenal neck;
- Individuals in whom an enlarging aneurysm is symptomatic, or greater than 4 cm in diameter and has increased in size by 0.5 cm in the last 6 months; or
- Patients with a ruptured or suspected ruptured abdominal aortic aneurysm.

Based upon our criteria and assessment of peer-reviewed literature, endovascular repair of descending thoracic aortic aneurysms with a FDA-approved endoprosthesis is considered a medically appropriate option.

Based upon our criteria and assessment of peer-reviewed literature, the placement of endovascular grafts in patients with a previous AAA repair or tortuosity of access vessels has not been proven to be medically effective and is considered investigational.

Genetic Testing for Specific Diseases is considered medically appropriate when the following situations exist:

- Offered in a setting with adequately trained health care professionals to provide appropriate pre- and post-test counseling and performed by a qualified laboratory;
- The patient’s family history indicates a significant risk for a genetic defect for which therapeutic measures, instituted as a result of knowledge of a particular defect, can prevent or mitigate future morbidity; or
- Symptomatic patients who may have genetic disease or asymptomatic individuals who may have genetic disease or strong family history of genetic disease where early diagnosis is important;
- There must be reasonable expectation based on family history, pedigree analysis, risk factors, and/or symptomatology that a genetically inherited condition exists. Autosomal recessive disorders may be present without a family history;
- The genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of the disease, and the analytical and clinical validity of the test must be established;
- The clinical utility of the test must be established, i.e. test results will influence decisions concerning disease treatment or prevention.

This policy is to be utilized ONLY when disease or condition-specific policies for genetic testing do not exist.

Lung Volume Reduction Surgery is a general term encompassing a variety of surgical procedures that are offered to alleviate the symptoms of advanced chronic lung disease due to emphysema. Evidence exists that LVRS provides clinically significant improvement in symptoms in a subset of patients with severe emphysema. Therefore, lung volume reduction surgery is considered medically appropriate when the specific criteria in the policy are met.

Plasmapheresis, Plasma Exchange and Apheresis are terms used interchangeably, but are actually different technologies. Apheresis is a general term describing the removal of blood from a subject. A portion of the blood is separated and retained while the rest is returned to the donor. The most common form of apheresis is plasmapheresis, which involves the extraction of plasma from withdrawn blood followed by re-transfusion of the formed elements into the donor. Plasma exchange (PE) is frequently done in conjunction with plasmapheresis. The plasma is isolated, then discarded and replaced with a substitution fluid such as albumin. Plasmapheresis and plasma exchange are considered medically appropriate for the following conditions which
include, but are not limited to, myasthenia gravis in crisis, hyperviscosity syndromes associated with multiple myeloma or Waldenström's macroglobulinemia, and thrombotic thrombocytopenic purpura (TTP). LDL apheresis (low-density lipoprotein apheresis) describes a technology used to acutely remove low-density lipoprotein (LDL) from the plasma. This year’s update has expanded the medically appropriate indications to include the use of plasmapheresis in the transplant setting, as a treatment prior to solid organ transplant for patients at high risk for antibody mediated rejection or following transplant as a treatment for antibody mediated rejection. LDL (low-density lipoprotein) apheresis has been medically proven to be an effective treatment option and therefore medically appropriate for severely hypercholesteremic patients as outlined within the medical policy.

CURRENT POLICIES recently updated with minimal changes

The following policies required only minimal changes (e.g., updating of references, changing language to meet legal needs). The coverage intent of the policies was not altered. These policies were recently approved for updating by the Health Plan Medical Directors and are available on our Web site.

- Automated Ambulatory Blood Pressure Monitoring
- Brachytherapy or Radioactive Seed Implants for Prostate Cancer
- Corneal Ultrasound Pachymetry
- Endoscopic Injection of Bulking Agents for Vesicoureteral Reflux
- Hyperthermia
- Intradiscal Electrothermotherapy (IDET)
- Magnetic Resonance Spectroscopy (MRS)
- Percutaneous Vertebroplasty/Kyphoplasty
- Photodynamic Therapy for Subfoveal Choroidal Neovascularization
- Signal-averaged Electrocardiogram (SAECG)
- Spinal Cord Stimulation
- Transmyocardial Revascularization (TMR)
- Transrectal Ultrasound (TRUS)
- Vacuum Assisted Wound Therapy

Deleted Medical Policies

The following medical policies have been transitioned to the Health Plan’s Pharmacy Department (FLRx) for future updating.

