



# IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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**To: Susan Parker, R.Ph., Pharm.D.**

**From: The Iowa Medicaid Drug Utilization Review Commission**

**Regarding: The Iowa Medicaid Smoking Cessation Program**

**Date: February 8, 2011**

Enclosed please find a copy of report to the Department relative to the Iowa Medicaid Smoking Cessation Program.

This report is divided into three sections: Background, Program Results, and DUR Review and Recommendations.

## **Background**

### **A. Program Review**

- The 2005-2006 General Assembly passed HF825 and HF841 requesting that the Department expand coverage under the medical assistance program to cover smoking cessation drugs. This was to be done in collaboration with the Iowa Department of Public Health programs relating to tobacco use prevention and cessation.
- Iowa Medicaid requested that the Iowa Medicaid Drug Utilization Review (DUR) Commission develop prior authorization criteria for the smoking cessation program incorporating counseling through Quitline Iowa. (Studies have shown that smoking cessation programs that incorporate counseling in conjunction with medication therapy have higher success rates.)
- The Pharmaceutical and Therapeutics (P&T) Committee were requested to review the smoking cessation products for inclusion on the Preferred Drug List.
- Effective January 1, 2007, the Iowa Medicaid Program expanded coverage to include select over-the-counter nicotine replacement patches and gum, and generic bupropion sustained-release (SR) products that are FDA-indicated for smoking cessation (generic Zyban®). Effective April 5, 2010, bupropion 150mg sustained-release products that are FDA-indicated for smoking cessation (generic Zyban®) require a prior authorization (PA). Prior to April 5, 2010, it was available without prior authorization. Over-the-counter nicotine replacement patches and gum are covered with a prior authorization.

- The Iowa Medicaid DUR Commission reviewed the clinical information available for varenicline (Chantix™) on several occasions and had recommended to the Department of Human Services the drug not be covered until more safety and efficacy data were made available. Specifically, the Commission was interested in seeing safety and efficacy data on varenicline (Chantix™) used in medically complex patients with multiple chronic conditions that more closely resembled the Medicaid population. To date, such data is not available. The Department of Human Services made the decision, however, to provide coverage of varenicline (Chantix™) since safety and efficacy had already been proven as part of the Food and Drug Administration's (FDA) approval process. Therefore, effective February 18, 2008, the Iowa Medicaid Program again expanded coverage to include the prescription product, varenicline (Chantix™) with a prior authorization.
- Section 4107 of HR 3590 requires coverage of all approved non-prescription nicotine replacement (NRT) for pregnant Medicaid members. Effective October 1, 2010, nicotine lozenges were added to the list of covered NRT products for all members for simplicity of administration.

#### B. Prior Authorization (PA) Criteria for Nicotine Replacement Therapy and Smoking Cessation Therapy

Following recommendations from both the DUR and P&T Committees, the prior authorization criterion were established as follows:

Prior Authorization is required for over-the-counter nicotine replacement patches, gum and lozenges. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline program for counseling.
- 2) Confirmation of enrollment in the Quitline counseling program is required for approval.
- 3) Approvals will only be granted for patients eighteen years of age and older.
- 4) The maximum allowed duration of therapy is twelve weeks within a twelve-month period.
- 5) Patients may receive nicotine replacement patches in combination with one of the oral nicotine replacement products (gum or lozenges). A maximum quantity of 14 nicotine replacement patches and 110 pieces of nicotine gum or 144 nicotine lozenges may be dispensed with the initial prescription. Subsequent prescription refills will be allowed to be dispensed as a 4-week supply at one unit per day of nicotine replacement patches and 330 pieces of nicotine gum or 288 nicotine lozenges. Following the first 28 days of therapy, continuation is available only with documentation of ongoing participation in the Quitline program.
- 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation

Prior Authorization is required for varenicline (Chantix™) or bupropion SR that is FDA approved for smoking cessation. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline program for counseling.

