



***The Bulletin of  
Medicaid Drug  
Utilization Review  
in Iowa***

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**Off-Label Pharmaceutical Marketing: How to Recognize and Report It**

The use of pharmaceuticals for unapproved symptoms or conditions, in unapproved patient groups, or in unapproved dosages, is referred to as “off-label” use. Promotion of such off-label use by pharmaceutical manufacturers is among the top four types of drug promotion problems identified by the U.S. Food and Drug Administration (FDA).

**Off-Label Promotion and the False Claims Act**

Unlawful off-label drug promotion has been the subject of significant health care fraud enforcement efforts by the United States Department of Justice (DOJ) and the State attorneys general using the Federal False Claims Act. The theory underlying these efforts is that, by promoting off-label uses that are not medically accepted, the manufacturers caused pharmacies to claim Medicaid payment for drugs used in ways that are not covered by Medicaid. Most, if not all, State Medicaid programs exclude coverage for drugs that are used in off-label indications that are not medically accepted. DOJ and State enforcement efforts have identified a wide range of deceptive practices that promoted off-label uses of many prescription drugs. These practices have resulted in large monetary settlements with a number of pharmaceutical manufacturers.

**How to Recognize Unlawful Off-Label Promotion**

Unlawful off-label promotion by pharmaceutical manufacturers can take a number of different forms. These forms include the following:

- Paying incentives to sales representatives based on sales for off-label use;
- Paying kickbacks to physicians to prescribe drugs for off-label use;
- Disseminating misleading posters promoting off-label use;
- Paying physicians:
  - To serve as authors of articles about off-label uses written by manufacturers’ agents;
  - To serve as members of “advisory boards” promoting off-label use;
  - To travel to resort locations to listen to promotions about off-label use; or
  - To give promotional lectures in favor of off-label use to fellow practitioners;
- Providing advice to prescribers on how to code their claims and document their medical records to support payment for off-label uses not covered by Medicaid;
- Publicizing studies showing efficacy of off-label uses while suppressing studies showing no efficacy; and
- Making false representations directly to Medicaid to influence decisions about payment for drugs used off-label.

**How to Report Unlawful Off-Label Promotion**

Because of the potential for patient harm that some off-label drug uses can cause, and because of the potential waste of taxpayer funds when

Medicaid pays for off-label uses that are not medically accepted, it is important for health care professionals, manufacturers, and pharmaceutical representatives to report unlawful off-label promotion in Medicaid.

Individuals that recognize off-label drug promotion should report it to:

- The FDA at [BadAd@fda.gov](mailto:BadAd@fda.gov) or 855-RX-BadAd, 877-RX-DDMAC;
- The State Medicaid agency or Medicaid Fraud Control Unit at the contact numbers found on the list at [http://www.cms.gov/medicare-medicare-coordination/fraud-prevention/fraudabuseforconsumers/report\\_fraud\\_and\\_suspected\\_fraud.html](http://www.cms.gov/medicare-medicare-coordination/fraud-prevention/fraudabuseforconsumers/report_fraud_and_suspected_fraud.html) on the Centers for Medicare & Medicaid website; or
- The U.S. Department of Health and Human Services, Office of Inspector General, at [HHSTips@oig.hhs.gov](mailto:HHSTips@oig.hhs.gov) or 1-800-447-8477 (1-800-HHS-TIPS).

Obtained from the CMS website at: <http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf>. Accessed 10/31/2014.

## How to Dispose of Unused Medications

The Drug Enforcement Administration (DEA) has announced a new regulation permitting consumers to return unused medications to authorized collectors, including pharmacies, beginning in October 2014. The decision comes after increasing concern over the rise in abuse rates for prescription drugs. The new regulation covers drugs designated as controlled substances which previously could only be disposed of by patients themselves or surrendered to law enforcement. Patients and their relatives will now also be allowed to mail unused drugs to authorized collectors using packages available at pharmacies and other locations. The program will be voluntary, and pharmacies may choose to register with the DEA to take back controlled substances or to receive them through the mail. See the news release for more information at <http://www.justice.gov/dea/divisions/hq/2014/hq090814.shtml>.

## FDA Updates

**REVLIMID** - Approval of updates to the Warnings and Boxed Warning sections of the prescribing information to include information on the risk of arterial thromboembolism. The Boxed Warning already included information on the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism). The updated Boxed Warning also states that there is an increased risk of myocardial infarction and stroke in patients with multiple myeloma receiving REVLIMID with dexamethasone. Further, the prescribing information now states that anti-thrombotic prophylaxis is recommended; whereas it previously stated that the decision to take prophylactic measures should be made carefully after an assessment of an individual patient's underlying risk factors.

