

Should Managed Care Organizations Pay for Nicotine Replacement Therapy?

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Because many managed care organizations (MCOs) do not routinely subsidize over-the-counter (OTC) medications, the recent approval of nicotine replacement therapy (NRT) for OTC use has led MCOs to question whether they should subsidize NRT. In this editorial, I suggest that MCOs should keep NRT on their formularies in order to offer effective, comprehensive smoking cessation programs to their customers.

Smoking and Nicotine Replacement: An Overview

Smokers Have Higher Healthcare Utilization Than Former Smokers. A large body of evidence supports that smokers who quit reduce their risk of lung cancer, coronary heart disease, and chronic lung disease.¹ A recent prospective study has specifically addressed the effects of smoking on health services in an HMO population.² Involving more than 2,500 smokers in randomized controlled trials, this study found that continued smoking was associated with an increase in inpatient and outpatient health services over a relatively short period of time. After just 5 years, smokers who did not quit had a 30%-40% increase in hospital admissions, a 75%-100% increase in hospital days, and a 7%-15% increase in outpatient visits. Even in an HMO setting, getting smokers to quit will lead to improved health and lower healthcare utilization.

Nicotine Replacement Therapy is Effective and Cost-Effective. There is no doubt that nicotine replacement is an effective therapy when given to smokers in the context of clinical trials. Two recent meta-analyses of

randomized controlled trials using NRT and at least brief behavioral counseling (including gum, patch, and nasal spray) concluded that NRT approximately doubled the smoking abstinence rates when compared with placebo.³ However, the absolute abstinence rates were only about 20% at 6 months for the active NRT groups. Put another way, four out of five smokers treated with nicotine replacement will ultimately fail. Like many other therapies used by physicians, nicotine replacement at the doses used in these studies works—it just doesn't work perfectly.

Nicotine replacement therapy is not only effective, it is also cost-effective. A recent cost-effectiveness analysis⁴ estimated that even with the limited effectiveness of nicotine replacement, the cost of 5 minutes of physician time and 8 weeks of nicotine patches (about \$200) led to highly acceptable cost-effectiveness ratios. The incremental cost-effectiveness ratios of the nicotine patch ranged from \$4,000 to \$11,000 per quality adjusted life year. Phrased in another way, the use of nicotine patches produced 1 additional lifetime quitter at a cost of about \$7,300.

The Use of Nicotine Gum Decreases as the Cost for Nicotine Gum Increases. Nicotine replacement therapy increases the chances of success for a smoker, but it has to be used. Some data (and a whole lot of common sense) suggest that smokers are less likely to use nicotine gum as the cost of the gum increases. In a study⁵ of 106 subjects enrolling in a smoking cessation program (of which nicotine gum was a component), smokers were randomized to paying either \$0 per box of nicotine gum, \$6 per box, or \$20 per box. The results showed that the use of nicotine gum went down as the cost of the nicotine gum went up. The percentage of smokers actually using the gum was 75% for the \$0/box group, 58% for the \$6/box group, and 47% for the \$20/box group. There was a trend for payment to influence 6-month abstinence; 6-month

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abstinence was 19% for the \$0/box group, 6% for the \$6/box group, and 8% for the \$20/box group. The lack of statistical significance may be due to the low number of subjects in the study.

The Current Study

In this issue,⁶ Sidorov and colleagues report the results of a nurse-led smoking cessation program conducted in twenty primary care clinics in Pennsylvania. The self-reported abstinence rates at 1 year ranged from 21%-36% depending upon patient compliance with three different financial incentives. They report that the two groups with some HMO-supported payment fared better than the non-HMO group that had to pay for the smoking cessation groups and nicotine patches on their own. Comparing the two groups that had some HMO-supported payment, the group that had to pay for their own nicotine patches did not have lower self-reported abstinence rates than the group that was given nicotine patches by the HMO. The authors suggest that these findings might give MCOs justification to withhold payment for NRT.

