

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Smoking Cessation Products	LAST REVIEW	5/8/2018
THERAPEUTIC CLASS:	Psychiatric Disorders	REVIEW HISTORY	5/17, 5/16, 5/15, 2/12
LOB AFFECTED:	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Use of Tobacco products can lead to a variety of conditions including lung/heart disease, cancer, and death. HPSJ is committed to encouraging patients to live smoke-free lives.

Healthcare providers can play a major role in supporting patients in their desire to quit smoking. Of current smokers, 74% would like to quit smoking, and the average smoker has attempted to quit smoking at least 3 times.¹ Many patients may not be aware that there are different treatment options available, with two thirds of those attempting to quit doing so without behavioral intervention or pharmacological treatment. Only 6% of patients attempting to quit smoking report using a combination of behavioral intervention and medication therapy.^{2,3,4} Effective smoking cessation ideally requires treatment targeted to both the physiological addiction to nicotine and the behavioral habit of using tobacco.

Resources available to assist in smoking cessation:

http://www.californiasmokershelpline.org or 1-800-NO-BUTTS (1-800-662-8887) Smoking cessation hotline: available in English, Spanish, Cantonese, Korean, Mandarin, Vietnamese, TDD/TTY <ul style="list-style-type: none">• Provides free literature by mail• Provides free smoking cessation counseling and support by phone
American Cancer Society: 1-800-227-2345 Free smoking cessation information available 24/7 in English and Spanish; other languages available
American Lung Association: http://www.freedomfromsmoking.org or 1-800-LUNG-USA (1-800-586-4872) Freedom from Smoking helpline. Information about smoking cessation in English and Spanish for both adults and teens
SmokeFree.gov or 1-877-44U-QUIT (1-877-448-7848) or 1-800-QUIT-NOW (1-800-784-8669) or text QUIT to 47848 Free smoking cessation information and counseling available in both English and Spanish

Besides the aforementioned resources, this document will aim to provide an understanding of the HPSJ formulary agents available for smoking cessation, as well as their place in therapy.

Table 1: Available Agents for Smoking Cessation (Current as of 4/2018)

Class	Drug	Available Strengths	Formulary Status	Restriction	Clinical Pearls	Cost Per Rx [¥]
Dopamine/ Norepinephrine reuptake blockade	Bupropion SR (Zyban) <i>Tablets</i>	150 mg	-	-	Initiate 1 week before quit date. (Takes 5-7 days to reach therapeutic levels)	\$30.65
Nicotine Receptor Blockers	Varenicline Tartrate (Chantix) <i>Tablets</i>	0.5 mg, 1 mg	QL; FL	Limited to one 3-month treatment course per 365 days without any PA submission.	Initiate 1 week before quit date to titrate to therapeutic levels.	\$366.00
Nicotine Replacement Therapy (NRT)	Nicoderm CQ <i>24 Hour Patch</i>	7 mg, 14 mg, 21 mg	QL; FL		PA is required for a second 3-month course to be covered.	Initiation of the patch for maintenance and lozenge/gum/nasal spray for breakthrough cravings may increase success rate.
	Nicorette <i>Lozenge</i>	2 mg, 4 mg	QL; FL	\$26.54		
	Nicorette <i>Gum</i>	2 mg, 4 mg	QL; FL	\$22.30		
	Nicotrol NS <i>Nasal Spray</i>	10 mg	QL; FL	-		
	Nicotrol Inhaler <i>Inhalation Cartridge</i>	10 mg	QL; FL	\$384.03		

SR = Sustained Release; QL = Quantity Limit; FL = Fill Limit; PA = Prior Authorization
[¥]based on claims data from 4/2017 to 3/2018

SELECTING THE APPROPRIATE AGENT FOR YOUR PATIENT:

All smokers attempting to quit are eligible to receive any of the three classes of smoking cessation therapy. There is no conclusive evidence to state that one therapy is better than any other. *Patient should be ready to quit smoking in the next few days or weeks.* Assess patient readiness via the 5 A's (ASK, ADVISE, ASSESS, ASSIST, and ARRANGE). Consider the following when prescribing smoking cessation therapy:

1. Is your patient pregnant?

It is unknown if NRT is safe or effective in pregnancy, though it is the only agent studied. However, it is known that nicotine is toxic to fetal development. As such, physicians are encouraged to consider smoking cessation counseling or group therapy, before considering closely monitored NRT.

2. Does counseling work?

Studies have shown that when patients are attempting to quit, having strategies to cope make a patient much more likely to stop smoking. While counseling is not required, it is HIGHLY ENCOURAGED. The California Smokers Helpline is a free resource available to all California residents. Call **1-800-NOBUTTS** for more information.

3. Is your patient concerned about weight gain?

Nicotine replacement therapy and Bupropion SR have been shown to delay weight gain, but not prevent it.

4. Are you initiating therapy for comorbid depression?

Bupropion SR is a good choice for patients with comorbid depression. Nortriptyline has also been studied, and may also be effective in helping patients quit.

Remember: Antidepressants may trigger mania in patients with bipolar disorder.

5. I would like to use smoking cessation therapy long term. What is the best option?

The health effects of nicotine replacement therapy long term are unknown at this time. There is a possibility that patients may become dependent on nicotine replacement therapy, and as such, long term use is not recommended. Consider using an agent like Bupropion SR for long-term pharmacotherapy.

