Adapted based on IHS PIMC Example
Pharmacy Tobacco Cessation Clinic Protocol

Tobacco Cessation Consultant/Supervising Physician:
Chief of Pharmacy:
Chief of Clinical Operations:
Pharmacy Clinic Co-Directors/Education Coordinators:

Purpose/Statement of Need:

Taken from the Clinical Practice Guideline "Treating Tobacco Use and Dependence: 2008 Update"[1]

Tobacco use has been cited as the chief avoidable cause of illness and death in our society and accounts for more than 435,000 deaths each year in the United States. Smoking is a known cause of multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease (COPD), and many other diseases. Despite these health dangers and the public's awareness of those dangers, tobacco use remains surprisingly prevalent. Recent estimates are that about 21 percent of adult Americans smoke, representing approximately 45 million current adult smokers. Smoking-attributable health care expenditures are estimated at $96 billion per year in direct medical expenses and $97 billion in lost productivity.

Specifically for the Native American and Alaskan Native population, smoking rates exceed the national average.[2] In 2006, American Indian/Alaskan Natives had a reported smoking prevalence of 32% compared to all other racial categories, including: White/Non-Hispanic (21.9%), African American or Black (21.5%), Hispanic/Latino (16.2%), and Asian American (13.3%).[2]

Epidemiologic data suggest that more than 70 percent of the 45 million smokers in the United States today report that they want to quit, and approximately 44 percent report that they try to quit each year. Unfortunately, most of these efforts are both unaided and unsuccessful. For example, among the 19 million adults who attempted to quit in 2005, only 4 to 7 percent were likely successful.

Rationale for a Multidisciplinary Approach and Pharmacy Services:

Taken from the Clinical Practice Guideline: "Treating Tobacco Use and Dependence: 2008 Update"[1]

Data strongly indicate that the consistent and effective delivery of tobacco interventions requires *coordinated interventions* among a multidisciplinary team within a health care system. The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. The Clinical Practice Guideline states that all smokers trying to quit should be offered medication, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents). Individual, group, and telephone counseling are effective tobacco use treatment formats. Whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking.

Purpose:
The [ ] Pharmacy Tobacco Cessation Clinic is designed primarily to provide pharmacologic support to adult patients participating in the [ ] Tobacco Cessation Programs – including the lecture based "STOP" program, the group oriented Tobacco Talking Circle, and individual counseling sessions.

Goals:
1. Maximize the benefits of pharmacologic options for tobacco cessation
2. Educate patients regarding indications, risks, and complications of tobacco cessation therapies
3. Identify patients who are at high risk for adverse outcomes of specific tobacco cessation therapies

Policy:
1. Patients attending the pharmacy clinic are highly recommended to be enrolled in an intensive cessation counseling program through the [ ], [ ] or Health Education Department counseling sessions. If patients are unable to attend counseling sessions with [ ] Health Education Department due to extenuating circumstances, trained clinical tobacco pharmacy providers may provide individual counseling during pharmacy visits in addition to providing pharmacologic support.
2. Patients may be referred to the Tobacco Cessation Clinic by any provider (e.g. nurse, pharmacist, dental hygienist, physician, etc.) who assesses the patient's desire to quit tobacco use. Patients will be referred through an EHR consult, preferably. Patients may also self-refer (present directly to the pharmacy or contact Health Education), or be referred through other recognized tobacco cessation programs. Trained Health Education personnel and pharmacists from the Tobacco Cessation Clinic will collaborate to determine the appropriateness of the request/referral and coordinate scheduling and appointments.
3. Medication(s) will be started and adjusted by pharmacists under this protocol based on the assessment of patient specific progress and medication-related problems/contraindications.
4. Pharmacy will be able to perform physical assessment (e.g. blood pressure and weight or other relevant assessments) and order/interpret labs as necessary.
5. If the need for ongoing tobacco cessation therapy and follow-up exceeds 6 months, the patient may be referred back to their primary physician or behavioral health provider for evaluation of risk vs. benefit for continued therapy. Pharmacy providers may consider placing a behavioral health consult or referring patients back to Health Education for additional counseling as well.
6. A designated supervising/consultation physician will retain responsibility for oversight of the [ ] Tobacco Cessation Clinic.
7. Patients enrolled in the [ ] Pharmacy Tobacco Cessation Clinic should be 15 years or older. Pharmacy providers must obtain approval through the Chief Pharmacist, Clinical Director(s), and Supervising/Consulting Physician to assist patients younger than 15 years.
8. For patients, between 15 and 18 years of age, pharmacy providers may provide counseling and only prescribe Nicotine Replacement Therapies (NRT's). Non-nicotine medications (i.e. bupropion or varenicline) may only be ordered by the patient's behavioral health provider or primary care provider.
9. For patients, 18 years and older, the pharmacy providers have the authority to prescribe NRTs and non-nicotine therapies to smokers or smokeless tobacco users per protocol.

