

RELAPSED SMOKERS WHO ARE READY TO TRY AGAIN: WHAT TO DO?

A 3-STEP PROTOCOL FOR CLINICIANS (PAGE 1 OF 2)

Many smokers who relapse do so because they fail to plan. Often, patients think that they can simply “make” themselves quit and do not avail themselves of the many proven behavior change programs provided by various sources. Furthermore, most smokers do not use a cessation medication or, if they do, they use it incorrectly. Generally speaking, patients significantly under-dose or stop pharmacologic therapy too soon.

You can help relapsed smokers regain abstinence by encouraging them to learn from their prior experiences rather than use those experiences as proof that they cannot quit. To underscore this perspective, inform patients that the best way to quit smoking is to combine a behavior change program with a cessation medication. The following **3-step protocol** will help you provide this information in an efficient, effective manner for patients who are ready to try again:

STEP 1: ASK

- “TELL ME ABOUT YOUR LAST QUIT ATTEMPT(S).”
- “DID YOU USE A SMOKING CESSATION MEDICATION?”
 - If yes: “EXPLAIN HOW YOU USED YOUR MEDICATION.”
 - Reinforce proper usage/ rectify incorrect usage or dosage
 - If no: “WHAT WAS YOUR REASONING FOR NOT USING A MEDICATION?”
- “DID YOU RECEIVE ANY PROFESSIONAL ADVICE OR ENROLL IN A BEHAVIOR CHANGE PROGRAM?”
 - If yes: “TELL ME WHAT YOU LIKED, OR DIDN’T LIKE ABOUT THE ASSISTANCE YOU RECEIVED.”
 - If no: “WHAT WAS YOUR REASONING FOR NOT SEEKING ADVICE OR ENROLLING IN A PROGRAM?”

STEP 2: ADVISE

- “ACCORDING TO THE MOST CURRENT RESEARCH AND THE SURGEON GENERAL, THE BEST WAY TO QUIT IS TO COMBINE A SMOKING CESSATION MEDICATION WITH A BEHAVIORAL PROGRAM.”

NOTE: Examples of behavior change programs are listed on the reverse side, under the “Refer” section of the protocol.
- “LET’S DISCUSS WHICH MEDICATION(S) WOULD BE BEST FOR YOU.”
- Review current level of tobacco use, past usage of medications, personal preference, precautions/ contraindications, etc. to determine best product for current quit attempt.

NOTE: Refer to attached *Pharmacologic Product Guide* for dosing instructions, etc. for FDA-approved smoking cessation medications.
- If patient has failed a serious quit attempt using monotherapy, consider the following options:
 - If prior medication was used correctly, was well tolerated, and appeared to have been effective, consider repeating the same medication regimen in conjunction with an enhanced behavioral program.
 - If prior medication was used incorrectly, carefully review usage instructions.
 - If prior medication was used correctly but did not control urges/withdrawal, or if patient prefers something new, review other medication options, including both single and combination therapy:

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Combination therapy currently is off-label for all cessation medications, but is supported by multiple clinical trials and the *Clinical Practice Guideline for Treating Tobacco Use and Dependence* (p. 77):

- *Safe*: Most smokers are highly tolerant to nicotine from years of smoking. Side effects are rare and easily mitigated by reducing or stopping use.
- *Effective*: Especially in those who failed with one medication. Also useful in patients who are heavily dependent (2 or more packs/day).

Suggested combinations:

- Nicotine patch as base therapy + gum, lozenge, or inhaler as needed for breakthrough urges

Sustained-release bupropion (Zyban) has been examined in combination with nicotine replacement therapies, but their combined effectiveness is not well established.

Currently, varenicline (Chantix) is not recommended for combination therapy.

STEP 3: REFER

The amount of counseling that patients receive is linearly related to their success in quitting. More counseling contacts yield higher quit rates. If you do not have the time or expertise to assist patients with quitting and to provide follow-up counseling, refer patients to other resources:

- To a behavior change program:
 - “HERE ARE SOME SUGGESTIONS. WHICH DO YOU THINK WOULD WORK BEST FOR YOU?”
 - 1 800 QUIT NOW, the national toll-free telephone quit line
 - All products are accompanied by a free behavior change program: Refer to usage instructions for enrollment procedures
 - Hospital-based or other local resources
 - www.quitnet.com, an on-line tobacco cessation support program
 - smokefree.gov, an on-line guide for quitting
 - American Lung Association, American Cancer Society, or American Heart Association web-sites or cessation programs (e.g., American Lung Association’s *Freedom From Smoking* group cessation program)
 - Local pharmacist, physician, or therapist specializing in cessation
- To a community pharmacist:
 - “WHEN YOU PURCHASE YOUR SMOKING CESSATION MEDICATION, PLEASE TAKE A FEW MINUTES TO DISCUSS PROPER USAGE WITH THE PHARMACIST, EVEN IF IT IS A PRODUCT YOU HAVE USED IN THE PAST. PROPER USAGE WILL GIVE YOU THE BEST CHANCE OF SUCCESS.”
- To other staff:
 - If you have dedicated cessation staff within your clinic or health-care organization, refer patient to these resources for follow-up counseling.