- Gonadotropin Releasing Hormone Analogs

NEW PROTOCOLS recently approved by Corporate Protocol Committee

There were none this reporting period.

CURRENT PROTOCOLS recently updated by Corporate Protocol Committee

There were none this reporting period.

CURRENT PROTOCOLS recently updated with minimal changes

The following protocols required only minimal changes (e.g., updating of references, changing language to meet legal needs). The coverage intent of the protocols was not altered. These protocols were recently approved for updating by the Health Plan Medical Directors and are available on our Web site.

There were none this reporting period.

Update on FluMist Influenza Vaccine
FluMist™ is an intranasally administered live attenuated influenza vaccine (LAIV), for use in healthy children and adults ages 5–49 years of age. Although there is no clear advantage in the use of FluMist™ over the injectable vaccine, in order to increase the availability of the inactivated vaccine for persons at high risk, FluMist™ will now be considered a medically appropriate option for healthy people aged 5 to 49 who may transmit influenza to individuals at increased risk of developing influenza-related complications. Previously, the Health Plan provided only limited coverage for FluMist™ (e.g., when there were shortages of the injectable influenza vaccine). Please be aware that a contract benefit must exist in order for immunizations to be covered.

Changes to the current Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) recommendations related to influenza vaccines for the 2006-2007 season will be added to the *Influenza Vaccines* medical policy when the ACIP/CDC recommendations are published.
New York State Department of Health (NYSDOH)  
Pesticide Poisoning Registry

Pesticide poisonings were added to the list of reportable conditions in New York State in 1990 as part of an effort to reduce the risk of pesticide poisoning in New York. Under these regulations, physicians and health facilities are required to report suspected or confirmed cases of pesticide poisoning. Clinical laboratories are required to report depressed blood cholinesterase levels or abnormally high levels of pesticides in human tissue samples. Physicians should call the NYSDOH Pesticide Poisoning Registry at 1-800-322-6850 within 48 hours of treating any patients they suspect of having pesticide poisoning.

A definitive diagnosis is not needed prior to calling, and there is no paperwork for physicians to complete. The NYSDOH staff will investigate the reported case to collect information to monitor the health effects of pesticides. They may intervene in situations where a continued risk of pesticide poisoning exists. The work of the Pesticide Poisoning Registry complements the work of the regional poison control centers. The poison control centers supply information on immediate treatment and other emergency responses. Poisonings may result from structural applications, yard applications, manufacturing or formulation settings, farm settings or any other location where pesticides are used and stored. Because of their toxicity and easy availability, accidental or intentional ingestion of pesticides is also an ever-present threat.

The Pesticide Poisoning Registry strives to increase awareness in the medical community of the possibility of pesticide-related health effect and to develop interventions to reduce the risk of pesticide poisoning.

An important public health issue in New York State is West Nile Virus (WNV). Some counties may apply pesticides to control mosquito populations. The New York State Department of Health will be conducting surveillance of reported health effects possibly resulting from exposure to the application of WNV-related pesticides.

Any physician who suspects or confirms that his/her patient is experiencing health effects due to exposure to WNV-related pesticides should report that case to the Pesticide Poisoning Registry at 1-800-322-6850.
New York State Department of Health
REQUEST FOR FORMS OR PUBLICATIONS

Submit Request to:
NYS Department of Health
Attn: Michael Margiasso
Corning Tower, Room 2029
Empire State Plaza
Albany, NY 12237
Phone: (518) 473-4852
Fax: (518) 486-1432

Deliver Supply To: (fill in address)

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Signature of Individual Submitting Form

Phone Number: _____________________________
Fax Number: _______________________________
Date Submitted: ___________________________
Zocor® Patent Expired June 23, 2006

The patent for Zocor (simvastatin) expired on June 23, 2006 and simvastatin is expected to be available generically by early July. Current users are likely to be automatically switched to simvastatin when filling their prescriptions (unless “DAW” is written on the script).

Simvastatin is the third statin available generically, preceded by pravastatin (Pravachol®) in April 2006, and lovastatin (Mevacor®) in 2003. Current medical evidence suggests that there is no one statin better at preventing or treating coronary artery disease when NCEP goals are reached. Therefore, with these three generic statins available, it is expected that the clinical needs of up to 75-85 percent of patients can be met through the use of one of these generics. Consequently, lowering cholesterol levels to “goal” is now more affordable than ever!

The cost of the generics is expected to drop substantially after they have been on the market for six months – approaching $15-$25 per month, compared to over $100 for their brand equivalents.

