### Contents:

- **National Provider Identifier Taxonomy Code**
  
  A taxonomy code, also known as specialty code, is a ten-character code (e.g., 193200000X) used to identify the provider type and area of specialization for all health care providers.

  The taxonomy code that a specialty provider adds to a claim will depend on the specialty under which the service was performed. For example: an anesthesiologist who also performs pain management services will use his or her NPI number and anesthesia taxonomy code when providing anesthesiology services and his or her NPI number with the pain management taxonomy code when performing pain management services.

  It is suggested that practitioners select the simplest, most generic taxonomy code to describe each specialty.

- **Multi-specialty providers will be required to bill with their taxonomy code. Failure to submit claims with your taxonomy code may result in incorrect payments. To view a list of taxonomy codes to choose from, please visit the Washington Publishing Company Web site at [http://www.wpc-edi.com/codes/taxonomy](http://www.wpc-edi.com/codes/taxonomy).**

  - **If you have not yet applied for an NPI, be sure to have your taxonomy code(s) available when you do apply, as you will be asked for this information during the application process.**

  - **Providing us with all of your necessary NPI information as soon as possible will help ensure a smooth transition and will reduce claim processing interruptions and payment delays. This issue includes forms you may use to share your NPI information with us.**

- **NPI Reminder for Billing Agencies**
  
  If your office uses a billing agency and/or practice management vendor, please share your NPI(s) and this important information with them.

- **As of May 23, 2007, Excellus BCBS will not accept electronic or papers claims for processing that do not include the NPI.**

  Between now and the May 23, 2007, deadline, you or your billing agency may bill us using your NPI(s), but you must also include the billing provider identification number that your office currently uses.

### Attachments:

- Medical Policy Update
- Ask Me 3™ Program
- News From FLRx
- Screening for Colorectal Cancer
- Web Improvements
- NPI Registration Forms
- Rx Facts - February/March 2007

Visit our Web site at excellusbcbs.com
Utilization Reviews Based on Need

All Excellus BCBS plans review health care services to determine if they are medically necessary. This process is called utilization review.

Reviews are conducted by licensed health care professionals and physicians and are based solely on the need for care and service. We do not compensate, reward or provide financial incentives to decision-makers for denying coverage or services.

Clinical Guideline Update

We’ve updated the clinical guidelines for Coronary Artery Disease: Secondary Prevention. You can view the update by visiting our Web site at excellusbcbs.com, then clicking Patient Care, then Access Clinical Practice Guidelines.

Reminder Regarding Payment Collection

Member cost-sharing is an important element of the responsible utilization of health care services. While we understand that providers may, in limited circumstances, decide to reduce or waive an individual member’s copayment, coinsurance and/or deductible, providers are generally required, and expected to collect cost-sharing amounts from members. Routine failure to collect such amounts from federal and certain state health care program beneficiaries may constitute illegal remuneration under the civil monetary penalties provision and/or the anti-kickback provision of the Social Security Act. Additionally, the practice of routinely waiving coinsurance may implicate the False Claims Act.

Providers with formal “sliding scale” policies for low-income patients may reduce or waive copayments subject to the terms of those policies.

Quality Improvement Program Description Available

The goals of the Quality Improvement Program support the mission of Excellus BCBS - to improve the quality of life in the communities that we serve. As a health plan, we work to engage members and employers to make healthy and well-informed choices and to influence practitioners and providers to render quality, cost-effective care. The success of the program is evidenced by measurable improvements in health and satisfaction.

If you would like to obtain a copy of our Quality Improvement Program Description, please contact our Quality Management Department at (800) 574-2390.

Upcoming Policy Change for Home Care Visits

Effective June 15, 2007, we will use InterQual® criteria as a basis for all decisions pertaining to requests for home care. This policy will apply to all Excellus BCBS lines of business.

If you have questions, please contact Provider Service.

IMPORTANT!

Providers are required to bill using their National Provider Identifier (NPI) as of May 23, 2007. Please make sure that you share your NPI with all health plans you participate with.