For more information, see Fiore MC, Bailey WC, Cohen SJ, et al. (2000). *Treating Tobacco Use and Dependence. Clinical Practice Guideline*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service. Available at: www.surgeongeneral.gov/tobacco.

For complete prescribing information, please refer to the manufacturers’ package inserts.



PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS						BUPROPION SR	VARENICLINE	
GUM		LOZENGE	TRANSDERMAL PREPARATIONS ¹		NASAL SPRAY			ORAL INHALER
PRODUCT	Nicorette ² , Generic OTC 2 mg, 4 mg; original, FreshMint ² , Fruit Chill ² , mint, orange ²	Commit ² , Generic OTC 2 mg, 4 mg mint	Nicoderm CQ ² OTC 24-hour release 7 mg, 14 mg, 21 mg	Generic Patch OTC/Rx (formerly Habitrol) 24-hour release 7 mg, 14 mg, 21 mg	Nicotrol NS ³ Rx Metered spray 0.5 mg nicotine in 50 µL aqueous nicotine solution	Nicotrol Inhaler ³ Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban ² , Generic Rx 150 mg sustained-release tablet	Chantix ³ Rx 0.5 mg, 1 mg tablet
PRECAUTIONS	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease 	<ul style="list-style-type: none"> ▪ Pregnancy (Category D) ▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease 	<ul style="list-style-type: none"> ▪ Pregnancy (Category C) ▪ Concomitant therapy with medications or medical conditions known to lower the seizure threshold ▪ Severe hepatic cirrhosis <p>Contraindications:</p> <ul style="list-style-type: none"> ▪ Seizure disorder ▪ Concomitant bupropion (e.g., Wellbutrin) therapy ▪ Current or prior diagnosis of bulimia or anorexia nervosa ▪ Simultaneous abrupt discontinuation of alcohol or sedatives (including benzodiazepines) ▪ MAO inhibitor therapy in previous 14 days 	<ul style="list-style-type: none"> ▪ Pregnancy (Category C) ▪ Severe renal impairment (dosage adjustment is necessary) 	
DOSING	<p>≥25 cigarettes/day: 4 mg <25 cigarettes/day: 2 mg</p> <p>Week 1–6: 1 piece q 1–2 hours</p> <p>Week 7–9: 1 piece q 2–4 hours</p> <p>Week 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when taste or tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 min before or during use ▪ Duration: up to 12 weeks 	<p>1st cigarette ≤30 minutes after waking: 4 mg 1st cigarette >30 minutes after waking: 2 mg</p> <p>Week 1–6: 1 lozenge q 1–2 hours</p> <p>Week 7–9: 1 lozenge q 2–4 hours</p> <p>Week 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks 	<p>>10 cigarettes/day: 21 mg/day x 6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks 	<p>>10 cigarettes/day: 21 mg/day x 4 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8 weeks 	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> ▪ Maximum <ul style="list-style-type: none"> – 5 doses/hour – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Patients should not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months 	<p>6–16 cartridges/day; individualized dosing</p> <ul style="list-style-type: none"> ▪ Initially, use at least 6 cartridges/day ▪ Best effects with continuous puffing for 20 minutes ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Patient should inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ Duration: up to 6 months 	<p>150 mg po q AM x 3 days, then increase to 150 mg po bid</p> <ul style="list-style-type: none"> ▪ Do not exceed 300 mg/day ▪ Treatment should be initiated while patient is still smoking ▪ Set quit date 1–2 weeks after initiation of therapy ▪ Allow at least 8 hours between doses ▪ Avoid bedtime dosing to minimize insomnia ▪ Dose tapering is not necessary ▪ Can be used safely with NRT ▪ Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1–3: 0.5 mg po q AM</p> <p>Days 4–7: 0.5 mg po bid</p> <p>Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> ▪ Patients should begin therapy 1 week prior to quit date ▪ Take dose after eating with a full glass of water ▪ Dose tapering is not necessary ▪ Nausea and insomnia are side effects that are usually temporary ▪ Duration: 12 weeks; an additional 12 week course may be used in selected patients