If you prescribe a branded statin like Lipitor®, consider simvastatin, pravastatin or lovastatin for existing patients and new starts. Switching your patients immediately will save them money now and as new generics become available. It will also help you in transitioning a large patient population.

Zoloft® Patent Expired June 30, 2006

The patent for Zoloft (sertraline) expired on June 30, 2006 and sertraline is expected to be available generically by early July. Current users will be automatically switched to sertraline when filling their prescriptions (unless “DAW” is written on the script).

Watch for additional information about new generics in upcoming editions of Connection.
Consumer Directed Health Plans

We are committed to responding to the market demand for products and services that help our members take greater control of their health care decisions.

Consumer Directed Health Plan (CDHP) products encourage our members to act as consumers when spending benefits dollars, much like they do when making any other purchasing decisions. More than one million Blue Cross and Blue Shield Plan members across the country are currently covered by a CDHP.

Excellus BCBS offers the following CDHP products:

- Blue PPO HSA (Health Savings Account)
- FourFront

Continued growth and success for CDHPs requires that all of our health care partners are well informed. It’s important to note that CDHP products vary across Blue Cross and Blue Shield Plans. Below you will find information about the distinct features of CDHPs, as well as helpful tips that will guide you when processing claims for our members with CDHPs.

**CDHP Key Features**

**High Deductible** – CDHPs offer members greater access to our network of participating providers. They are usually combined with features such as employer-funded HSAs or Health Reimbursement Accounts (HRAs) to help members better manage health care costs. Depending on the plan, common deductible amounts range from $1,000 to $5,000 for a single member, with minimal restrictions on the choice of providers.

**Debit Card** - The debit card allows members to pay for and track out-of-pocket costs using funds from their HRA or HSA. Some cards are “stand-alone” debit cards to cover out-of-pocket costs, while others also serve as member ID cards.

**Provider Tips**

- Ask each member for his/her current member ID card and make a copy of the front and back of the card at each visit. This will enable you to submit claims with the appropriate member information (including alpha prefix) and avoid unnecessary claims payment delays.
- Check eligibility and benefits for out-of-area members by calling 1-800-676-BLUE (2583) and provide the alpha prefix, or visit our Web site at excellusbcbs.com and click on For Providers, then Online Services and choose Member Eligibility.
- If the member presents a health care debit card, be sure to submit the claim for service prior to seeking reimbursement from the member. However, subsequent to claim payment, the member may be billed for the appropriate copayment, deductible or coinsurance amount. The debit card may be used to pay the balance due, or the member may issue a check from his/her HSA funds.

- For BlueCard members with CDHPs, file claims with your local Excellus BCBS office.
Medicare Advantage Overview

Medicare Advantage is the alternative to standard Medicare Part A and Part B fee-for-service coverage (generally referred to as “traditional Medicare”). The Medicare Advantage program offers Medicare beneficiaries several product options, including health maintenance organization (HMO), preferred provider organization (PPO), point-of-service (POS) and private fee-for-service (PFFS) plans. All Medicare Advantage plans must offer beneficiaries at least the standard Medicare Part A and B benefits, but many offer additional covered services (enhanced vision and dental benefits) as well.

In January 1, 2006, many Medicare Advantage plans began offering Medicare prescription drug coverage for their members under the new Medicare Part D benefit program. Medicare Advantage plans may allow in-network and out-of-network benefits, depending on the type of product selected.

Providers should confirm the level of coverage for all Medicare Advantage members prior to providing service, since the level of benefits and coverage rules may vary.

Here are some important things to remember with the Medicare Advantage program:

- **Be sure to ask for the member ID card.** Medicare Advantage Members will have an ID card that contains the Blue Cross and/or Blue Shield logo(s). While these members may also carry the traditional Medicare card, they should present and use the Medicare Advantage ID card with the Blue Cross and/or Blue Shield logo(s).

- **Verify eligibility** by contacting your local Provider Service for local subscribers or 1(800) 676-2583 for out-of-area BlueCard subscribers. You will be asked for the member’s ID number, including the three-character alpha prefix. Be sure to ask if Medicare Advantage benefits apply.

- **Submit claims to your local Excellus BlueCross BlueShield office.** Do not bill Medicare directly for any services rendered to a Medicare Advantage member. Payment will be made directly by your local Excellus BlueCross BlueShield. Please review the remittance notice concerning Medicare Advantage plan payment, member’s payment responsibility and balance billing limitations. It is important to indicate whether you accept Medicare assignment on these claims. See the October 2005 issue of this newsletter for complete details.
Improving the Health of Adolescents

Adolescence is a unique period in the life cycle that presents special challenges and opportunities for health care professionals. As young people transition from childhood to adolescence, they establish patterns of behavior and make lifestyle choices that can impact their current and future health.