After May 23, 2007, claims submitted without NPI will be denied.
2006 Behavioral Health Treatment Record Review (TRR) Results

53 managed care practitioners met criteria for a TRR and were reviewed during 2006. The highest review score was 100% and the lowest was 85%. The average score for BH practitioners was 95.6%. The Excellus BCBS Behavioral Health Department reviews treatment records of practitioners who are being recredentialed to ensure these records meet established Behavioral Health Managed Care Standards. These standards address the organization and content of treatment records and the maintenance of complete, current, pertinent and retrievable documentation. The Behavioral Health TRR Standards promote efficient and thorough assessment, effective treatment, health promotion, and delivery of behavioral health services. There is a strong emphasis on monitoring continuity and coordination of care with the member’s primary care physician and other behavioral health caregivers. The TRR quality indicators most frequently out of compliance in 2006 were:

1. Documentation of dates for follow-up appointments or discharge plan
2. The record containing the necessary written “Releases of Information” from the patient to speak with the PCP and other behavioral health caregivers as required by the New York State Department of Health
3. Documentation of continuity of care with the patient’s primary care physician (PCP)
4. Documentation when the patient drops out of treatment prematurely
5. Treatment plans having objective and measurable goals

The TRR standards require completion of a thorough biopsychosocial evaluation for each new patient by the third visit, and documentation of communication with the patient’s PCP and other behavioral health caregivers.

Optional chart templates for record keeping, tools, and the TRR criteria are conveniently located in the BH views on the Health Plan's web site at https://www.excellusbcbs.com/providers/patient_care/behavioral_health.shtml. Providers who would like additional information may contact Behavioral Health Quality Management at (800) 240-6956.

Talk to your patients about generic drugs. They’re safe, effective and affordable.
MEET YOUR NEW personal assistant.
stepup.excellusbcbs.com
Medical Policy Update – March 2007

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 (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 March 2007:

- Allogeneic Stem cell Transplant
- Autologous Stem Cell Transplant
- Endovascular Grafts for Abdominal and Thoracic Aortic Aneurysm
- Genetic Testing for Specific Diseases
- Lung Volume Reduction Surgery

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 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 excellusbcbs.com. To access our policies, members need to click on For Members, followed by Health and Wellness, then View our Medical Policies.

Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists. Excellus BCBS medical policies 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

Lumbar Traction, a treatment for low back pain is often used in combination with other modalities. Lumbar traction can be provided manually by a therapist or by mechanical means and may also be self administered using portable devices. Lumbar traction by any method (e.g., vertebral axial decompression devices, home lumbar traction devices) has not been medically proven to be effective in improving clinical outcomes and is therefore considered investigational.

CURRENT POLICIES recently updated

Computed Tomography for Detection of Coronary Artery Calcification which includes electron beam computed tomography/EBCT, spiral CT or multidetector-row CT for imaging of the heart to detect coronary artery calcifications is considered not medically necessary when used as a screening tool for asymptomatic patients. However, it is considered medically appropriate for patients who are candidates for cardiac computed tomographic angiography (CTA) to have calcium scoring performed as part of a CTA procedure.

Genetic Testing for Hemochromatosis (HFE-associated hereditary hemochromatosis or HFE-HHC) is medically appropriate when offered in a setting with adequately trained health care providers to provide appropriate pre-and post-test genetic counseling and performed by a qualified laboratory for the following indications:

- Confirmatory diagnostic testing of individuals with clinical symptoms of iron overload consistent with HFE-HHC (fasting transferrin saturation value higher than 45%); or
- Carrier testing of asymptomatic relatives of a HFE-HHC proband (high penetrance genotype: C282Y/H63D or C282Y/C282Y).

Based upon our criteria and assessment of the peer-reviewed literature, routine genetic screening for hereditary hemochromatosis in the asymptomatic general population has not been medically proven to be effective and is considered investigational.