As the authors state, this study was observational, not experimental, and should be interpreted with caution. The smokers were not randomly assigned, but selected themselves to be in the HMO pharmacy-benefit group, the HMO no-pharmacy-benefit group, or the non-HMO group. Because this was not a randomized controlled trial, the most significant methodological questions to ask are: (1) were the groups really similar at baseline?⁷ and (2) did the groups receive similar treatment?⁷ Because the smokers chose to be in the HMO pharmacy-benefit group, HMO non-pharmacy benefit group, or non-HMO group, and outcome of smoking abstinence was compared among these three groups, the possibility should be considered that systematic differences between the groups were present that may have altered the outcome. From previous research, factors related to smoking abstinence include motivation to quit smoking and nicotine dependence. Is it possible that smokers who had to pay for their own NRT were more motivated to quit since they participated despite the cost? Is it possible that smokers who had to pay for their own NRT were less nicotine-dependent because they participated even though they knew they had to pay for NRT? Highly nicotine dependent smokers probably have had many failures in the past and may be more ambivalent about starting a program when faced with the cost of NRT.

Because cost may be a factor that prevents smokers from using NRT, and there were differences in cost of NRT among the treatment groups, it is important to know what the use of NRT was in the three groups. Unfortunately, the use of the nicotine patch was not reported in the study. If the HMO no-pharmacy-benefit group were more motivated, less nicotine dependent, or used NRT at a higher rate than other groups, it would be inappropriate to draw conclusions based on a comparison between these groups.

Current Recommendations. Several expert panels and accreditation organizations recommend that MCOs provide effective smoking cessation programs. The Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline proposes that by the year 2000, all health plans should offer treatment of nicotine addiction, of which NRT is a component.⁸ The American Psychiatric Association Practice Guideline states that "nicotine replacement therapy should be considered in all smokers who have seriously tried to quit on their own and failed."⁹ Finally, the National Committee for Quality Assurance has targeting smoking cessation in the evaluation of MCOs in HEDIS 3.0.¹⁰

Conclusion

The effectiveness of NRT is based on more than a dozen high-level randomized controlled trials in which subjects did not pay for their therapy. Sidorov's observational study finds that making smokers pay for their NRT may not lead to lower success rates. This study should not be regarded as definitive. I believe that the burden of proof still falls on MCOs to prove that *not* subsidizing NRT does not result in *lower* NRT utilization and *lower* success rates. There are very few treatments in clinical medicine that actually save money, but many treatments improve health at reasonable cost. Because of the cost-effectiveness of using NRT, subsidizing NRT for smokers who are trying to quit not only makes good clinical sense—it also makes good financial sense.

... REFERENCES ...

1. US Dept of Health and Human Services. The health benefits of smoking cessation: A report of the surgeon general. Bethesda, MD; 1990: Dept of Health and Human Services Publication no 90-8416.
2. Wagner EH, Curry SJ, Grothaus L, Saunders KW, McBride CM. The impact of smoking and quitting on health care use. *Arch Int Med* 1995;155:1789-1795.

3. Silagy C, Mant D, Fowler G, Lancaster T. The effect of nicotine replacement therapy on smoking cessation. Tobacco Addiction Module of the Cochrane Database of Systemic Reviews Available in the Cochrane Library; Issue 2 Oxford: Update Software; 1996.
4. Fiscella K, Franks P. Cost-effectiveness of the transdermal nicotine patch as an adjunct to physicians' smoking cessation counseling. *JAMA* 1996;275:1247-1251.
5. Hughes JR, Wadland WC, Fenwick JW, Lewis J, Bickel WK. Effect of cost on the self-administration and efficacy of nicotine gum: A preliminary study. *Prev Med* 1991;20:486-496.
6. Sidorov J, Christianson M, Girolami S, Wydra C. A successful tobacco cessation program led by primary care nurses in a managed care setting. *Am J Man Care* 1997;3:207-214.
7. Sackett D, Haynes RB, Guyatt GH, Tugwell P. *Clinical Epidemiology: A Basic Science for Clinical Medicine*. 2nd ed. Boston: Little, Brown and Company; 1991.
8. The Smoking Cessation Clinical Practice Guideline Panel and Staff. The Agency for Health Care Policy and Research Smoking cessation Clinical Practice Guideline. *JAMA* 1996;275:1270-1280.
9. American Psychiatric Association Practice Guideline for the Treatment of Patients with Nicotine Dependence. *Am J Psychiatry* 1996;153:1-31.
10. O'Kane ME. Accreditation standards in managed care. *Am J Man Care* 1996;2:1081-1086.