Guidelines:
1. Collaboration with Multidisciplinary Teams
   Pharmacy will collaborate with the [ ] Program and the [ ] Program. [ ] patients referred by a consult via the Electronic Health Record (EHR) will initially be contacted by Health Education personnel, typically. Patients will be scheduled, as appropriate, for attendance in one of the health education sessions and scheduled for an initial pharmacy visit. Information regarding the Pharmacy Tobacco Cessation Clinic will also be distributed at the first class of each new health

education session to inform patients of available treatment options and how to make a pharmacy appointment if tobacco cessation medication is desired.

a. The first pharmacy appointment will be scheduled approximately 7-10 days prior to the patient's decided quit date, preferably
b. Appointments will be scheduled during outpatient pharmacy hours

2. Initial Evaluation and Management
   The pharmacist will interview and assess patients in order to:
   a. Determine any contraindications for pharmacotherapy
   b. Provide patient specific education on medication therapy and behavioral modification
   c. Provide first fill of medication, with a maximum of 2 weeks supply

3. Pharmacy Refills
   Patient follow up is based on the standard for "Best Practice" for Intensive Interventions as outlined in the US Public Health Service Guideline: "Treating Tobacco Use and Dependence"
   a. At every encounter patients will be interviewed for progress, medication side effects and therapy goals.
   b. The first refill visit should be within 2 weeks of the initial pharmacy appointment. This initial refill will be done in person in order to assess the patient's tolerance to the medication and to document physical assessment values, such as weight or blood pressure, if necessary.
   c. Subsequent refills are patient specific and may be processed in person or via telephone.

4. Missed Appointment Policy
   The pharmacist will make reasonable attempts to contact the patient to reschedule the appointment and arrange for follow-up and medication refills. Patients who cannot be contacted or fail to appear in clinic either in person or by telephone will be discharged. Patients may be accepted back into the clinic at any time, realizing that tobacco dependence is recognized as a chronic disease with a relapsing nature.[1] Relapse should not discourage the clinician or the tobacco user from renewed quit attempts.[1]

5. Documentation
   a. All patient visits (physical and telephone) and medication refills will be documented in an EHR note including:
      i. Initial visit:
         a. Patient assessment information, subjective information about the patient's tobacco use history, and may include the Fagerstrom Tolerance score
         b. Patient's medication choice at the initial visit
         c. Education provided and plan for medication therapy
      ii. Follow-up visits:
         a. Medication related side effects
         b. Patient's progress and therapy goals
         c. Education provided and plan for medication therapy
   b. All Tobacco Cessation visits will require additional EHR documentation for billing purposes, including appropriate purpose of visit (POV) choices, CPT billing codes, selection of visit provider, and Health Factor selection.

      i. POV code:
         a. ICD-9 code 305.1 Tobacco Use Disorder will be automatically selected for every visit when using the EHR superbill. It should be ranked as the PRIMARY purpose of visit.
      ii. CPT codes:
         At least once CPT must be selected, preferably focusing on the behavioral change CPT codes.
         4000F - Tobacco Use Treatment, Counseling
         4001F - Tobacco Use Treatment, Pharmacologic

99406 - Behavior Change Smoking 3-10 min
99407 - Behavior Change Smoking >10 min

iii. Visit Provider
The pharmacy provider should select themselves as the primary visit provider, using their CPS designation.

iv. Tobacco Health Factor
At each visit the Tobacco Health Factor must be updated. The EHR superbill will automatically select “cessation smoker”, but this may require modification if the patient has not reached their quit date and, therefore, would still be categorized as a “current smoker”.