**CHANTIX** - Approval of updates to the prescribing information to provide two new warnings, seizures and an interaction with alcohol, and additional clinical trial data. Reports of new-onset or recurrence of seizures have occurred with CHANTIX, and these events occurred most commonly in the first month of the therapy. In addition, there have been post-marketing reports of patients experiencing increased intoxicating effects of alcohol while taking CHANTIX, with some patients experiencing unusual and sometimes aggressive behavior. Finally, revisions were made to the warning regarding neuropsychiatric symptoms and suicidality to include pooled data from clinical trials and data from observational trials. The results of a meta-analysis of five randomized, double-blind trials showed no increase in the incidence of suicidal ideation and/or behavior in patients treated with CHANTIX compared to those treated with placebo. A further pooled analysis of 18 double-blind randomized trials found a similar incidence of common psychiatric events in patients treated with CHANTIX and placebo. Observational studies generally supported the conclusions of the randomized trials (although limitations to the observational studies were noted).

## New and Updated Drug Prior Authorization Criteria

**Pharmacy Prior Authorization:** The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity.

1. **Duplicate use** of drugs from the same therapeutic category or therapeutic duplication will not be considered.
2. **All required trials** must be of appropriate dose and duration for the indication and must be documented by the prescriber, on the request for prior authorization form, including dates, dose, and nature of failure.
3. **The use of pharmaceutical samples** (from the prescriber or manufacturer medication assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

**Omalizumab (Xolair)** – Added Chronic Idiopathic Urticaria indication and criteria (only new criteria listed below)

### **Chronic Idiopathic Urticaria**

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. Patient is 12 years of age or older; and
3. Patient has documentation of a trial and therapy failure with at least one second-generation antihistamine, one of which must be cetirizine at a dose of up to 20mg per day; and
4. Patient has documentation of a trial and therapy failure with at least one first-generation antihistamine; and
5. Patient has documentation of a trial and therapy failure with at least one potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
6. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first-or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the needed for continued therapy.

## Coverage of Naloxone

**Effective October 1, 2014**, injectable naloxone will be a preferred drug on the Preferred Drug List (PDL) and may be prescribed as a rescue medication for a potentially life-threatening overdose. In addition, coverage of a mucosal atomization device (LMA MAD Nasal) will be available through the pharmacy Point of Sale (POS) system.

### **a) Stocking the Materials:**

- 2mg/ml naloxone (NDC 76329-3369-01) is available from pharmacy wholesalers.
- The LMA MAD Nasal is available from some wholesalers or directly from the manufacturer, Teleflex.

### **b) Billing:**

- Use NDC 76329-3369-01 to bill for 2mg/ml naloxone.
- Use NDC 99999-2718-02 to bill for the LMA MAD Nasal Mucosal Atomization Device without syringe. Reimbursement is \$5.75 per unit and no dispensing fee will be paid for claims for this item.
- The quantity limit for naloxone rescue prescriptions is two syringes (4mls) and two nasal mucosal atomization devices per 30 days.

**Medicaid Statistics for Prescription Claims**

**from July 1, 2014 to September 30, 2014\***

Number of claims paid: 1,063,606

Average amount paid per claim: \$64.26

Total dollars paid: \$68,350,517

Average amount paid per claim, brand: \$282.17

Percent generic prescriptions: 83%

Average Amount paid per claim, generic: \$19.57

<b>Top Drugs by Number of Prescriptions</b>	<b>Top Drugs by Dollars Spent</b>	<b>Top Therapeutic Class by Dollars Spent</b>
Hydrocodone/APAP 5-325mg \$14.16/RX	<i>Abilify</i> 20mg \$1,288,237 \$484.66/RX	Antipsychotics – Atypicals \$6.9 million
Ventolin HFA \$54.23/RX	<i>Lantus</i> Injection 100/ml \$1,275,288 \$192.35/RX	Stimulants – Amphetamines – Long Acting \$4.5 million
Loratadine 10mg \$9.03/RX	Methylphenidate ER 36mg \$1,128,249 \$178.29/RX	Anticonvulsants \$4.3 million
Cetirizine 10mg \$10.35/RX	<i>Abilify</i> 30mg \$1,011,284 \$498.17/RX	Stimulants- Methylphenidate- Long Acting \$3.1 million
Tramadol 50mg \$10.67/RX	<i>Ventolin HFA</i> \$969,476 \$54.23/RX	Antidepressants – Selected SSRIs \$2.5 million

\*All dollars reported are pre-rebate