

Wyoming Drug Utilization Review

Overview of Tobacco Cessation Therapy

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In 2005, 21% of the adult population in Wyoming were smokers, with 16% admitting to smoking daily. This has decreased slightly since 2002 while the percentage of occasional smokers has stayed relatively constant. Smoking varies by age, income and education levels with the highest rates in those 18 – 34 years old, earning less than \$15,000 per year and with less than a high school education¹.

Wyoming Medicaid began covering products for tobacco cessation on January 1, 2007. These products include bupropion SR, varenicline and nicotine replacement therapy (NRT). This article provides an overview of tobacco cessation therapy.

Bupropion SR (Zyban®) is a dopamine/norepinephrine reuptake inhibitor that has proven to be an effective aid in tobacco cessation. The usual dose is 150 mg daily for three days followed by 150 mg twice daily. Patients should set a quit date and start bupropion seven to fourteen days prior to the quit date to ensure steady state levels are reached. Therapy should generally continue for at least three to six months. Bupropion may increase the risk for seizures and should be used with caution in patients with a history of seizures or eating disorders². Bupropion is a pregnancy category C and does enter breast milk³.

Varenicline (Chantix™) is a partial agonist at nicotinic acetylcholine receptors and has a greater affinity for the receptors than nicotine⁴. Nicotine addiction is thought to be mediated through the nicotinic acetylcholine receptors which stimulate release of dopamine. Varenicline works through agonistic activity (maintaining moderate levels of dopamine to decrease withdrawal symptoms) as well as antagonistic activity (decreas-

ing satisfaction from smoking). Varenicline has been shown to be three times more effective than placebo⁵.

The medication should be titrated up to a total dose of 1 mg twice daily beginning with 0.5 mg daily for three days, followed by 0.5 mg twice daily for days 4 – 7. The dose should be decreased for those with severe renal impairment. Varenicline should be started seven days prior to the quit date and should be continued for three to six months. Adverse effects associated with this medication are mild with nausea being reported most frequently. Mild physical dependence may occur with the use of varenicline; however, addiction and abuse have not been reported⁴. Varenicline is a pregnancy category C and excretion in breast milk is unknown³.

Nicotine replacement therapy (NRT) has been shown to almost double success in long-term smoking cessation⁶. NRT is available in a variety of dosage forms including patches, gum, lozenges, nasal spray and an oral inhaler. The patches provide a continuous nicotine dosage over sixteen to twenty-four hours depending on the brand used. The gum, lozenges, nasal spray and oral inhaler can be used as needed for cravings. Adverse effects are generally mild and include mouth and throat irritation, nausea, indigestion and insomnia depending on the dosage form chosen. Nicotine is a pregnancy category D, however, as with any drug, the risk of smoking should be weighed against the use of nicotine². Excretion in breast milk is unknown, however, nicotine from cigarette smoke is found in breast milk at concentrations 1.5 to 3 times higher than maternal plasma concentrations³.

Comparative studies: No evidence shows that one form of NRT is more effective than another⁵. Three studies showed varenicline to be more effective than bupropion⁶. Evidence shows that bupropion is more effective than the nicotine patch and bupropion plus the nicotine patch is more effective than the nicotine patch alone but not significantly more effective than bupropion alone⁵. A randomized, double-blind trial showed four week quit rates of 67% for bupropion plus nicotine, 60% for bupropion alone, 48% for nicotine alone and 34% for placebo. After twelve months, quit rates were 36% for combination therapy, 30% for bupropion alone, 16% for the nicotine patch and 16% for placebo². The number of patients needed to treat for one successful quitter is 8 for varenicline, 15 for bupropion and 20 for all forms of NRT⁶.

Combination therapy: Bupropion therapy may be combined with any form of NRT. Treatment emergent hypertension may occur in patients treated with bupropion and the nicotine patch². Nausea, headache, vomiting, dizziness, dyspepsia and fatigue occur more frequently with the combination of varenicline and nicotine than with either medication alone. In one study, discontinuation of therapy was much higher with varenicline plus NRT than with NRT and placebo⁴.

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WY-DUR Board Meeting Update

The DUR Board met for its bimonthly business meeting on March 29, 2007 via teleconference (due to inclement weather). Highlights of this meeting include:

- Smoking cessation coverage continues to receive a favorable response. At the time of the meeting, 125 clients had received medications for smoking cessation. Of 120 who were contacted, 20 reported quitting, 15 had cut down and 3 reported no change.
- Cerebral palsy will be added as an exception to current prior authorization for the anti-epileptic medications. Clients with cerebral palsy will no longer be required to obtain prior authorization for these medications.

Criteria for Coverage of Smoking Cessation Products

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ZYBAN and DIRECT GENERIC EQUIVALENT OF BUPROPION: Course of therapy should not exceed 84 days or 168 tablets.

CHANTIX: Course of therapy should not exceed 84 days or 168 tablets.

NICOTINE POLACRILEX (GUM): Course of therapy should not exceed 84 days or 735 pieces for the 2mg and 4 mg strengths, as well as for the lozenges.

NICOTINE TRANSDERMAL: Course of therapy for Nicotrol or generic equivalent: 15 mg patches should not exceed 42 days or 42 patches, 10 mg patches should not exceed 42 days or 42 patches, and the 5 mg patches should not exceed 14 days or 14 patches.

Course of therapy for Nicoderm or generic equivalent: 21mg patches should not exceed 42 days or 42 patches, and the 14 mg and 7 mg patches should not exceed 14 days or 14 patches each.

***Zyban or its generic equivalent can be used in conjunction with one course of a nicotine replacement product (i.e. gum or patches).

