



STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
PATTY JUDGE, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
EUGENE I. GESSOW, DIRECTOR

January 15, 2009

Michael Marshall
Secretary of Senate
State Capitol
LOCAL

Mark Brandsgard
Chief Clerk of the House
State Capitol
LOCAL

Dear Mr. Marshall and Mr. Brandsgard:

Enclosed please find copies of reports to the General Assembly relative to the Iowa Medicaid smoking cessation benefit as prepared by the Iowa Medicaid Drug Utilization (DUR) Commission.

These reports were prepared pursuant to directive contained in Section 10 of Senate File 2425 which is listed below:

- The Drug Utilization Review Commission shall monitor the smoking cessation benefit provided under the medical assistance program and shall provide a report of utilization, client success, cost-effectiveness, and recommendations for any changes in the benefit to the persons designated in this Act to receive reports by January 15, 2009. If a prescriber determines that all smoking cessation aids on the preferred drug list are not effective or medically appropriate for a patient, the prescriber may apply for an exception to policy for another product approved by the United States Food and Drug Administration for smoking cessation pursuant to 441 IAC 5 1.8(1).

Members of the DUR Commission are appointed by the Department of Human Services and include health care professionals who possess knowledge and expertise in appropriate prescribing of drugs. The Commission meets eight times each year. Their purpose is advisory to DHS for the federally mandated retrospective drug utilization review program and for clinical prior authorization criteria development. Membership is as follows:

Member	Area of Clinical Expertise
Bruce Alexander, R.Ph., Pharm.D., BCPP	Pharmacy/Psychiatry
Mark Graber, M.D., FACEP	Emergency Medicine/Family Medicine
Laura Ann Griffith, D.O.	Occupational Medicine
Craig Logemann, R.Ph., Pharm.D., BCPS	Pharmacy/Family Medicine
Dan Murphy, R.Ph.	Pharmacy
Laurie Pestel, R.Ph., Pharm.D.	Pharmacy
Richard Rinehart, M.D.	Psychiatry
Sara Schutte-Schenck, D.O., FAAP	Pediatrics

The enclosed report was adopted by the members of the DUR Commission at their December 3, 2008 meeting following deliberations during their September and November (2008) meetings. The DUR Commission includes the evaluation of the Medicaid Smoking Cessation Program as part of their regular business and did not meet for the sole purpose of generating this report. Data exists to validate the clinical impacts of the recommendations made to the Department of Human Services.

The Department of Human Services has adopted the recommendations from the DUR Commission. Please contact me if I may be of further assistance.

Sincerely,

Molly Kottmeyer
Legislative Liaison

Enclosure

cc: Governor Chet Culver
Legislative Service Agency
Kris Bell, Senate Majority Caucus
Peter Matthes, Senate Minority Caucus
Zeke Furlong, House Majority Caucus
Brad Trow, House Minority Caucus



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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Pamela Smith, R.Ph.

To: The Iowa General Assembly
From: The Iowa Medicaid Drug Utilization Review Commission
Regarding: The Iowa Medicaid Smoking Cessation Program
Date: January 15, 2009

Enclosed please find copies of reports to the General Assembly relative to the Iowa Medicaid Smoking Cessation Program.

These reports were prepared pursuant to the directive contained in SF2425, which is listed below:

10. The Drug Utilization Review Commission shall monitor the smoking cessation benefit provided under the medical assistance program and shall provide a report of utilization, client success, cost-effectiveness, and recommendations for any changes in the benefit to the persons designated in this Act to receive reports by January 15, 2009. If a prescriber determines that all smoking cessation aids on the preferred drug list are not effective or medically appropriate for a patient, the prescriber may apply for an exception to policy for another product approved by the United States Food and Drug Administration for smoking cessation pursuant to 441 IAC 5 1.8(1).

This report by the Iowa Medicaid Drug Utilization Review (DUR) Commission is in response to a request by the Iowa General Assembly to monitor the smoking cessation benefit for Iowa Medicaid members. This review is performed on an ongoing basis to ensure all the elements of the legislation are met.