Table 1. Tobacco Health Factors

Health Factor - Smoker	Definition
Never Smoked	Does not and has never used tobacco products.
Current Smoker, Every Day	Currently smokes tobacco (cigarettes, cigars, pipe, etc)
Current Smoker, Some Day	Currently smokes tobacco (cigarettes, cigars, pipe, etc) regularly, but not every day
Cessation Smoker	Is transitioning from a Current Smoker to a Previous Smoker. The time period between stopping smoking and 6 months.
Cessation Smokeless	Is transitioning from a Current Smokeless tobacco user to a Previous Smokeless tobacco user. The time period between stopping smokeless tobacco and 6 months.
Previous Smoker	Has quit smoking tobacco for 6 months or more.
Ceremonial Use Only	Uses tobacco for ceremonial or religious purposes only.

Health Factor - Smokeless	Definition
Never Used Smokeless	Does not and has never used smokeless tobacco products.
Current Smokeless, Every Day	Currently uses smokeless tobacco (chew, dip, snuff, etc) every day.
Current Smokeless, Some Day	Currently uses smokeless tobacco (chew, dip, snuff, etc) regularly, but not every day.
Current Smokeless	Currently uses smokeless tobacco (chew, dip, snuff, etc).
Cessation Smokeless	Is transitioning from a Current Smokeless tobacco user to a Previous Smokeless tobacco user. The time period between stopping smokeless tobacco and 6 months.
Previous Smokeless	Has quit smokeless tobacco for 6 months or more.

Health Factor – Exposure	Definition
Exposure to Environmental Tobacco Smoke	Is exposed to second hand smoke at work or outside of the home.
Smoker in Home	Is exposed to second hand smoke at home.
Smoke Free Home	There is no exposure to tobacco smoke at home.

c. Patient Education/Behavior Modification:
Education involving GPRA standards will be documented as part of the patient education component of EHR. Some portions are built in to the EHR superbill for tobacco cessation visits, but additional topics discussed will require documentation.

Table 2. Patient Education Codes

Tobacco Use Topic	Outcome & Standard Teaching for Patient/Family
Anatomy & Physiology	Understand anatomy and physiology as it relates to tobacco use.
Complications	Understand the slow progression of disease and disability resulting from tobacco use and its effect on family members.
Cultural/Spiritual Aspects of Health	Understand the impact and influences cultural that spiritual traditions, practices, and beliefs have on health and wellness.
Disease Process	Understand the slow progression of disease & disability associated with tobacco use.
Exercise	Understand the role of increased physical activity in this patient's disease process and will make a plan to increase regular activity by an agreed-upon amount.
Follow-up	Understand the importance of follow-up in the treatment of nicotine addiction. Refer to the 5A Approach (Ask, Advise, Assess, Assist, Arrange).
Help Line	Understand how to access and benefit from a telephone tobacco help line, also known a quit line. Refer to the 5A Approach (Ask, Advise, Assess, Assist, Arrange).
Hygiene	Understand hygiene as it applies to tobacco use.
Information & Referral	Understand the process of referral and treatment for nicotine dependence. Refer to the 5A Approach (Ask, Advise, Assess, Assist, Arrange).
Lifestyle Adaptations	See tobacco abstinence as a way of life.
Literature	Receive literature about tobacco use or cessation.
Medical Nutrition Therapy	Understand the specific nutritional intervention(s) needed in tobacco use.
Medications	Understand the purpose, proper use, and expected outcomes of prescribed drug therapy.
Nutrition	Understand the role of nutrition and tobacco use.
Pre-conception Care	Understand the importance of pre-conception care.
Prevention	Understand tobacco use prevention.
Quit	Understand that tobacco cessation will improve quality of life, that cessation will benefit health, and how participation in a support program may prevent relapse. Refer to the 5A Approach (Ask, Advise, Assess, Assist, Arrange).
Safety	Understand safety issues as they apply tobacco use.
Second-Hand Smoke	Understand the adverse health consequences associated with exposure to second & third-hand tobacco smoke.
Stress Management	Understand the role of stress management in tobacco abuse and its positive effect on tobacco cessation.