- 2) Confirmation of enrollment and ongoing participation in the Quitline counseling program is required for approval and continued coverage.
- 3) Approvals will only be granted for patients eighteen years of age and older.
- 4) The duration of therapy is initially limited to twelve weeks within a twelve-month period. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment will be considered with a prior authorization request. The maximum duration of approvable therapy is 24 weeks within a twelve-month period.
- 5) Requests for varenicline to be used in combination with bupropion SR or nicotine replacement therapy will not be approved.
- 6) The 72-hour emergency supply rule does not apply for drugs used for the treatment of smoking cessation

### C. Prior Authorization (PA) Process

- Iowa Medicaid members who want assistance in quitting smoking need to be referred to Quitline by their healthcare provider.
- If it is determined that the member would benefit from using over-the-counter nicotine replacement patches and/or gum, a Nicotine Replacement Therapy Prior Authorization form must be completed by the member and the prescriber. Alternatively, if it is determined that the member would benefit from using varenicline (Chantix™) or bupropion SR that is FDA indicated for smoking cessation, a Smoking Cessation Therapy - Oral Prior Authorization form must be completed by the member and the prescriber. The completed form(s) is then faxed to Quitline. Quitline will follow up with the member and assess the member's smoking cessation counseling needs.
- Following this initial consultation, Quitline will submit the prior authorization request to the Iowa Medicaid Pharmacy Prior Authorization Unit for coverage of the necessary smoking cessation products.
- In the event that the member chooses to disenroll from the Quitline program, all approved prior authorizations will be cancelled and notification will be faxed to the provider and pharmacy, while a letter will be mailed to the member.

## **Program Results**

### Quitline Program

National Jewish Medical and Research Center began providing Quitline services for the Iowa Department of Public Health (IDPH) on January 1, 2008. The University of Northern Iowa has partnered with National Jewish to evaluate participant satisfaction and quit rates. The relationship between Iowa Medicaid and IDPH is a collaborative effort to provide smoking cessation products through Medicaid and counseling services through IDPH (via the contractual relationship with National Jewish Medical Center) to those who qualify for Iowa Medicaid.

Current literature for all populations, not solely Medicaid members, that examine quit rates for various interventions reports that the odds ratio of maintaining abstinence from smoking at six months following multiple proactive call back counseling sessions after contact was initiated by a motivated quitter

(similar to how the Quitline program works) is 1.41.<sup>1</sup> It has also been found that higher intensity disease management is associated with higher abstinence from smoking.<sup>2</sup> When smoking cessation counseling is combined with drug therapy, the odds of achieving cessation are often times doubled.

When looking at the odds ratio of maintaining abstinence from smoking six months after using pharmacotherapy, current literature (not exclusively looking at a Medicaid population) report the following: nicotine patches – 1.9; nicotine gum – 1.5; bupropion SR – 2.0, and varenicline – 3.1.<sup>3</sup> Some studies have compared varenicline with nicotine replacement. In an open-label randomized trial of 757 smokers, the four-week continuous abstinence rate at the end treatment was higher for the varenicline group (56%) compared to the nicotine patch group (43%). Continuous abstinence rates through week 52 narrowed to 26% versus 20% respectively.<sup>4</sup>

Quitline received 4,760 faxed referrals for Iowa Medicaid members between October 1, 2009 and September 30, 2010. From these referrals, 2,855 members were enrolled in the Quitline program. From October 1, 2009 through August 31, 2010, 3,943 members were disenrolled from the Quitline program. (This represents only 11 months of disenrolls due to Quitlines inability to report the number of disenrolls from the month of September 2010 forward). The inability to reach the member was a barrier to the enrollment process as Quitline counselors often received constant busy signals, invalid phone numbers, or disconnected phones. For the specified time period above, 1,323 (28%) members could not be reached by the Quitline counselors, 221 (5%) members declined enrollment, and 361 (8%) members requested information only. Compared to data from last year, 1,659 (30%) members could not be reached by the Quitline counselors, 222 (4%) members declined enrollment, and 253 (5%) members requested information only.