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®). Bupropion 150mg sustained-release products that are FDA-indicated for smoking cessation (generic Zyban®) are available without prior authorization (PA). 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.

B. Prior Authorization (PA) Criteria for Nicotine Replacement Therapy and Varenicline (Chantix™)

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 and nicotine gum. Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment in the Quitline Iowa 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) A maximum quantity of 14 nicotine replacement patches and/or 110 pieces of nicotine gum 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 /or 330 pieces of nicotine gum. Following the first 28 days of therapy,

continuation is available only with documentation of ongoing participation in the Quitline Iowa 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™). Requests for authorization must include:

- 1) Diagnosis of nicotine dependence and referral to the Quitline Iowa program for counseling.
- 2) Confirmation of enrollment and ongoing participation in the Quitline Iowa 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 that is FDA indicated for smoking cessation 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 Iowa 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™), a Varenicline (Chantix™) Prior Authorization form must be completed by the member and the prescriber. The completed form(s) is then faxed to Quitline Iowa. Quitline Iowa will follow up with the member and assess the member's smoking cessation counseling needs.
- Following this initial consultation, Quitline Iowa 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 Iowa 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 state of Iowa on January 1, 2008. The University of Northern Iowa has partnered with National Jewish to evaluate participant satisfaction and quit rates.

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 Iowa program works) is 1.41.¹ When smoking cessation counseling is combined with drug therapy, the odds of achieving cessation are often times doubled. When looking at the smoking cessation products available to Iowa Medicaid members, current literature (not exclusively looking at a Medicaid population) reports the odds ratio of maintaining abstinence from smoking six months after using pharmacotherapy are as follows: nicotine patches – 1.81; nicotine gum – 1.66; bupropion – 2.06. When compared to varenicline (Chantix™), the odds ratio of maintaining abstinence from smoking after 12 weeks of therapy ranges from 2.70 to 5.50.²

Quitline Iowa received 5,184 faxed referrals for Iowa Medicaid members between January 1, 2008 and September 30, 2008. From these referrals, 3,324 members were enrolled in the Quitline program. 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; 1,418 members could not be reached by the Quitline counselors, 201 members declined enrollment, and 241 members requested information only.

For the time period of January 1, 2008 through September 30, 2008, Quitline Iowa reports 3,324 Medicaid members that successfully enrolled in the smoking cessation program. Outcomes data of these members is highlighted below:

- Quitline Iowa reports 1,809 members dropped out of the Quitline program between January 1, 2008 through September 30, 2008, which is defined by the following scenarios:
 1. The counselors made multiple attempts to reach 1,362 members by phone and mail and the member did not call them back.
 2. 109 members made a conscious decision to not continue with the counseling and informed the counselor of that during their last counseling call.
 3. 338 members were disenrolled from the program due to completion of the entire program or successfully quitting smoking and requesting to be disenrolled, as they no longer felt they required assistance.
 4. 37 unique members re-enrolled in the Quitline program after originally dropping out. Of the 37 re-enrolled members, 18 were disenrolled from Quitline a second time due to completing the program during the second attempt (10) or dropping out of the counseling program (8). At the time of this report, 19 of the 37 members who re-enrolled were still actively participating.

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

² Nides, M. Update on Pharmacologic Options for Smoking Cessation Treatment. *Am J Medicine*. 2008; 121(4 suppl 1): S20-31.

- The University of Northern Iowa is responsible for completing follow-up interviews with Iowa Medicaid members who participated in the Quitline Iowa counseling program. They perform 3, 6, and 12 month follow-up interviews with a random sample of Medicaid members who participated in the program. This is done by a computer-assisted telephone interview lasting 7 – 9 minutes. At the time of this report, the University of Northern Iowa has completed surveys of 188 unique members enrolled in Quitline between July 1, 2008 and September 30, 2008. Of these 188 members, 47 (25%) completed eight or more counseling calls.
 - Of these 47 members, 42 individuals were considered smoke free at the completion of counseling, which is defined as not having had a cigarette in the 30 days prior to the follow-up interview.