The health risks that endanger young people are staggering.
- More than 1 in 5 high school students in the United States are current smokers.
- Almost 80 percent of high school students do not eat the recommended five servings of fruits and vegetables a day.
- Only 28 percent of high school students participate in daily physical education classes.
- Nearly one in three children and adolescents are overweight or at risk of becoming overweight.
- Every year, more than 870,000 adolescents become pregnant and over three million become infected with a sexually transmitted disease.
- People aged 13-24 account for 12 percent of HIV cases reported in areas with confidential reporting.
- Young people miss 14 million school days a year because of asthma.

In response to these increasing health risk factors, the Centers for Disease Control and Prevention (CDC) has instituted the National Initiative to Improve Adolescent Health by the Year 2010 (NIIAH 2010). As a result of this initiative, new Quality Assurance Reporting Requirements (QARR) measures have been added. These measures focus on documentation that includes:
- BMI screening
- Screening for depression
- Assessment/counseling/education focused on nutrition and exercise, risk behaviors associated with sexual activity, risks of tobacco use, and risks of substance abuse including alcohol

During an office visit with an adolescent patient, it is important to capture the teaching, counseling and assessment that you have discussed and/or completed. An effective way to document this is by using a trigger questionnaire.

The trigger questionnaire, developed by the Adolescent Quality Improvement Work Group, helps to identify any areas of concern. It can be completed by the teen while waiting for an exam or by the practitioner and teen as part of an interview.

To obtain a copy of a trigger questionnaire, please visit the University of Rochester Medical Center Web site at http://www.urmc.rochester.edu/gchas/div/adol/leah/resources.HTM

For more information regarding the NIIAH 2010, please visit the CDC Web site at www.cdc.gov/HealthyYouth/AdolescentHealth/NationalInitiative.
New Drug Warnings

Tequin®- Bristol-Myers Squibb has announced that it will stop making and selling the antibiotic Tequin (gatifloxacin). Current stock of Tequin will not be recalled. Tequin has been linked to serious cases of both hypoglycemia and hyperglycemia, and a contraindication for use in diabetic patients was recently added to the prescribing information.

Ketek®- Sanofi-Aventis’ antibiotic Ketek (telithromycin) has been implicated in at least 10 cases of liver failure, and is currently the subject of a Senate investigation of possible fraud in the clinical trials. The FDA has issued no official warning. However, in January 2006, the FDA issued a public health advisory in response to a New England Journal of Medicine report of three cases of serious liver failure. Reference: [http://www.fda.gov/cder/drug/advisory/telithromycin.htm](http://www.fda.gov/cder/drug/advisory/telithromycin.htm)

ACE Inhibitor Exposure in the First Trimester Can Cause Birth Defects

A new study published in the New England Journal of Medicine has raised questions regarding ACEI exposure in the first trimester. Before the publication of the study, the belief has been that while ACEI exposure in the second and third trimester is contraindicated, exposure in the first trimester was not associated with an increase in birth defects. However, a recent epidemiologic study found an increase in major congenital defects in infants who were only exposed to ACE inhibitors in the first trimester. The study included 29,507 infants born between 1985 and 2000 in the Tennessee Medicaid program. 411 of these infants were exposed to an ACEI in only the first trimester and 202 infants were exposed to another antihypertensive medication, such as diuretics, in the first trimester only. The overall rate of major congenital malformation in the ACEI exposed infants was 7.1%, compared to 2.6% in infants who were not exposed to any antihypertensive, and 1.7% in infants exposed to an antihypertensive other than an ACEI. The increase was primarily found in defects of the cardiovascular system (risk ratio 3.27) and central nervous system (risk ratio 4.39). An increased risk of renal defects was also found on post hoc analysis (risk ratio 9.32). The authors concluded, “Our data suggest that such exposures cannot be considered safe and should be avoided.” Reference: NEJM 354; 23 June 8, 2006

Did You Know?