The evaluation of Quitline is conducted by the University of Northern Iowa Center for Social and Behavioral Research (CSBR). As a part of this evaluation, CSBR conducts follow-up interviews with Quitline Iowa callers. On July 1, 2010, the protocol for the follow-up interviews changed. This change was mandated by the US Centers for Disease Control and Prevention (CDC). The original protocol (implemented prior to July 1, 2010) included follow-up calls to three cohorts of participants: one at 3 months following their first call to Quitline, one at 6 months, and one at 12 months. On July 1, 2010, the protocol changed to include only one cohort of participants, contacted 7 months after their first call to Quitline. In addition, the questionnaire used for the follow-up interview was changed.

Due to changes in the protocol, the following data is presented as the original protocol (October 1, 2009 through June 30, 2010) and the new protocol (July 1, 2010 through September 30, 2010). Numbers reported are not unique members.

#### *Original Protocol – October 1, 2009 through June 30, 2010*

Due to the small sample size of relevant evaluation participants who are classified as Medicaid clients, results from all three groups of participants are presented together in this section. Smoking status was assessed by the following question: “During the past 30 days, on how many days did you smoke

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<sup>1</sup> Meites, Elissa. Telephone Counseling Improves Smoking Cessation Rates. *Am Fam Physician*. 2007; 75(5): 650.

<sup>2</sup> Ellerbeck EF, Mahnken JD, Cuperjino AP et al. Effect of varying levels of disease management on smoking cessation : a randomized trial. *Ann Intern Med*. 2009;150(7):437-46

<sup>3</sup> Fiore, MC, Jaen, CR, Baker, TB, et al. Treating tobacco use and dependence: 2008 update. US Department of Health and Human Services 2008. [www.surgeongeneral.gov/tobacco/treating\\_tobacco\\_use08.pdf](http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf) (Accessed on December 16, 2010).

<sup>4</sup> Aubin, HJ, Bobak, A, Britton, JR, et al. Varenicline versus transdermal nicotine patch for smoking cessation: results from a randomized open-label trial. *Thorax* 2008; 63:717.

cigarettes?” Participants who said they had not smoked on any of the past 30 days were considered to have quit smoking.

Overall, 1,512 people completed follow-up interviews. Of those 1,512 participants, 300 (19.8%) were classified as being Medicaid clients of Quitline. Of these 300 participants:

- 293 (99.0%) said they smoked cigarettes around the time of their first call to Quitline
- Of these 293 participants, 66 (22.7%) said they had not smoked cigarettes on any of the past 30 days at follow-up.
  - 296 participants (23.6%) provided an answer to the question “how many times did you speak with a Quitline representative?”
    - 1 time: 39 (14.5%)
    - 2 times: 50 (17.1%)
    - 3 to 5 times: 93 (31.7%)
    - 6 to 10 times: 57 (19.5%)
    - More than 10 times: 30 (10.2%)
  - Of the 180 participants who said they spoke with a Quitline representative 3 or more times, 42 (23.3%) reported they had not smoked cigarettes on any of the past 30 days at follow-up.

#### *New Protocol – July 1, 2010 through September 30, 2010*

Tobacco use status was assessed using several questions. The following question was used in this analysis: “Have you smoked any cigarettes or used other tobacco, even a puff or a pinch, in the last 30 days?” Participants who answered no were classified as having quit using tobacco.

Overall, 442 follow-up interviews with the new protocol were completed with Quitline Iowa callers. Of those 442 participants, 195 (44.1%) were classified by Quitline as being Medicaid referred callers.

- Of these 195 Medicaid-referred participants, 58 (29.2%) said they had not used any tobacco in the 30 days prior to the follow-up interview.