The mean time of participation in the Quitline program for all Medicaid members who enrolled was 74.53 days. The mean time of participation in the Quitline program for Medicaid members who re-enrolled in the program was 68.46.

At this time, Quitline is unable to provide data on the number of unique individuals who were smoke free at 6 and/or 12 months.

Prior Authorization Program

For the time period of January 1, 2008 through September 30, 2008, members received a total of 6,067 prescriptions for smoking cessation products. Of this number, 4,316 prescriptions were for varenicline, 1,435 prescriptions were for nicotine patches, 155 for nicotine gum, and 161 for bupropion. The total cost (federal and state dollars before applicable rebates) for these smoking cessation products was \$568,541.63.

Through September 2008, 5,637 Prior Authorizations (PAs) were approved for varenicline (Chantix™), 1,547 PAs were approved for nicotine patches, and 124 PAs were approved for nicotine gum. Reasons for denials were: member was under 18 years of age, member was not originally enrolled in Quitline, the PA request form was incomplete, the PA request was for varenicline (Chantix™) and the member was dual eligible for Medicaid and Medicare Part D, or the member disenrolled from Quitline. There were 27 requests for noncovered products; two of which resulted in requests for an Exception to Policy, which were not granted.

DUR Review and Recommendations

The Commission continues to monitor utilization, client success, and cost effectiveness for the Iowa Medicaid Smoking Cessation Program. From January 1, 2008 through September 30, 2008, there were 1,671 prior authorizations for nicotine replacement products that have been approved for a total cost (federal and state dollars before applicable rebates) of \$72,756.74. There were 5,637 prior authorizations for varenicline (Chantix™) that have been approved for a total cost (federal and state dollars before applicable rebates) of \$482,540.59. In addition, \$13,244.30 (federal and state dollars before applicable rebates) was spent on 161 prescriptions for bupropion SR. The total cost (federal and state dollars before applicable rebates) for the program for drug therapy between January 1, 2008 and September 30, 2008 was \$568,541.63. There has also been an additional cost of \$102,083 during this time frame to administer the pharmacy prior authorization component of the smoking cessation program.

Any additional costs for administration of the Quitline Iowa program would be incurred by the Iowa Department of Public Health.

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. 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 recommends that Quitline continue to establish ways to collect better efficacy data on the program and product utilization. Specifically, long-term cessation data collected beyond three months of completion of the counseling program (i.e. at six months, nine months, and twelve months following the completion of the counseling program). This will aid in the Commission's future recommendations to the Department of Human Services as to what products should be included or excluded. 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 Iowa General Assembly.

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Attachments (3)

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	
Jan-08	271	\$12,223.11	24	\$950.06	29	\$2,754.74			\$15,927.91
Feb-08	160	\$7,205.38	12	\$550.88	24	\$2,440.41	33	\$3,417.12	\$13,613.79
Mar-08	181	\$8,390.74	16	\$732.09	23	\$1,909.36	503	\$56,508.57	\$67,540.76
Apr-08	158	\$7,389.67	23	\$1,037.14	19	\$1,660.00	774	\$86,292.88	\$96,379.69
May-08	122	\$5,564.81	17	\$781.98	21	\$1,461.92	744	\$83,777.45	\$91,586.16
Jun-08	131	\$6,119.90	18	\$815.80	8	\$501.19	588	\$65,382.79	\$72,819.68
Jul-08	136	\$6,328.68	16	\$733.10	13	\$938.08	614	\$68,921.84	\$76,921.70
Aug-08	147	\$6,740.95	11	\$490.68	17	\$1,111.50	569	\$63,529.41	\$71,872.54
Sep-08	129	\$5,871.46	18	\$830.31	7	\$467.10	491	\$54,710.53	\$61,879.40
Oct-08									
Nov-08									
Dec-08									
YTD Total	1435	\$65,834.70	155	\$6,922.04	161	\$13,244.30	4316	\$482,540.59	\$568,541.63
Average	159	\$7,314.97	17	\$769.12	18	\$1,471.59	540	\$60,317.57	\$63,171.29