MRI Guided Ultrasonic Ablation of Tumors is a minimally invasive technique for ablation of tumors utilizing high intensity focused ultrasound guided by magnetic resonance imaging (MRI). Based upon our criteria and the lack of peer-reviewed literature, MRI guided focused ultrasonic (MRgFUS) tumor (e.g., uterine fibroids; tumors of the breast, brain, liver, prostate and bone) ablation has not been medically proven to be effective and is considered investigational.

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.

- Airway Clearance Devices
- Artificial Intervertebral Disc Devices
- Chelation Therapy
- Deep Brain Stimulation
- Extracorporeal Shockwave Therapy (ESWT) for Musculoskeletal Conditions
Archived medical policies

Policies are archived either because the technology has become standard of care or because there has been little utilization or few requests. Archived policies are now available on the Internet Web site.

The Elective Medical Termination of Pregnancy policy addresses the use of methotrexate, mifepristone and misoprostol for the elective medical termination of pregnancy.

Placental and Cord Blood contains stem and progenitor cells capable of restoring hematopoietic function after myeloablation. This “cord” blood or placental and umbilical cord blood stem cell transplants (PCB-SCT) have been used as an alternative source of allogeneic stem cells transplants. Placental and cord blood as a source of stem cells from related or unrelated donors is medically appropriate when an allogeneic transplant is imminent in an identified recipient with a diagnosis that is consistent with the possible need for allogeneic transplant but is without an identified hematopoietic stem cell donor.
Ask Me 3™ Program Promotes Patient Health Literacy

Excellus BCBS is pleased to share information about Ask Me 3, a program promoting patient health literacy created by the Partnership for Clear Health Communication™.

Ask Me 3 is an effective tool designed to improve health communication between patients and providers. The program promotes the use of simple approaches and techniques to encourage patients to ask questions and take an active role in their health care.

The average American reads at the eighth or ninth grade level, but most health information is written at a much higher reading level. It is crucial that each patient understands what is being asked of him/her and why it is important. Ask Me 3 encourages providers to make sure that each patient understands the answers to the following three questions before he/she leaves an office visit:

1. What is my main problem?
2. What do I need to do?
3. Why is it important for me to do this?

The Ask Me 3 Web site is a valuable resource for provider offices. The site contains statistics and information on low health literacy, research studies, a list of literacy resources, and helpful tips and communication tools to assist you in your practice. You may download and print Ask Me 3 educational brochures, fact sheets and posters free of charge directly from the Ask Me 3 Web site listed below. You may also order these educational materials in bulk for delivery to your office. Please visit www.askme3.org for more details.
Impressive Increase in Generic Fill Rate in 2006

In 2006, nearly 800 participating health care professionals increased their generic fill rate by five points and over 400 achieved a generic fill rate of over 70 percent. This translates into hundreds of thousands of our members who saved out-of-pocket costs by replacing high cost brand medications with generics.

Last month, prescribing summaries were mailed detailing results from the fourth quarter of 2006. The profiles focused on generic opportunities in the HMG/statin drug class. A rapid increase in the use of generic HMGs/statins was seen after the release of simvastatin (generic Zocor®) in July 2006. Simvastatin provides cholesterol treatment for under $15 a month and may save your patients up to hundreds of dollars per year.

For more information on generics or to request a list of your patients with generic opportunities, please complete the fax back request form included in this issue.

Suggestions to Increase Your Generic Fill Rate:

• **Continued focus on opportunities in the HMG/Statin category.** Several generic options are available for cholesterol treatment, including: simvastatin, pravastatin and lovastatin.

• **Generic Trial Program:** In addition to cholesterol medications, other generics included in the program are used to treat depression, heartburn, high blood pressure and incontinence. For program details, visit our Web site at excellusbcbs.com. The Generic Trial program may not apply to a small number of benefit plans.
Please provide me with the following Tools/Services:

<table>
<thead>
<tr>
<th>PHARMACY SERVICES SUPPORT:</th>
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<tbody>
<tr>
<td>□ A listing of my patients prescribed Lipitor with generic opportunities</td>
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<tr>
<td>□ A listing of my patients with any generic opportunities</td>
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<tr>
<td>□ Individual Patient Chart Reminder:</td>
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<tr>
<td>□ Telephone call from Pharmacy Service Consultant regarding:</td>
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<tr>
<td>□ Please e-mail my Quarterly Rx Summaries to the address below</td>
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<tr>
<td>□ Please register me for a subscription to Rx Facts monthly pharmacy newsletter (indicate if you would like to receive this via fax or e-mail below)</td>
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<table>
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<tr>
<th>GENERIC TOOL KIT SUPPLIES</th>
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<tr>
<td>Brochures:</td>
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<tr>
<td>▪ Generics are Real</td>
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<tr>
<td>▪ Heartburn Prevention and Treatment</td>
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<td>▪ Osteoporosis</td>
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<td>▪ Allergic Rhinitis</td>
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<td>▪ Safe Use of Over-the-Counter Medications</td>
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<tr>
<td>▪ Migraine Headaches</td>
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<tr>
<td>Generic Tip Sheets (set of 6):</td>
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<td>▪ PPI</td>
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<td>▪ Cholesterol</td>
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<td>▪ Antidepressants</td>
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<td>▪ Blood Pressure</td>
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<td>▪ Allergy</td>
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<td>▪ Arthritis/Pain</td>
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<td>Additional Generic Supplies:</td>
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<td>□ Generics Posters (set of 3)</td>
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<td>□ Generic Options Chart</td>
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<tr>
<td>□ Generic Fact Sheet</td>
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Please let us know other ways we can assist you:

PLEASE PRINT CLEARLY:

Physician Name:   DEA #
Address:
Contact Name:
Phone #:   Fax #:    E-Mail Address:

Please FAX this form to Pharmacy Services Support at 1-877-812-5306
Screening for Colorectal Cancer

March is National Colorectal Cancer Awareness Month

Evidence is clear that detecting and removing adenomatous polyps can prevent the development of colorectal adenocarcinoma and that detecting and treating early-stage cancers can lower the mortality rate for colorectal cancer. Polyps and early-stage cancers are usually asymptomatic.

The U.S. Preventive Services Task Force strongly recommends screening for average risk persons over the age of 50 using one of the following techniques:

- fecal occult blood testing each year,
- flexible sigmoidoscopy every five years,
- fecal occult blood testing every year combined with flexible sigmoidoscopy every five years,
- double-contrast barium enema every five to 10 years; or
- colonoscopy every 10 years.

Screening of persons with risk factors should begin at an earlier age, depending on the family history of colorectal cancer or polyps.

Our most recent HEDIS measurement showed that 67 percent of our members over the age of 50 in the Rochester region were screened for colorectal cancer. This is a significant increase from the prior year and is well above the national average. Relative to other health plans nationally, our performance is in the 90th percentile.

This is promising news, but there are still many individuals who are not being tested. You can make a difference by encouraging your patients to get this potentially lifesaving screening.
Web Improvements for Out-of-Area Member Eligibility Inquiries and More

In past issues of this newsletter, we summarized enhancements to our Web site pertaining to eligibility and benefits inquiries for members from other BlueCross BlueShield plans.

Here are some highlights:

- Specific benefit type inquiries give providers only the information they request, making it quicker and easier to obtain valuable eligibility and benefit data.

- New types of service codes facilitate inquiries about service types that were previously not available, bringing satisfaction to a new segment of providers.

- Patient liability inquiries for specific services are now available and any limits for restricted visits, or treatments, and places where services can be rendered will be present in this enhanced tool, providing specifics regarding benefit limits and place-of-service information. For example, the number of times a member can visit for chiropractic or physical therapy or the maximum age for “well child” care can be presented for you.

- An alert is noted if the member’s benefits differ according to where the service is performed—for example, $10 copay for surgery in a dermatologist’s office or $50 copay for surgery as a hospital outpatient.