***Only one course of therapy is allowed in a 365 day period for each client. If a client tries to refill an above mentioned product once the maximum days supply or quantity has been used, the claim will deny. The client will then have to provide proof that he/she is receiving some behavior modification counseling or working with the Wyoming Department of Health Substance Abuse program's QuitNet or Quit Line before another course of treatment will be authorized.

- Prior authorization criteria for the ADHD/ADD medications and carisoprodol will be sent out for public comment in April. A letter will be sent to a random sample of providers in the state. In addition, the criteria will be posted on the website at www.uwyo.edu/DUR. If you do not receive a letter and wish to comment, please email comments to alewis13@uwyo.edu or lgm@uwyo.edu. In addition, comments may be mailed to

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- Age and quantity limits will be implemented for tramadol. Claims will be denied for those under 17 years of age. In addition, the immediate release formulation will be limited to 400 mg per day and the extended release formulation to 300 mg per day.

The next meeting will be held May 31, 2007 in Casper, Wyoming. Items for discussion will include prior authorization criteria for ADHD medications and carisoprodol, and off-label utilization of Provigil. An agenda will be available prior to the meeting at www.uwyo.edu/DUR.

Overview of Tobacco Cessation Therapy, continued

Tobacco smoke increases the metabolism of many drugs. Doses should be adjusted accordingly upon successful smoking cessation regardless of therapy with nicotine replacement therapy².

Wyoming Tobacco Cessation Resources: The Wyoming Quit Tobacco Program is a source of free or low-cost tobacco cessation medications, counseling and education to those who are ready to quit. The program can be reached at 1-800-QUIT-NOW (784-8669). Free counseling is provided through the 800 number as well as online at <http://wy.quitnet.com>⁷.

References

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Wyoming Formularies Available on Epocrates®

Wyoming Department of Health, Office of Pharmacy Services

The Wyoming Department of Health is excited to announce that their formularies can now be accessed through Epocrates® drug reference software using your mobile device (Palm, Pocket-PC, smartphone) or an Internet-connected computer. This service is available free of charge to all Wyoming medical doctors, nurse practitioners, and physician assistants beginning January 1, 2007.

By downloading the Epocrates® application to your handheld or through the Internet, you can check formulary status, prior authorization requirements, formulary alternatives, generic substitutes and quantity limits.

Emergency Supply of Prescription Medication

Pharmacies are able to dispense an emergency 72-hour supply of either a brand name medication with multi-source generics or a medication requiring prior authorization. In the event of an emergency and the ACS Clinical Call Desk is closed, the pharmacy is authorized to dispense up to a 72-hour emergency supply to the client by entering a med cert code 8 in the PA medical certification field, the first position of NCPDP field number 416. In the case of brand name medications, a Dispense As Written (DAW) code of 1 must be used. A med cert code 8 can be used once for each drug per month. A dispensing fee will not apply.

A Very Important Message on Payments from Medicaid

Have you gotten your NPI number yet? Don't forget that **ALL** pharmacy claims will require the Pharmacy Provider's NPI number in order for pharmacies to receive payment for claims submitted starting May 23, 2007. Each pharmacy facility, whether corporate or independent, will need its own NPI number and an updated provider agreement on file with Wyoming Medicaid in order for pharmacy claims to pay starting May 23, 2007.

Provider enrollment packets were sent out at the end of January 2007. If you did not receive one or have lost it, please contact ACS at 1-800-251-1268 or visit their website at <http://wyequalitycare.acs-inc.com/> to obtain another one. **It is extremely important that the Wyoming Medicaid fiscal agent, ACS, receive updated provider forms with NPI numbers prior to May 23, if you want your pharmacy claims to pay after the May 23, 2007 NPI implementation deadline.**

Questions? Contact ACS 1-800-251-1268 or the Office of Pharmacy Services at 1-800-438-5785.

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.

Instructions for downloading the formulary:

1. Go to: www.epocrates.com.
2. Log into account or register.
3. For handhelds, click "Edit formularies" link in the Account section.

For online desktop product, click "Epocrates Online" at the top right hand side of any Epocrates® web page. Click on menu bar to the right of "Select formulary." Scroll down and choose "[+] Add formulary."

4. Select the "Wyoming Medicaid" formulary (under "Wyoming" and "Health Plan").
5. Click on "Add to My List."
6. For handheld, click on "Done" and AutoUpdate your PDA to install the formularies.

For online desktop product, the formulary is available in the Formulary drop down menu.

Recent FDA Warnings

Xolair – The FDA has requested that Genentech add a boxed warning regarding the risk of anaphylaxis following treatment with Xolair. Anaphylaxis may occur after any dose of Xolair, even if the patient did not have an allergic reaction to the first dose. <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Xolair>

ADHD Medications – All manufacturers of ADHD medications have been directed to develop patient medication guides to alert patients of potential cardiovascular risks and the risk of psychiatric symptoms associated with these medications. <http://www.fda.gov/medwatch/safety/2007/safety07.htm#ADHD>

Rosiglitazone (Avandia) – Glaxo SmithKline announced that the results of a recent study (ADOPT) revealed that female patients who received rosiglitazone experienced significantly more fractures in the upper arm, hand and foot than those who received metformin or glyburide. <http://www.fda.gov/medwatch/safety/2007/safety07.htm#rosiglitazone>

A similar warning was released for pioglitazone (Actos). <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Actos>

Sedative-hypnotics – The FDA has requested that manufacturers of sedative-hypnotics strengthen their labeling to include language concerning potential risks including severe allergic reactions and complex sleep-related behavior such as sleep driving. <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Sedative>

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