6. Anticipated Duration of Pharmacy Monitored Treatment
    a. Nicotine Transdermal Patch and/or Nicotine Gum or Lozenge: 8-12 weeks
    b. Bupropion SR or other oral pharmacological agent for tobacco cessation: 3-6 months
    c. Actual length of therapy and tapering of the nicotine replacement products will vary between each patient.
    d. Varenicline: 12 weeks, may be used an additional 12 weeks to reduce relapse rates
    e. As stated previously, patients requiring greater than 6 months of therapy may be referred back to the primary physician or behavioral health provider for evaluation of risk vs. benefit for continued therapy. Pharmacy providers may consider placing a behavioral health consult or referring patients back to Health Education for additional counseling as well.

7. Pharmacist Certification
    a. Initial pharmacist certification for privileges in the [ ]Tobacco Cessation Clinic
        i. Complete the Basic Tobacco Intervention Skills Certification (such as the University of Arizona/Healthcare Partnership)
        ii. Complete and pass the [ ] protocol competency test
        iii. Observe at least 5 patient visits seen by supervising MD or certified [ ] Tobacco Cessation Clinic pharmacist, and then see 5 patients independently with observation

of a certified [ ] Tobacco Cessation Clinic pharmacist, either through direct observation of the visit, verbal case discussion, or EHR chart review.

b. Continuing Competency Certification
    i. Annual peer/physician review of 5 to 10 patient visits. The review process will evaluate EHR documentation, therapy selection, and decision-making. Significant fallouts or problems discovered will be reported to the pharmacist, Chief of Pharmacy and the Consultant/Supervising Physician. Recommendations for improved practice or documentation will be discussed with the individual pharmacists.
    ii. Completion of tobacco related continuing education hours as specified by the education coordinator.
    iii. The chief pharmacist will assign continuing privileges in the clinic based on peer review.
c. Highly recommend Tobacco Cessation Clinic pharmacists to be trained as a Tobacco Treatment Specialist. Our goal is to have pharmacy clinic providers achieve this certification.
d. Filing of Credentials
    i. All certification paperwork will be reviewed and signed by the Supervising/Consultation Physician, Chief of Pharmacy and Pharmacy Clinic Director(s).
    ii. Information pertaining to each pharmacist practicing in the Tobacco Cessation Clinic will be kept on file in the clinic documents, as well as in each pharmacists Pharmacy VIIb file.

8. Clinic Outcome Evaluation and Performance Improvement - Evaluation of clinic data and outcomes will be reported on an annual basis. Evaluation should include summary of medications regimens, costs associated with the clinic, patient success rates, as well as any unexpected adverse events. Pharmacy will collaborate with Health Education to share relevant data and outcomes. Reports will be submitted to the Tobacco Cessation Supervising/Consultant Physician, Chief of Pharmacy and the National Clinical Pharmacy Specialist Committee.

   The protocol will be reviewed annually by the clinic director(s) to determine the need for formal revision. Pharmacy providers, health education personnel and other interested parties may recommend changes in daily operation of the clinic at any time. Health Education and Pharmacy will meet several times per year and as needed to address the clinic, the referral process, and education sessions available. Pharmacy clinic providers will meet individually or as a group at least yearly to discuss clinic successes and shortcomings and revise the clinic processes.

PHARMACOTHERAPY

PHS Guideline Recommended First-Line Medications[1]

Nicotine Replacement Medications

- Nicotine gum
- Nicotine patch
- Nicotine lozenge
- Nicotine nasal spray*
- Nicotine inhaler*

Non-Nicotine Medications

- Bupropion SR
- Varenicline

**denotes non-formulary agent at [ ]. These medications would require a non-formulary review based on patient specific factors before being allowed for use in that patient. Patients may choose to utilize outside resources to obtain medications. If outside resources are used, the prescriber would be responsible for patient monitoring of that medication.

PHS Guideline Recommended Second Line Medications[1]

Indicated for patients on a case-by-case basis after first line medications have been used or considered.

Non-nicotine medications

Clonidine
Nortriptyline

[ ] Formulary:

1. Transdermal NRT patch: 21mg/24hr, 14mg/24hr & 7mg/24hr
2. NRT Nicotine Gum 2mg
3. NRT Nicotine Lozenge 2mg (restricted to failure/intolerance to gum)
4. Bupropion 150mg SR
5. Varenicline (Chantix™) – 2nd line per formulary
6. Second line oral agents (clonidine or nortriptyline), if clinically indicated, after consultation with primary provider and order for prescription obtained

Pharmacotherapy Selection and Use:

Pharmacotherapy for tobacco use cessation is divided into two categories: nicotine replacement therapy (NRT) and non-nicotine products.