Pharmaceutical manufacturers have a variety of ways to delay the introduction of less expensive generic versions of their brand name drugs. Some of these tactics include making their own “authorized generics” to undercut the generic company, and paying generic manufacturers to NOT make generic copies of their products. Did you know that Bristol-Myers Squibb and Sanofi-Aventis recently made a settlement with the generic manufacturer Apotex? In exchange for a payment of $40 million, Apotex agreed to not pursue a generic version of Plavix until 2011. Without this deal, Apotex would have challenged the patent on Plavix and may have been able to produce a generic version much earlier. Reference: [http://biz.yahoo.com/ap/060526/authorized_generic_drugs.html?v=3](http://biz.yahoo.com/ap/060526/authorized_generic_drugs.html?v=3)

New Generics

Zocor®
- Simvastatin (generic Zocor) is expected to be available early July. Simvastatin is the third statin available generically, preceded by pravastatin (Pravachol®) in April 2006, and lovastatin (Mevacor®) in 2003. The cost of the generics is expected to drop substantially after they have been on the market for six months – approaching $15-$25 per month, compared to over $100 for their brand equivalents.

Zoloft®
- Sertraline (generic Zoloft) is expected to be available generically by early July.

Proscar®
- Finasteride (generic Proscar) is now available generically.
TWO NEW MEDICATIONS COMING IN JUNE: Exubera® and Daytrana®

FLRx Comment: There has been a great deal of direct-to-consumer advertising for Exubera and Daytrana. As a result, you may have already received questions regarding the two drugs. The following information is designed to provide you with a few key points about the drugs; however, it is not all-inclusive.

Exubera (inhaled insulin)

Indication: Inhaled human insulin (IHI) is indicated for the control of hyperglycemia in adult patients with diabetes mellitus (DM).

Unique Pharmacokinetics Compared to Injectable Insulin

Smoking – the systemic exposure for IHI in smokers is **two-to-five-fold higher** than in non-smokers because smoke causes a chronic inflammatory response, thus enhancing absorption of the drug.

Second-hand Cigarette Smoke – the systemic exposure is reduced by approximately 20% because the lung’s initial response to cigarette smoke is bronchoconstriction.

Mild Asthmatics - absorption following administration of IHI was approximately **20% lower**.

Chronic Obstruction Pulmonary Disease (COPD) – the systemic exposure of insulin absorption following IHI was approximately **two-fold higher**.

Warnings/Precautions

Pulmonary Function Tests (PFTs) should be assessed prior to initiating therapy and during therapy. IHI should be discontinued in patients who experience a 20% or higher decline in FEV₁ from baseline.

Safety/Side Effects

**Contraindications** – patients who smoke or have smoked within six months of initiating therapy. Patients with unstable or poorly controlled lung disease, as variations in lung function can affect insulin absorption.

**Drug Interactions** – bronchodilators and other inhaled products may alter the absorption of IHI.


Daytrana (methylphenidate patch for ADHD)

Indication: Treatment of attention deficit hyperactivity disorder (ADHD) in children 6-12 years of age.

Administration: Daytrana should be applied to a clean, dry area of the hip, alternating hips every day. **Absorption increases if area is inflamed. Additionally, when heat is applied, both rate and extent of absorption are increased.**

Concerns: Contact sensitization – once sensitized to the patch, patients may not be able to take the oral form of methylphenidate. Patients must be started on oral under close supervision.

*Use longer than seven weeks, or in children older than 12, has not been studied.*


PER FDA Advisory Committee Meeting (Posted December 2, 2005)

- “Oral methylphenidate drugs should be considered prior to selecting Daytrana patch for treatment of attention deficit/hyperactivity disorder due to concerns about skin sensitization.” (FDA’s Psychopharmacologic Drugs Advisory Committee)

- The committee members agreed that the methylphenidate patch should carry strong warnings concerning the potential for future allergic reactions to other oral methylphenidate products if a user experiences an allergic skin reaction to the patch. Such a reaction could lead physicians to stop prescribing methylphenidate products for those patients. Most committee members, however, stopped short of recommending a boxed warning on the skin sensitization side effect.

Reference: http://www.fdaadvisorycommittee.com/FDC/AdvisoryCommittee/Committees/Psychopharmacologic+Drugs/120205_Methypatch/120205_Daytrana.htm

FLRx Safety Comment: Pediatricians surveyed thus far consider Daytrana to be a drug of concern, and as such, do not recommend it as first or second line therapy.

Daytrana poses an additional risk due to the potential for lack of adult supervision during application and removal, as well as possible tampering or sharing of the patch.

The Associated Press released the following statement (May 2006) “Scientists at the Centers for Disease Control and Prevention estimated that problems with the stimulant drugs drive nearly 3,100 people to ERs each year. Nearly 66% of overdoses and accidental use can be prevented if parents locked the pills away.” (Also Discussed in May Issue of NEJM.)