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

Smoking Cessation PA Statistics

	Nicotine Patches						Nicotine Gum						Chantix						Total				
	Approved		Denied		Incomplete		Approved		Denied		Incomplete		Approved		Denied		Incomplete			Not Required			
Jan-08	211	38.93%	291	53.69%	12 of the original 291 denials ended up getting a pa	40	7.38%	25	37.31%	40	59.70%	0 out of the 40 denials ended up getting a pa	2	2.99%	Not Covered Until February 2008								
Feb-08	211	51.21%	181	43.93%	8 of the original 181 denials ended up getting a pa	20	4.85%	11	36.67%	18	60.00%	1 out of the original 18 denials ended up getting a pa	1	3.33%	77	72.64%	13	12.26%	16	15.09%	0	0.00%	106
Mar-08	203	78.38%	24	9.27%	5 of the original 24 denials ended up getting a pa	32	12.36%	19	76.00%	4	16.00%	1 of the original 4 denials ended up getting a pa	2	8.00%	1046	81.15%	34	2.64%	201	15.59%	8	0.62%	1289
Apr-08	181	87.44%	11	5.31%	9 of the original 11 denials ended up getting a pa	15	7.25%	18	85.71%	0	0.00%		3	14.29%	1036	83.68%	22	1.78%	135	10.90%	45	3.63%	1238
May-08	129	66.49%	48	24.74%	6 of the original 48 denials ended up getting a pa	17	8.76%	8	80.00%	1	10.00%	0 of the original 1 denial ended up getting a pa	1	10.00%	972	79.09%	93	7.57%	112	9.11%	52	4.23%	1229
Jun-08	141	58.02%	88	36.21%	8 of the original 88 denials ended up getting a pa	14	5.76%	11	55.00%	6	30.00%	0 of the original 6 denials ended up getting a pa	3	15.00%	571	61.66%	245	26.46%	84	9.07%	26	2.81%	926
Jul-08	168	88.89%	6	3.17%	6 of the original 6 denials ended up getting a pa	15	7.94%	12	63.16%	1	5.26%	0 of the original 1 denial ended up getting a pa	6	31.58%	763	85.73%	26	2.92%	79	8.88%	22	2.47%	890
Aug-08	176	78.92%	30	13.45%	1 of the original 30 denials ended up getting a pa	17	7.62%	12	70.59%	3	17.65%	0 of the original 3 denials ended up getting a pa	2	11.76%	674	75.14%	138	15.38%	70	7.80%	15	1.67%	897
Sep-08	127	85.81%	4	2.70%	0 of the original 4 denials ended up getting a pa	17	11.49%	8	100.00%	0	0.00%	0 of the original 0 denials ended up getting a pa	0	0.00%	498	85.13%	16	2.74%	58	9.91%	13	2.22%	585
Oct-08																							
Nov-08																							
Dec-08																							
YTD Total	1547		683			187		124		73			20		5637		587		755		181		7160
Average	172	64.00%	76	28.26%		21	7.74%	14	57.14%	8	33.64%		2	9.22%	705	78.73%	73	8.20%	94	10.54%	23	2.53%	895

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
2 0 0 8	Jan	324	255	326
	Feb	229	191	199
	Mar	723	662	23
	Apr	974	903	15
	May	904	855	124
	Jun	745	688	355
	Jul	779	727	15
	Aug	744	693	158
	Sep	645	599	15
	Oct			
	Nov			
	Dec			
YTD Total		6067	5573	1230
Average		674	619	137

Quitline did not report all disenrolls this month
Quitline did not report all disenrolls this month