6. Should I avoid using nicotine replacement in patients with cardiovascular disease?

Clinical judgment about patient status and risks and benefits should be weighed. NRT has not been shown to cause adverse cardiovascular effects. Though this is the case, avoid use if nicotine replacement immediately after the acute phase of a myocardial infarction, heart failure exacerbation, or in patients with unstable angina. Consider the long-term cardiovascular effects of smoking when considering smoking cessation therapy.

7. Are e-cigarettes a safe and effective method for smoking cessation?

E-cigarettes are not regulated by the FDA and have not been proven safe or effective cessation aids. Patients should be strongly discouraged from using e-cigarettes as a means of smoking cessation.

CLINICAL JUSTIFICATION

An All Plan Letter (effective Nov. 30, 2016) requires all tobacco cessation medications to be covered for a 90-day treatment regimen without any requirements, restrictions, or barriers.⁸

Hence, smoking cessation agents do not require prior authorization for initial approval. Bupropion is available on the formulary without restrictions. However, if the patient exceeds the quantity limit for Chantix or the Nicotine products, a prior authorization form needs to be submitted to ensure member is consistently being encouraged and followed for their smoking cessation therapy.

Nicotine replacement products are intended to be used for a maximum of 12 weeks (90 days). Longer use is not recommended by manufacturers of these products. Please submit a Prior Authorization for treatment longer than 12 weeks (90 days).

There is evidence that combining nicotine patch with either nicotine gum, lozenges, or nasal spray can help encourage abstinence rates, long-term, when compared to monotherapy.

- ➔ Nicotine patch should be used to control cravings throughout the day.
- ➔ Gum/lozenges should be used sparingly for breakthrough cravings.

⊞ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Dopamine/Norepinephrine Reuptake Blocker

Bupropion SR (Zyban)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** Good for use in comorbid depression. Watch for signs of mental status change.

Nicotine Receptor Blockers

Varenicline (Chantix)

- Coverage Criteria:** Chantix is limited to 1 (one) three-month course of any smoking cessation agent per 365 days.
- Limits:** 1 three month course per 365 days.
- Required Information for Approval:** Submittal of PA form for therapy beyond 3 months.
 - If continued therapy beyond three months is approved then only a SECOND 3-month course will be APPROVED. Smoking cessation products are limited to two 3-month courses PER 365 DAYS. If your patient requires more than 24 weeks of therapy, re-evaluation of patient readiness for smoking cessation is necessary.
- Other Notes:** Neuropsychiatric status should be monitored carefully for changes in mood, including agitation and depression.

Nicotine Replacement Therapy

Nicotine Patch (Nicoderm CQ), Nicotine Lozenge (Nicorette Lozenge), Nicotine Gum (Nicorette Gum), Nicotine Nasal Spray (Nicotrol NS), Nicotine Inhaler (Nicotrol Inhaler)

- Coverage Criteria:** Nicotine replacement therapy is limited to 1 (one) three-month course of any smoking cessation agent per 365 days.
- Limits:** 1 three month course per 365 days.
- Required Information for Approval:** Submittal of PA form for therapy beyond 3 months.
 - If continued therapy beyond three months is approved then only a SECOND 3-month course will be APPROVED. Smoking cessation products are limited to two 3-month courses PER 365 DAYS. If your patient requires more than 24 weeks of therapy, re-evaluation of patient readiness for smoking cessation is necessary.
- Other Notes:** None

⊞ REFERENCES

1. Newport, F. Most U.S. Smokers Want to Quit, Have Tried Multiple Times. Gallup Poll News Service. July 13, 2013. <http://www.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx>
2. Shiffman S, Brockwell SE, Pillitteri JL, Gitchell JE. Individual differences in adoption of treatment for smoking cessation: Demographic and smoking history characteristics. *Drug Alcohol Depend.* 2008; 93: 121-131.
3. Fiore MC, Jaen CR, Baker TB, et al. Treating tobacco use and dependence: 2008 update. Clinical Practice Guideline. Rockvill, MD: USDHHS, Public Health Service, 2008.
4. Shiffman S, Brockwell SE, Pillitteri JL, Gitchell JG. Use of smoking cessation treatments in the United States. *Am J Prev Med.* 2008; 34: 102-111. Zyban® [prescribing information]. Triangle Park, North Carolina: GlaxoSmithKline; 2015.
5. Chantix® [prescribing information]. New York, New York: Pfizer; 2015.
6. Nicotine (inhaler, spray) [prescribing information]. New York, New York: Pfizer; 2010.
7. NicoDerm CQ® [prescribing information]. Moon Township, Pennsylvania: GlaxoSmithKline; 2014.
8. Department of Health Care Services. All Plan Letter 16-014 (Supersedes Policy Letter 14-006) – Comprehensive Tobacco Prevention and Cessation Services for Medi-Cal Beneficiaries. State of California-Health and Human Services Agency. 2016. Effective November 30, 2016. Accessed May 8, 2017.

☒ **REVIEW & EDIT HISTORY**

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Chantix.doc	2/2007	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment for PT 11-20-12.xlsx	11/2012	Allen Shek PharmD BCPS
Update to Policy	PL14-006 (Tobacco Cessation Services).pdf	9/2014	Jonathan Szkotak PharmD, BCACP
Update to Policy	HPSJ Coverage Policy - Psychiatric - Smoking Cessation 2015-05.docx	5/2015	Jonathan Szkotak PharmD, BCACP
Update to Policy	HPSJ Coverage Policy - Psychiatric - Smoking Cessation 2016-05.docx	5/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Psychiatric - Smoking Cessation 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Psychiatric - Smoking Cessation 2018-05.docx	5/2018	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy