

Wyoming Drug Utilization Review

Off-Label Use of Provigil®

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Modafinil (Provigil®) is a wakefulness-promoting agent with sympathomimetic actions similar to amphetamine and methylphenidate. Modafinil is FDA approved for excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder. Side effects include headache, back pain, nausea, diarrhea, nervousness, insomnia, anxiety, dizziness, and dyspepsia with discontinuation rates of 8% due to adverse effects. In addition, Stevens-Johnson syndrome, leukopenia and agranulocytosis have been reported, although rarely.¹

A review of Wyoming Medicaid claims from January 1, 2006 through February 28, 2007 was conducted. This review included 852 claims for 165 patients for a total cost of \$197,568. A large number of the claims reviewed were for off-label indications including multiple sclerosis, depression, schizoaffective disorder, manic depression, intracranial injury, and opioid-induced fatigue.

A review of available literature on the off-label uses of modafinil was accomplished using a MEDLINE search, contact with the manufacturer, and a search of www.clinicaltrials.gov. The results of this review are in Table 1 on this page.

Due to the lack of supporting evidence for off-label utilization, modafinil should be used with caution, if at all, for these conditions. The cost of potentially inappropriate utilization of medications diverts available dollars from more appropriate uses, including provider reimbursement, and may lead to additional limits on prescription drug coverage.

Table 1

Indication	Number of Trials	Conclusions
Major Depression ^{2,3}	2	No benefit
Seasonal Affective Disorder	0	
Multiple Sclerosis ^{4,5}	2	No benefit
Opioid-induced sedation ^{6,7}	2	No benefit
Brain Injury	0	
ADHD (adults) ^{8,9}	2	One study revealed no benefit, one study showed a benefit using a formulation that is not available in the U.S.
ADHD (Pediatrics) ^{10,11,12,13,14,15}	7	Two trials revealed a benefit, two trials revealed no benefit, three trials revealed a benefit using a formulation that is not available in the U.S. The FDA gave a not approvable letter in August 2006 due to serious side effects.
Cognitive performance during prolonged wakefulness ^{16,17,18,19,20}	5	Studies comparing modafinil to caffeine revealed no benefit.

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WY-DUR Board Meeting Update

The DUR Board met for its bimonthly business meeting on July 19, 2007. Highlights of this meeting include:

- The Department of Health gave an update on the regulation requiring the use of tamper resistant prescription pads effective October 1, 2007 for all Medicaid prescriptions. The Office of Pharmacy Services will write to Wyoming's Congressional delegation regarding their concerns. The intent of the bill was to require tamper resistant prescription pads for narcotics only, which is currently required in Wyoming. The Department will monitor the situation on the national level.
- Review and finalization of the antidepressant criteria was tabled until the September meeting as the Department continues to work on acceptable preferred drugs and prior authorization criteria for the class.
- A review of paliperidone was conducted with respect to its differences from risperidone. Based on review of the literature and current utilization, the Board recommended prior authorization for dosages above 6 mg daily, recipients under 18 years of age and diagnoses other than schizophrenia, bipolar and psychotic disorders. Prior authorization criteria will be drafted to reflect this recommendation and presented for Board approval in September. Following approval of the Board, the criteria will be released for public comment.
- The approval of Lyrica for fibromyalgia was discussed at length. It was determined that educational opportunities should be explored and presented in September. The Board recommended that Lyrica be approved for fibromyalgia.

Following the open portion of the meeting, the Board met for an annual planning session. The following revised mission statement and goals were approved:

Mission

The mission of the Wyoming Drug Utilization Review Board is to enhance quality of patient care by assuring appropriate drug therapy, optimal patient outcomes, and education for health care providers.

Goals

- Goal 1: Criteria and standards developed by WYDUR shall be clinically relevant and derived through evaluation of peer-reviewed literature, compendia, guidelines obtained from professional groups, health care providers, data and experience obtained by WYDUR.
- Goal 2: Criteria and standards developed by WYDUR shall be non-proprietary and shall be developed and revised through a consensus process. The criteria and standards development and revision process shall consider timely public comment before adoption.
- Goal 3: The costs of drug therapy shall be considered after clinical and patient considerations are addressed.
- Goal 4: WYDUR shall provide consistent education to providers and the public.

The next meeting will be held September 27, 2007 in Cheyenne, Wyoming. Items for discussion will include prior authorization criteria for antidepressants, prior authorization criteria for paliperidone and educational opportunities for fibromyalgia. An agenda will be available prior to the meeting at <http://www.uwyo.edu/DUR/>.