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS								
	GUM	LOZENGE	TRANSDERMAL PREPARATIONS		NASAL SPRAY	ORAL INHALER	BUPROPION SR	VARENICLINE
			NICODERM CQ	GENERIC PATCH				
ADVERSE EFFECTS	<ul style="list-style-type: none"> Mouth/jaw soreness Hiccups Dyspepsia Hypersalivation Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> Lightheadedness Nausea/vomiting Throat and mouth irritation 	<ul style="list-style-type: none"> Nausea Hiccups Cough Heartburn Headache Flatulence Insomnia 	<ul style="list-style-type: none"> Local skin reactions (erythema, pruritus, burning) Headache Sleep disturbances (insomnia) or abnormal/vivid dreams (associated with nocturnal nicotine absorption) 		<ul style="list-style-type: none"> Nasal and/or throat irritation (hot, peppery, or burning sensation) Rhinitis Tearing Sneezing Cough Headache 	<ul style="list-style-type: none"> Mouth and/or throat irritation Unpleasant taste Cough Rhinitis Dyspepsia Hiccups Headache 	<ul style="list-style-type: none"> Insomnia Dry mouth Nervousness/difficulty concentrating Rash Constipation Seizures (risk is 1/1,000 [0.1%]) 	<ul style="list-style-type: none"> Nausea Sleep disturbances (insomnia, abnormal dreams) Constipation Flatulence Vomiting
ADVANTAGES	<ul style="list-style-type: none"> Gum use might satisfy oral cravings Gum use may delay weight gain Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> Lozenge use might satisfy oral cravings Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> Provides consistent nicotine levels over 24 hours Easy to use and conceal Once-a-day dosing associated with fewer compliance problems 		<ul style="list-style-type: none"> Patients can titrate therapy to manage withdrawal symptoms 	<ul style="list-style-type: none"> Patients can titrate therapy to manage withdrawal symptoms Mimics hand-to-mouth ritual of smoking 	<ul style="list-style-type: none"> Easy to use; oral formulation might be associated with fewer compliance problems Can be used with NRT Might be beneficial in patients with depression 	<ul style="list-style-type: none"> Easy to use; oral formulation might be associated with fewer compliance problems Offers a new mechanism of action for patients who have failed other agents
DISADVANTAGES	<ul style="list-style-type: none"> Gum chewing may not be socially acceptable Gum is difficult to use with dentures Patients must use proper chewing technique to minimize adverse effects 	<ul style="list-style-type: none"> Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> Patients cannot titrate the dose Allergic reactions to adhesive might occur Patients with dermatologic conditions should not use the patch 		<ul style="list-style-type: none"> Nasal/throat irritation may be bothersome Dependence can result Patients must wait 5 minutes before driving or operating heavy machinery Patients with chronic nasal disorders or severe reactive airway disease should not use the spray 	<ul style="list-style-type: none"> Initial throat or mouth irritation can be bothersome Cartridges should not be stored in very warm conditions or used in very cold conditions Patients with underlying bronchospastic disease must use the inhaler with caution 	<ul style="list-style-type: none"> Seizure risk is increased Several contraindications and precautions preclude use (see PRECAUTIONS, above) 	<ul style="list-style-type: none"> May induce nausea in up to one third of patients Post-marketing surveillance data not yet available
WEB-SITE	www.nicorette.com	www.commitlozenge.com	www.nicodermcq.com	www.habitrol.com	www.nicotrol.com	www.nicotrol.com	----	www.chantix.com
COST/DAY ⁴	2 mg: \$2.65–\$5.16 (9 pieces) 4 mg: \$3.18–\$5.81 (9 pieces)	2 mg: \$4.92 (9 pieces) 4 mg: \$5.26 (9 pieces)	\$3.35–\$3.91 (1 patch)	\$2.10–\$2.94 (1 patch)	\$3.67 (8 doses)	\$5.25–\$6.07 (6 cartridges)	\$3.62–\$5.73 (2 tablets)	\$4.00–\$4.22 (2 tablets)

¹ Transdermal patch formulations previously marketed, but no longer available: Nicotrol 5 mg, 10 mg, 15 mg delivered over 16 hours (Pfizer) and generic patch (formerly Prostep) 11 mg and 22 mg delivered over 24 hours.

² Marketed by GlaxoSmithKline.

³ Marketed by Pfizer.

⁴ Average wholesale price from 2006 Drug Topics Redbook. Montvale, NJ: Medical Economics Company, Inc., December 2006.

Abbreviations: Hx, history; MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, (over-the-counter) non-prescription product; Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

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