You may access these features by visiting our Web site at excellusbcbs.com.

Log on to excellusbcbs.com, click on the For Providers link and select Member Eligibility or Benefits for Other BlueCross Plan Members from the left menu.

This information is also available through all QuickLink and ANSI inquiries. Your Provider Relations representative can provide you with an updated QuickLink manual upon request.
NOTICE OF NATIONAL PROVIDER IDENTIFIER (NPI) FOR TYPE I INDIVIDUAL PRACTITIONER OR TYPE II GROUP PRACTICE

Instructions:
- Please use the template included on the back of this sheet, or create your own spreadsheet in the format we have provided. The template is also available for completion on our Web site, excellusbcbs.com.
- Complete all fields applicable to your practice.
- If completing for a group practice, please include all of the required information for each practitioner in the group.
- Please coordinate with other practice administrators if the members of your group participate in other group practices as well.
- Send the completed form(s) to one of the following:
  1. Fax Number: (800) 561-6504
  2. Email the form as an attachment to: NPIEXCEL@excellus.com
  3. Mail to: Attn: Techniplex
     NPI Project
     165 Court Street
     Rochester, NY 14647-0001

(continued on reverse)

Note: Excellus BCBS will use this form to update the provider file repository containing your practice-specific information. Excellus BCBS does not issue NPI numbers; however, it is a federal requirement that you obtain the NPI through Fox Systems, Inc. in order to receive payment for services rendered on or after May 23, 2007. For more information, visit www.FOXsys.com or apply for your NPI online at https://nppes.cms.hhs.gov
***The fields located in the box below are required for Group Practices*****

<table>
<thead>
<tr>
<th>Group Name (if applicable)*</th>
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<tr>
<th>Group NPI #</th>
<th>Group Taxonomy</th>
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<td>(1)</td>
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<td>(2)</td>
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*Please note that the Group name must match the name used for IRS reporting.

<table>
<thead>
<tr>
<th>Tax ID</th>
<th>License #</th>
<th>Individual NPI #</th>
<th>Taxonomy Code</th>
<th>Provider Last Name</th>
<th>Provider First Name</th>
<th>Title (MD, OD, etc.)</th>
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This form serves as notification that the providers listed above have obtained a National Provider Identifier (NPI) through Fox Systems, Inc.
NOTICE OF NATIONAL PROVIDER IDENTIFIER (NPI) FOR
TYPE II NON-HOSPITAL/ANCILLARY PROVIDER

This form serves as notification that the provider listed below has obtained a National Provider Identifier (NPI) through Fox Systems, Inc.

Instructions: Please complete all applicable fields. If you’ve obtained individual NPI(s) for subparts, please list each entity and send the completed form to one of the following:
1. Fax Number: (800) 561-6504
2. Email the form as an attachment to: NPIEXCEL@excellus.com
3. Mail to: Attn: Techniplex
   NPI Project
   165 Court Street
   Rochester, NY 14647-0001

NAME: _________________________________
TAX ID NUMBER: _______________________ LIC/CERT NUMBER (if app.): ______________________

<table>
<thead>
<tr>
<th>NPI NUMBER</th>
<th>TAXONOMY CODE</th>
<th>DIVISION/DEPT.</th>
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PROVIDER TYPE:
_ Laboratory
_ Certified/Licensed Home Health Agency
_ Skilled Nursing Facility
_ Infusion Therapy
_ Other (specify): _______________________

__ DME/Supply Vendor
__ Hearing Aid Dealer
__ Vision (Optician) Center
__ Free-Standing Ambulatory Surgery Center
__ Hospice Agency
__ Free-Standing Dialysis Center
__ Ambulance
__ Outpatient Mental Health/OASAS

OFFICE CONTACT: _________________________ PHONE NUMBER: _______________________

Note: Excellus BCBS will use this form to update the provider file repository containing your practice-specific information. Excellus BCBS does not issue NPI numbers; however, it is a federal requirement that you obtain the NPI through Fox Systems, Inc. in order to receive payment for services rendered on or after May 23, 2007. For more information, visit www.FOXsys.com or apply for your NPI online at https://nppes.cms.hhs.gov
### Contraceptive Classification List