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Medication Donation Program

The Medication Donation Program was instituted during the 2005 legislative session. Any person/group/facility can donate unused/unopened medications at the locations listed below. Medications may be mailed or dropped off at any of the locations.

1. The Cheyenne Community Clinic at 3100 Henderson Drive in Cheyenne, WY 82001 (phone – 307-638-6841)
2. The Platte County Public Health Office at 718 9th St., Wheatland, WY 82201 (phone – 307-322-2740)
3. City of Casper/Natrona County Public Health Office at 475 S. Spruce St. in Casper, Wyoming 82601 (phone – 307-235-9340)
4. The Northwest Wyoming Family Planning Clinic at 231 Rumsey Ave in Cody, WY 82414 (phone – 307-527-5174)

Donations are limited to those medications which are unit or individually-dosed sealed packages. This means NO pill bottles with loose tablets can be accepted. Also, controlled (CII/III/IV) drugs, injectables, and those meds which require refrigeration cannot be accepted.

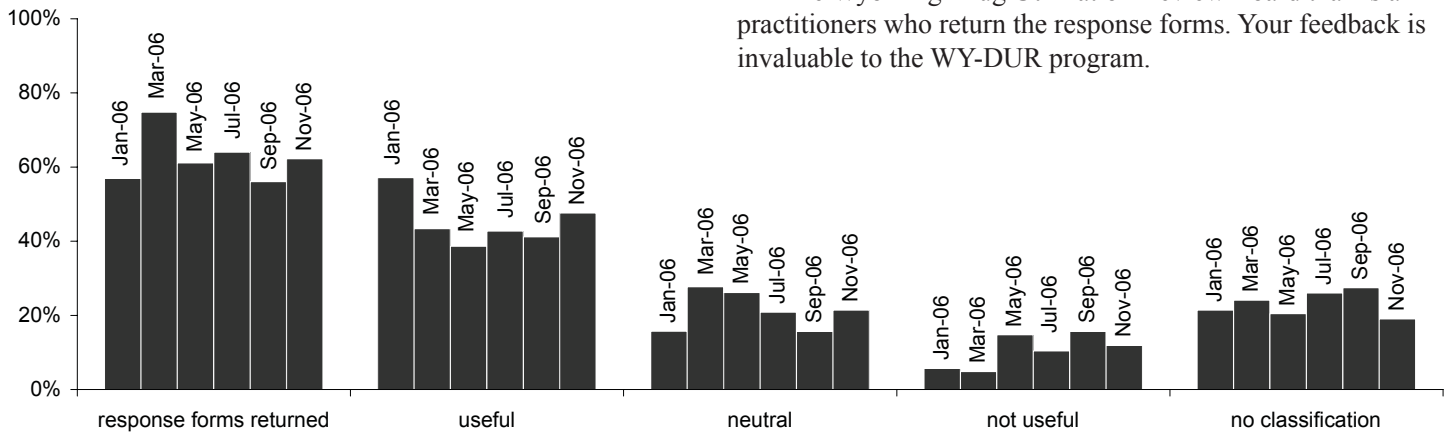
Over-the-counter meds and supplies including, but not limited to, bandages, drainage bags, and syringes are not subject to the provisions of this bill. Accepting such items is at the discretion of the individual participating donation site. We would very much appreciate you informing patients of this program. Please contact Donna Artery, Pharm.D. at the Wyoming Department of Health, Office of Pharmacy Services at 307-777-6923 if there are any questions concerning this program.

2006 Education Letter Responses

The Wyoming Drug Utilization Review Program sends out 6 cycles of education letters to prescribers each year. Each prescriber who receives an education alert letter is asked to complete and return a response form. In the response form, we ask the prescriber to classify the information in the alert letter as *useful*, *neutral*, or *not useful*.

The graph below shows the following information: the return rate for prescriber response forms for 2006, the percentage of returned provider response forms that fall into each of the 3 classifications (*useful*, *neutral*, and *not useful*), and the percentage of *no classification*, which is assigned if the provider fails to classify the information in the alert letter. Response rates are over 55% and responses are coded as either *useful* or *neutral* by over 60% of the respondents.

The Wyoming Drug Utilization Review Board thanks all practitioners who return the response forms. Your feedback is invaluable to the WY-DUR program.



Please contact WY-DUR at 307-766-6750 if you would like to have your name added or removed from our mailing list, or if you need to have your address updated. The WY-DUR newsletter is also available on-line at www.uwyo.edu/DUR/newsletters.

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