



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 5, 2010

Enclosed please find copies of reports 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®). 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 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 Iowa program works) is 1.41.¹ It has also been found that higher intensity

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

disease management is associated with higher abstinence from smoking.² 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 – 1.81; 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 5.50.³ Currently, the only statistic available for the Chantix™ odds ratio is 12 weeks.

Quitline Iowa received 5,473 faxed referrals for Iowa Medicaid members between October 1, 2008 and September 30, 2009. From these referrals, 3,339 members were enrolled in the Quitline program. During the same time frame, 1,663 members were disenrolled from 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. For the specified time period above, 1,659 (30%) members could not be reached by the Quitline counselors, 222 (4%) members declined enrollment, and 253 (5%) members requested information only. Compared to data from last year, 1,418 (27%) members could not be reached by the Quitline counselors, 201 (4%) members declined enrollment, and 241 (5%) members requested information only. It should be noted, data from last year was only for a nine month time frame.

The University of Northern Iowa is responsible for completing follow-up interviews with Iowa Medicaid members who participated in the Quitline Iowa counseling program. Interviews assess whether the participant has “quit smoking”, which is defined as not having had a cigarette in the 30 days prior to the follow-up interview. Three groups of members are interviewed by the University of Northern Iowa: one at 3 months following their first call to Quitline, one at 6 months, and one at 12 months from a random sample of Medicaid members. Numbers reported are not unique members.

Overall, 4,426 people completed follow-up interviews. Of those 4,426 participants, 888 were classified as being Medicaid clients of Quitline. Of these 888 participants:

- 868 (99.2%) said they smoked cigarettes around the time of their first call to Quitline
- Of these 868 participants, 185 (21.1%) quit smoking
- 195 participants (23.6%) said they spoke with a Quitline representative 8 or more times.
 - Of these 195 participants, 50 (25.8%) quit smoking

In the 3-month cohort of the follow-up evaluation, 377 participants were classified as being Medicaid clients of Quitline. Of these 377 participants:

- 367 (98.9%) participants said they smoked cigarettes around the time of their first call to Quitline
 - Of these 367 participants, 86 (23.3%) quit smoking
- 68 participants (18.9%) said they spoke with a Quitline representative 8 or more times
 - Of these 68 participants, 22 (32.8%) quit smoking

In the 6-month cohort of the follow-up evaluation, 292 participants were classified as being Medicaid clients of Quitline. Of these 292 participants:

² 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

³ Nides, M. Update on Pharmacologic Options for Smoking Cessation Treatment. *Am J Medicine.* 2008; 121(4 suppl 1): S20-31.

- 287 (99.3%) participants said they smoked cigarettes around the time of their first call to Quitline
 - Of these 287 participants, 55 (19.0%) quit smoking
- 72 participants (26.9%) said they spoke with a Quitline representative 8 or more times
 - Of these 72 participants, 14 (19.4%) quit smoking

In the 12-month cohort of the follow-up evaluation, 219 participants were classified as being Medicaid clients of Quitline. Of these 219 participants:

- 214 (99.5%) participants said they smoked cigarettes around the time of their first call to Quitline
 - Of these 214 participants, 44 (20.3%) quit smoking
- 55 participants (27.6%) said they spoke with a Quitline representative 8 or more times
 - Of these 55 participants, 14 (25.5%) quit smoking

The mean number of contacts in the Quitline program for all Medicaid members who enrolled was five.

Prior Authorization Program

For the time period of October 1, 2008 through September 30, 2009, 6,852 Prior Authorizations (PA) were approved for smoking cessation products out of a total of 9,207 requests or 74% 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 12 PA requests for noncovered products; two of which resulted in requests for an Exception to Policy which were not granted.

For this time period of October 1, 2008 through September 30, 2009, members received a total of 5,682 prescriptions for smoking cessation products at a total cost (federal and state dollars before rebates) of \$512,403. Administration of the pharmacy prior authorization component of the smoking cessation program during this timeframe was \$102,083 total dollars (federal and state). Any additional costs for administration of the Quitline Iowa program would be incurred by the Iowa Department of Public Health.

	Number of Prescriptions	Number of PAs Approved	Amount Paid
Bupropion	112	N/A	\$7,056
Nicotine Replacement Therapy	2,263	2,625/ 3,278 (80%)	\$103,144
Chantix	3,307	4,227/5,929 (71%)	\$402,203
Total	5,682	6,852/9,207 (74%)	\$512,403

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. 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)