#### MONOPHASIC COMBINATIONS

<table>
<thead>
<tr>
<th>Chemical Ingredients</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desogestrel - ethinyl estradiol 0.15-0.03 mg</td>
<td>Apri, Solia, Reciplsen</td>
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<td>Desogen, Ortho-CEPT</td>
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<tr>
<td>Drospirenone - ethinyl estradiol 3.0-0.3 mg</td>
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<tr>
<td>Drospirenone - ethinyl estradiol 3.0-0.2 mg</td>
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<tr>
<td>Ethynodiol - ethinyl estradiol 1-0.035 mg</td>
<td>Zovia 1/35, Kelnor 1/35</td>
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<td>Demulen 1/35</td>
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<tr>
<td>Ethynodiol - ethinyl estradiol 1-0.05 mg</td>
<td>Zovia 1/50E</td>
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<td>Demulen 1/50</td>
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<tr>
<td>Levonorgestrel - ethinyl estradiol 0.1-0.02 mg</td>
<td>Aviane, Lessina, Lutera, Sronyx</td>
<td>Alesse, Levite</td>
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<tr>
<td>Levonorgestrel - ethinyl estradiol 0.15-0.03 mg</td>
<td>Levora, Portia, Jolessa, Quasense (91 day)</td>
<td>Nordette, Levlen Seasonale (91 day continuous)</td>
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<tr>
<td>Norethindrone - ethinyl estradiol 0.4-0.035 mg</td>
<td>Balziva, Zenchent</td>
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<td>Femcon FE, Ovcon 35</td>
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<tr>
<td>Norethindrone - ethinyl estradiol 0.4-0.050 mg</td>
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<td>Ovcon 50</td>
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<tr>
<td>Norethindrone 0.35 mg</td>
<td>Camila, Nora Be, Erin, Jovillete</td>
<td></td>
<td>Nor-QD, Ortho Micronor</td>
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<tr>
<td>Norethindrone - ethinyl estradiol 0.5-0.035 mg</td>
<td>Necon 0.5/35, Nortrel 0.5/35</td>
<td>Breviscon, Modicon Ortho-Novum 1/50, Norinyl 1/50</td>
<td>Ortho-Novum 1/35, Norinyl 1/35</td>
</tr>
<tr>
<td>Norethindrone - mestranol 1-0.05 mg</td>
<td>Necon 1/50, Necon 1/35, Nortrel 1/35</td>
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</tbody>
</table>
FDA Removes Unapproved Quinine from the Market: On December 11, 2006, the FDA ordered manufacturers to stop distributing unapproved products containing quinine sulfate or its salts due to serious safety concerns, including death. The FDA reviewed the labeling of unapproved products and found they did not provide the most current information for physicians to prescribe quinine safely and effectively, and thus recommended its removal from the market.

The only FDA approved product is Qualaquin® (quinine sulfate) manufactured by Mutual Pharmaceutical Company, Inc. and contains 324 mg of quinine sulfate per capsule. It is indicated for treatment of uncomplicated malaria caused by plasmodium falciparum.

Why is the FDA taking this action?

- A narrow therapeutic index associated with quinine is linked with a number of serious adverse events that have led to fatalities.
- Quinine interacts with many drugs including: neuromuscular blocking agents, class IA and III antiarrhythmic agents, astemizole (Hismanil), rifampin, cisapride (Propulsid), erythromycin, and other medications known to cause QT prolongation.
- Quinine is contraindicated in patients with prolonged QT interval, G-6-PD deficiency, myasthenia gravis, and optic neuritis.
- The risk associated with the use of quinine sulfate in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating and/or preventing this benign, self-limiting condition.