In summary, of the 495 participants identified as Medicaid referrals, 124 (25%) said they had not smoked cigarettes during the past 30 days at follow-up. Interestingly, cessation rates appear to be higher with the new protocol than the previous protocol (29.2% vs. 22.7%).

#### Prior Authorization Program

For the time period of October 1, 2009 through September 30, 2010, 7,701 Prior Authorizations (PA) were approved for smoking cessation products out of a total of 11,667 requests or 66% were approved. Reasons for denial of the PA include: the member was under 18 years of age, the member was not enrolled in Quitline, the PA request form was incomplete, the PA request was for a Medicare covered product for a dual eligible, or the member had disenrolled from Quitline. There were also 25 PA requests for noncovered products; one of which resulted in a request for an Exception to Policy which was not granted.

For this time period of October 1, 2009 through September 30, 2010, members received a total of 5,897 prescriptions for smoking cessation products at a total cost (federal and state dollars before rebates) of \$508,540.48. Additional costs for administration of the Quitline Iowa program would be incurred by the Iowa Department of Public Health.

**October 1, 2009 through September 30, 2010**

	<b>Number of Prescriptions</b>	<b>Number of PAs Approved</b>	<b>Amount Paid†</b>
Bupropion SR	60	6/14 *(43%)	\$3,955
Nicotine Replacement Therapy	2,878	3,614/ 4,995 (72%)	\$132,342
Chantix	2,959	4,081/6,658 (61%)	\$372,243
<b>Total</b>	<b>5,897</b>	<b>7,638/11,667 (65%)</b>	<b>\$508,540</b>

\*Effective April 5, 2010, PA required

† Total dollars pre-rebate (state and federal)

**DUR Review and Recommendations**

The Commission continues to evaluate the safety and efficacy data that becomes available for varenicline (Chantix™). At their meeting held in September 2008, the Commission reviewed new safety information relative to use of varenicline in various mental health disorders. The clinical prior authorization criteria were reviewed and compared to the Veteran’s Administration prior authorization criteria. The Commission came to the consensus that no recommended changes to the Medicaid clinical prior authorization criteria were required at this time. Also, the DUR Commission elected not to review the clinical PA criteria as part of the annual review of criterion during their meeting in August 2009 and October 2010. However, the Commission will continue to monitor safety data and other third party payers’ prior authorization criteria to determine if any changes would be appropriate in the future.

The Commission also reviewed the November 6, 2009 MMWR article *State Medicaid Coverage for Tobacco-Dependence Treatments – United States, 2007* at their meeting in December 2009. Although the article recommends open access to tobacco-dependence treatments without barriers or limitations in Medicaid populations, the Commission felt it was not appropriate for Iowa Medicaid to change the current smoking cessation program due to the low rate of requests for non-covered products and there have been no requests for use of smoking cessation therapy beyond the time limits currently in place.

The Commission recommends that Quitline continue to establish ways to collect better efficacy data on the program and specific product efficacy and utilization data including adverse drug reactions from covered medications specific to the Iowa Medicaid population. In addition, the Commission recommends that Quitline continue to develop strategies to identify and resolve communication barriers with Iowa Medicaid enrollees. At this time, the Commission has no recommended changes on the products currently covered under the smoking cessation program.

The Iowa Medicaid DUR Commission appreciates the opportunity to make these recommendations to the Department.

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Attachments (3)

