

OKLAHOMA HEALTH CARE AUTHORITY



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NEWSLETTER

DRUG UTILIZATION REVIEW FOR OKLAHOMA MEDICAID

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UPDATES

- Some SSRIs require prior authorization. See page 4 for more information.
- To verify receipt or check status of PA requests, please call the OHCA Pharmacy Help Desk. Please allow 24 hours for processing before sending duplicate petitions.
- Please note that all providers (including residents, physician assistants, and nurse practitioners) who prescribe for Oklahoma Medicaid clients should have a unique 7-digit OHCA prescriber number. To obtain a provider's OHCA prescriber number, please contact the pharmacy help desk, or visit the OHCA web site. Failure to process pharmacy claims with the correct prescriber number may result in recoupment of funds.

OHCA OFFERING FREE DRUG REFERENCE SOFTWARE

"The Oklahoma Health Care Authority is now offering prescription drug reference software free to all providers who have handheld personal data assistants (PDAs)," said Alex Easton, OHCA pharmacy operations manager.

"It's really a great tool," Easton said. "We are the seventh state to be implementing this for Medicaid, so we're on the cutting edge. Several of our providers already are using it, especially a lot of recent graduates."

The ePocrates software, which covers more than 3,000 brand-name and generic drugs, is intended to help providers improve quality of care and cut lag time for many Medicaid patients who now must wait for prior authorization to receive their prescriptions.

"With the software, providers can see at the point of care what drugs are available and whether the prescription requires prior authorization or has quantity limits," Easton said.

If so, providers can view a list of therapeutically equivalent alternative drugs that are covered without restrictions.

In the past, a provider may not have found out that a prescribed drug required prior authorization until the patient took the prescription to the pharmacy. The pharmacy then had to contact the provider to begin the approval process.

The software also can point to the availability of generic drugs, show clinical guidelines and warn of adverse reactions or contraindications.

While the provider is responsible for purchasing the PDA, OHCA will provide the software and regularly update the drug list. "The list includes other health plans, as well as Medicaid," Easton said.

To use the software, providers need to have a Palm OS or Pocket PC handheld with 3.0 MB of free memory. ePocrates also offers a version of the software for personal computers with Internet access at an extra cost of about \$60 per year.

Until the end of the year providers are eligible for a 20 percent discount on ePocrates premium products. The discount code to use on the ePocrates website is "OKMED120".

For more information on ePocrates, visit www.epocrates.com or contact the OHCA Pharmacy Help Desk.

GENERIC SUBSTITUTION OF A-RATED DRUGS

Beginning November 2004, Oklahoma Medicaid will require a prior authorization for reimbursement at the brand name level if an equivalent A-rated generic has a State Maximum Allowable Cost applied. The prescriber's instruction to "dispense as written" coded as DAW-1 will no longer trigger the brand name reimbursement. The *prescriber* must complete and submit the brand name drug override petition to the pharmacy prior authorization unit. Petitions are available at: www.ohca.State.ok.us/provider/pharmacy/pdflib/Brand_Name.pdf.

Requiring the substitution of an A-rated generic for a brand name drug is a common cost-saving approach for payers. Some prescribers harbor doubts that generic drugs are as good as the brand name. It is the opinion of the United States Food and Drug Administration (FDA) that if a generic is A-rated, it is therapeutically equivalent to and completely interchangeable with its brand name counterpart.

The FDA's Orange Book (available at: www.fda.gov/cder/orange/default.htm) states: "Evaluations of therapeutic equivalence for prescription drugs are based on scientific and medical evaluations by FDA. Products evaluated as therapeutically equivalent can be expected... to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling."

Bioequivalence testing is required before the FDA rates a generic as equivalent to the brand name drug. Some claim that the bioequivalence range of 20% below to 25% above the reference value as permitted by the FDA is too broad. This claim is due to a lack of understanding. This range is not as broad as it sounds. The entire 90% confidence interval must fall within the required range. If the mean for the generic were 20% dissimilar from the mean for the brand, it would never be approved as bioequivalent because the upper or lower boundary of the 90% confidence interval would fall outside the per-

mitted range.

In most cases, the bioavailability of a generic is much closer to that of the brand product than required. In fact, when the FDA compared 224 generics to their brand-name counterparts, the observed mean bioavailability difference between them was only 3.5%. If the FDA is concerned about a product's possible lack of bioequivalence, it can request additional testing before approving a product.

Variation in bioavailability between lots or batches for both brand and generic drugs is judged by this same bioequivalence standard, as is the difference between the brand name drug tested in clinical trials and the brand name drug as marketed, since there are often changes in formulation and manufacturing processes in the interim.

Some clinicians may believe that the standards of production of generic manufacturers are not as stringent as those of the branded products. All drugs that are approved by the FDA, whether brand or generic, are required to meet the same manufacturing and quality control standards. In fact, brand name products are sometimes made by generic manufacturers and generic products by brand manufacturers. It has been estimated that brand manufacturers produce about 70-80% of the generic drugs marketed.