Risks Associated with Quinine Use

- From 1969 to 2006, the FDA received 665 reports of adverse events with serious outcomes, including 93 deaths.
- Quinine toxicity has been documented and includes: tinnitus, dizziness, auditory deficits, nausea, visual changes, disorientation, severe skin rashes and cardiac arrhythmias including torsades de pointes, hematological changes, renal failure, hypoglycemia, and generalized anaphylaxis.

FDA Warning Against the Use of Quinine for Nocturnal Leg Cramps

- These products may not be sold for prevention and treatment of nocturnal leg cramps without approved applications due to numerous safety concerns.
- The labeling of Qualaquin contains numerous warnings regarding the use of this product for prevention and/or treatment of nocturnal leg cramps.


Concerns Regarding Low-Dose Oral Contraceptive Failure

Recent press has noted the FDA has been approving low-dose oral contraceptives (typically defined as 35mcg or less of the estrogen component) with higher failure rate per year of treatment. Traditional oral contraceptives (such as products approved in the 1960’s with higher strengths of estrogen) resulted in less than 1% failure rate (<1 pregnancy in 100 woman per year of use), while newer agents have between 1% and 2% failure rate. In practice however, it has been estimated that all oral contraceptives may have between a 3% and 5% failure rate.

FLRx Comment: Recent studies have suggested that an increase in failure rate may be correlated with BMI as well as the lower estrogen contents of newer oral contraceptives. Women with a BMI of greater than 32.2 kg/m2 may have up to a 70% increased risk of oral contraceptive failure resulting in pregnancy.

This information is preliminary. Large-scale prospective studies are necessary to further investigate these correlations.
Considerations for Oral Contraceptive Use:

- Inform practitioners and pharmacists that patients are taking oral contraceptives to avoid effects certain medications have on oral contraceptive efficacy.
- Practitioners may consider alternatives to low-dose oral contraceptives, or recommend additional contraceptive measures in patients with BMI’s greater than 32 kg/m2.

For your convenience we have included a current contraceptive classification list on page three.


Infant Deaths Associated with Cough and Cold Medications

On January 12, 2007 the CDC, through their Morbidity and Mortality Weekly Report (MMWR), published a notice about the association between infant deaths and cough and cold medications. In 2005, the deaths of three infants between 1-6 months old were determined to have been caused by cough and cold medications. Two of the infants had evidence of a respiratory infection, and all three had high levels of pseudoephedrine in their blood samples postmortem. One infant received a prescription and over-the-counter cough and cold combination simultaneously. Other reports linking cough and cold medications to infant deaths also exist.

FLRx Comment: As an alternative to pseudoephedrine and other nasal decongestant, infants could be treated with saline nose drops or cool-mist humidifiers to soften secretions, and nasal congestion could be cleared with a rubber suction bulb. Furthermore, it may be dangerous for clinicians to extrapolate doses from the dosing guidelines for adults and older children to infants less than 2 years of age because the physiology of the disease and effects of drugs may be different in a pediatric population.


Updated Study on FluMist® Use in Children

Our January 2007 edition of Rx Facts included an article on the results of a recent study demonstrating that FluMist was less effective in adults than the standard flu shot. In the adult population studied, FluMist was effective in 30-57% of adults while the flu shot was effective in 67-77% of adults. (NEJM 2006; 355(24):2513-22)

While FluMist is not FDA approved for children under age 5, a recent article published in the New England Journal of Medicine reported the results of a study involving two groups of children given FluMist vs. the standard flu shot. Over 7,800 children between the ages of 6-59 months were studied. The group that received FluMist (a live attenuated influenza vaccine) experienced 54.9% fewer cases of laboratory confirmed influenza than the second group that received the standard flu shot (inactivated vaccine).

Patients age 12 months or younger who received the FluMist vaccine, experienced an increase in medically significant wheezing. The rate of serious side effects did not differ between the two groups. However, the hospitalizations for any cause in the 6-11 month age range was higher in the FluMist group. The authors concluded that FluMist appears to be a safe and effective option in children ages 12-59 months with no history of wheezing or asthma. (NEJM 2007; 356(7):685-96)