# Smoking Cessation PA Statistics

	Nicotine Patches						Nicotine Gum						Chantix						Bupropion													
	Approved		Denied		Incomplete		Approved		Denied		Incomplete		Approved		Denied		Incomplete		Not Required		Total		Approved		Denied		Incomplete		Not Required		Total	
Oct-09	231	63.64%	122	33.61%	1 of the original 122 denials ended up getting a pa	10	2.75%	13	72.22%	5	27.78%	0 of the original 5 denials ended up getting a pa	0	0.00%	312	52.97%	227	38.54%	48	8.15%	2	0.34%							589			
Nov-09	301	78.39%	67	17.45%	2 of the original 67 denials ended up getting a pa	16	4.17%	17	70.83%	6	25.00%	1 of the original 6 denials ended up getting a pa	1	4.17%	368	68.66%	129	24.07%	35	6.53%	4	0.75%							536			
Dec-09	279	62.84%	150	33.78%	8 of the original 150 denials ended up getting a pa	15	3.38%	13	34.21%	23	60.53%	1 of the original 23 denials ended up getting a pa	2	5.26%	433	53.00%	333	40.76%	41	5.02%	10	1.22%							817			
Jan-10	244	66.85%	105	28.77%	10 of the original 105 denials ended up getting a pa	16	4.38%	22	68.75%	10	31.25%	1 of the original 10 denials ended up getting a pa	0	0.00%	341	60.89%	175	31.25%	42	7.50%	2	0.36%							560			
Feb-10	335	79.76%	68	16.19%	6 of the original 66 denials ended up getting a pa	17	4.05%	20	64.52%	9	29.03%	2 of the original 9 denials ended up getting a pa	2	6.45%	417	61.32%	206	30.29%	40	5.88%	17	2.50%							680			
Mar-10	367	74.75%	100	20.37%	9 of the original 100 denials ended up getting a pa	24	4.89%	23	67.65%	11	32.35%	0 of the original 11 denials ended up getting a pa	0	0.00%	437	61.29%	231	32.40%	38	5.33%	7	0.98%							713			
Apr-10	333	74.16%	102	22.72%	12 of the original 102 denials ended up getting a pa	14	3.12%	21	58.33%	13	36.11%	4 of the original 13 denials ended up getting a pa	2	5.56%	416	66.77%	169	27.13%	32	5.14%	6	0.96%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	
May-10	269	73.50%	82	22.40%	10 of the original 82 denials ended up getting a pa	15	4.10%	20	71.43%	8	28.57%	0 of the original 8 denials ended up getting a pa	0	0.00%	320	65.31%	136	27.76%	28	5.71%	6	1.22%	1	50.00%	1	50.00%	0	0.00%	0	0.00%	2	
Jun-10	364	72.37%	120	23.86%	1 of the original 120 denials ended up getting a pa	19	3.78%	22	57.89%	14	36.84%	0 of the original 14 denials ended up getting a pa	2	5.26%	309	54.02%	230	40.21%	29	5.07%	4	0.70%	0	0.00%	1	33.33%	2	66.67%	0	0.00%	3	
Jul-10	203	78.68%	44	17.05%	7 of the original 44 denials ended up getting a pa	11	4.26%	6	54.55%	5	45.45%	1 of the original 5 denials ended up getting a pa	0	0.00%	234	71.78%	63	19.33%	23	7.06%	6	1.84%	1	50.00%	0	0.00%	1	50.00%	0	0.00%	2	
Aug-10	252	71.79%	88	25.07%	3 of the original 88 denials ended up getting a pa	11	3.13%	11	42.31%	15	57.69%	0 of the original 15 denials ended up getting a pa	0	0.00%	256	57.92%	143	32.35%	29	6.56%	14	3.17%	0	0.00%	0	0.00%	2	100.00%	0	0.00%	2	
Sep-10	236	86.45%	24	8.79%	2 of the original 24 denials ended up getting a pa	13	4.76%	12	100.00%	0	0.00%	N/A	0	0.00%	238	76.77%	54	17.42%	11	3.55%	7	2.26%	4	80.00%	0	0.00%	0	0.00%	1	20.00%	5	
<b>Total</b>	<b>3414</b>		<b>1072</b>			<b>181</b>		<b>200</b>		<b>119</b>			<b>9</b>		<b>4081</b>		<b>2096</b>		<b>396</b>		<b>85</b>		<b>6658</b>	<b>6</b>		<b>2</b>		<b>5</b>		<b>1</b>		<b>14</b>
<b>Average</b>	<b>285</b>	<b>73.60%</b>	<b>89</b>	<b>22.50%</b>		<b>15</b>	<b>3.90%</b>	<b>17</b>	<b>63.56%</b>	<b>10</b>	<b>34.22%</b>		<b>1</b>	<b>2.23%</b>	<b>340</b>	<b>62.56%</b>	<b>175</b>	<b>30.12%</b>	<b>33</b>	<b>5.96%</b>	<b>7</b>	<b>1.36%</b>	<b>555</b>	<b>1</b>	<b>30.00%</b>	<b>0</b>	<b>13.89%</b>	<b>1</b>	<b>36.11%</b>	<b>0</b>	<b>3.33%</b>	<b>2</b>