Even in the face of this scientific evidence, some clinicians continue to question whether generics are truly therapeutically equivalent to their brand counterparts. Case studies and anecdotal evidence are often used to dramatize perceived problems. Unfortunately, case studies cannot reliably reveal cause and effect, and negative reports can be found about brand products as well as generics. The generic drug scandal of the late 1980's further bolstered practitioner wariness of generics. However, the corruption in the generic drug industry revealed at that time was not caused by weakness in the stan-

GENERIC SUBSTITUTION OF A-RATED DRUGS (CONTINUED)

dards but rather by lack of enforcement of the standards. Enforcement has since improved.

Despite the FDA's assurances, some clinicians continue to distrust generic drugs. They claim that when their patients switch from brand to generic, there are negative outcomes. For drugs that require laboratory monitoring for therapeutic levels, they claim that the lab test results change and show that the generics are not working or have increased levels and toxicity risk.

When these events happen, prescribers should report them to the FDA's MedWatch program. MedWatch forms may be completed and sent to the FDA by patients themselves as well as by prescribers, pharmacists, and other health-care providers either online or on paper. MedWatch

forms and information are available at:
<http://www.fda.gov/medwatch/>.

If prescribers have knowledge of a brand or generic drug problem, it is their duty to forward documentation to the FDA so it can investigate and take the necessary action. This is the only way that medication safety and patient care can be improved.

Generic drug use will continue to increase as payers look for cost-effective strategies to manage rising pharmacy costs. A-rated generics have been scientifically tested and proven to be equivalent and interchangeable with brand-name drugs. Prescribers who have concerns with any drug products should document specific problems and report them to the FDA.

SYNAGIS PRIOR AUTHORIZATION

Effective September 20, 2004, prior authorization is required for coverage of Synagis. Use of Synagis will be authorized only during the Respiratory Syncytial Virus (RSV) season as determined by the Oklahoma State Department of Health, typically November 1st through April 30th. A single prior authorization will be valid for the duration of the RSV season.

In order for Synagis to be authorized, the client must be included in one of the following age groups at the beginning of the RSV season:

- Infants and children less than 24 months old with Chronic Lung Disease (CLD) who have required medical treatment (Oxygen, bronchodilator, diuretic, or corticosteroid therapy) for CLD in the 6 months prior to the RSV season
- Infants less than 12 months old, born at 28 weeks gestation or earlier
- Infants less than 6 months old, born at 29-32 weeks gestation
- Children up to 24 months old with hemody-

namically significant cyanotic and acyanotic congenital heart disease

- Children up to 12 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure
- Infants up to 6 months of age, born at 32-36 weeks gestation who have 2 or more of the following risk factors:
 - A. Child care attendance
 - B. School-aged siblings
 - C. Exposure to environmental air pollutants (*Please Note: Tobacco smoke is not considered a risk factor since this can be controlled by the family.*)
 - D. Congenital abnormalities of the airway
 - E. Severe neuromuscular disease

For more information, or to obtain PA forms, please visit www.ohca.state.ok.us/provider/pharmacy/billing/forms.htm, or contact the OHCA Pharmacy Help Desk.

SSRI PRIOR AUTHORIZATION

Effective October 11, 2004, prior authorization is required for Selective Serotonin Reuptake Inhibitors (SSRIs) classified as Tier-2 medications. Tier-1 SSRIs will continue to be covered with no prior authorization requirement.

In order to prevent disruption of therapy for individuals who are currently utilizing Tier-2 medications, clients whose prescription history reflects a Tier-2 SSRI Medicaid claim within the previous 100 days will be allowed to continue therapy without interruption.

Approval of prior authorization requests for clients who have not previously utilized Tier-2 SSRIs will be subject to the following criteria:

- Documented trial with a Tier-1 medication with inadequate results after a minimum of 4 weeks of continuous use within the last 100 days
- OR–
- Documented adverse effect, drug interaction, or contraindication to the Tier-1 products

SSRIs (SELECTIVE SEROTONIN REUPTAKE INHIBITORS)

- Tier-1 products are covered—no authorization is necessary.
- Tier-2 authorization requires one 4-week trial of a Tier-1 product within the last 100 days.
- Paroxetine requires authorization for clients under age 18.

TIER-1 (NO PA REQUIRED)	TIER-2 (REQUIRES PA)
fluvoxamine (Luvox)	citalopram (Celexa)
paroxetine (Paxil, Paxil CR, Pexeva)	escitalopram (Lexapro)
fluoxetine 10mg & 20mg caps (Prozac)	fluoxetine (Sarafem)
sertraline (Zoloft)	



Visit the OHCA secure provider website:

<https://www.OHCAprovider.com>

Oklahoma Medicaid Pharmacy Help Desk

Pharmacies Call: Physicians Call:

OKC Metro: (405) 271-6349 (405) 271-9048
 Statewide Toll-Free: (800) 831-8921 (877) 269-2728



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