# Smoking Cessation Prescription and Paid Dollar Amounts\*

	Nicotine Patches		Nicotine Gum		Bupropion		Chantix		Total Monthly Paid Amount for Patches, Gum, Bupropion, and Chantix
	Number of Prescriptions	Amount Paid	Number of Prescriptions	Amount Paid	Number of Prescriptions	Amount Paid	Number of Prescriptions	Amount Paid	
<b>Oct-09</b>	170	\$7,823.65	10	\$498.92	12	\$767.99	238	\$28,029.40	\$37,119.96
<b>Nov-09</b>	215	\$9,726.58	11	\$518.72	10	\$654.00	230	\$26,775.75	\$37,675.05
<b>Dec-09</b>	197	\$9,105.18	15	\$657.75	8	\$466.24	290	\$33,970.75	\$44,199.92
<b>Jan-10</b>	180	\$8,227.80	21	\$966.51	10	\$715.87	246	\$30,799.50	\$40,709.68
<b>Feb-10</b>	235	\$11,005.00	17	\$823.66	6	\$397.28	297	\$38,213.12	\$50,439.06
<b>Mar-10</b>	299	\$13,560.69	22	\$967.85	13	\$916.43	340	\$43,422.59	\$58,867.56
<b>Apr-10</b>	322	\$14,631.45	25	\$1,058.42	0	\$0.00	325	\$41,751.53	\$57,441.40
<b>May-10</b>	223	\$10,401.42	18	\$806.53	0	\$0.00	271	\$34,617.91	\$45,825.86
<b>Jun-10</b>	241	\$11,322.36	20	\$854.92	0	\$0.00	255	\$32,440.40	\$44,617.68
<b>Jul-10</b>	231	\$10,896.83	15	\$686.37	0	\$0.00	180	\$23,876.16	\$35,459.36
<b>Aug-10</b>	245	\$11,116.50	11	\$484.12	0	\$0.00	194	\$25,971.78	\$37,572.40
<b>Sep-10</b>	128	\$5,886.34	7	\$314.22	1	\$37.63	93	\$12,374.36	\$18,612.55
<b>Total</b>	2686	123704	192	\$8,637.99	60	\$3,955.44	2959	\$372,243.25	\$508,540.48
<b>Average</b>	224	\$10,308.65	16	\$719.83	5	\$329.62	247	\$31,020.27	\$42,378.37

\* This report reflects total numbers for all Smoking Cessation prescriptions, including Iowa Care.



# Smoking Cessation Total Prescriptions, Unique Client Count, and Disenrolled

	Total Prescription for Patches, Gum, Bupropion, and Chantix	Total Monthly Unique Client Count Per Month for Patches, Gum, Bupropion, and Chantix	Disenrolled
Oct-09	430	378	439
Nov-09	467	400	227
Dec-09	510	412	574
Jan-10	457	402	269
Feb-10	475	556	585
Mar-10	674	557	437
Apr-10	672	563	395
May-10	512	446	344
Jun-10	516	440	309
Jul-10	426	343	246
Aug-10	450	359	118
Sep-10	229	206	Not Available
<b>Total</b>	<b>5818</b>	<b>5062</b>	<b>3943</b>
<b>Average</b>	<b>485</b>	<b>422</b>	<b>358</b>