The formulary choices and agents most frequently used in the [ ] Tobacco Cessation Clinic were selected based on the evidence based PHS guideline recommendations. Abstinence rates for each medication or combination therapy and patient specific factors should guide medication selection.

Medication use in combination with tobacco cessation counseling is the more effective than medication alone, therefore counseling should be provided to patients at every visit. Additional counseling through [ ] Health Education, the [ ] Smokers Helpline or any other behavioral counseling that may increase smoking cessation success should be encouraged.

Specific considerations that may guide the choice of therapy:

- Previous patient experience with the medication
- Patient preference
- Patient characteristics (i.e. history of depression or concern about weight gain)
- Presence of special circumstances or contraindications

Table 3. Abstinence Rate Comparison Type of Therapy.
Taken from *Clinical Practice Guideline: Update 2008*[1]

Treatment	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Medication alone	8	1.0	21.6
Medication and counseling	39	1.3 (1.1, 1.6)	27.0 (22.7, 31.4)

Table 4. Meta-analysis (2008): Effectiveness & abstinence rates for various medications & medication combinations compared to placebo at 6-months post-quit (n = 86 studies). **Taken from *Clinical Practice Guideline: Update 2008*[1]**

Medication	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Placebo	80	1.0	13.8
Combination therapies			
Patch (long-term; > 14 weeks) + ad lib NRT (gum or spray)	3	3.6 (2.5, 5.2)	36.5 (28.6, 45.3)
Patch + Bupropion SR	3	2.5 (1.9, 3.4)	28.9 (23.5, 35.1)
Patch + Nortriptyline	2	2.3 (1.3, 4.2)	27.3 (17.2, 40.4)
Patch + Inhaler	2	2.2 (1.3–3.6)	25.8 (17.4–36.5)
Patch + Second generation antidepressants (paroxetine, venlafaxine)	3	2.0 (1.2–3.4)	24.3 (16.1–35.0)
Selective Serotonin Re-uptake Inhibitors (SSRIs)** ***Not found to be effective***	3	1.0 (0.7–1.4)	13.7 (10.2–18.0)
Medication	**Number of arms**	**Estimated odds ratio (95% C.I.)**	**Estimated abstinence rate (95% C.I.)**
Monotherapies			
Bupropion SR	26	2.0 (1.8, 2.2)	24.2 (22.2, 26.4)
Varenicline (1mg/day)	3	2.1 (1.5,3.0)	25.4 (19.6, 32.2)
Varenicline (2mg/day)	5	3.1 (2.5,3.8)	33.2 (28.9, 37.8)
Nicotine Patch (6-14 weeks)	32	1.9 (1.7, 2.2)	23.4 (21.3, 25.8)
Long-Term Nicotine Patch (> 14 weeks)	10	1.9 (1.7, 2.3)	23.7 (21.0, 26.6)
High Dose Nicotine Patch (> 25 mg) (standard or long-term duration)	4	2.3 (1.7, 3.0)	26.5 (21.3, 32.5)
Nicotine Gum (6-14 weeks)	15	1.5 (1.2, 1.7)	19.0 (16.5, 21.9)
Long-Term Nicotine Gum (> 14 weeks)	6	2.2 (1.5, 3.2)	26.1 (19.7, 33.6)
Nortriptyline	5	1.8 (1.3, 2.6)	22.5 (16.8, 29.4)
Clonidine	3	2.1 (1.2, 3.7)	25.0 (15.7, 37.3)

Factors that may impact NRT use:
Level of nicotine addiction: The use of tobacco is reinforced by the pharmacologic actions of nicotine, and abstinence is hindered by nicotine withdrawal symptoms. Patients who are highly addicted to nicotine are more likely to be successful at quitting when nicotine replacement is included in treatment. The Fagerstrom Tolerance Questionnaire is used as a reliable instrument for assessing nicotine addiction. Nicotine replacement (patch or gum) may be particularly useful when there is a high degree of addiction

- Smoking > 25 cigarettes/day

- Difficulty in refraining from smoking in prohibited areas
- Smoking 1st cigarette less than 30 minutes after arising

Nicotine Replacement Dosing[3]

1 cigarette = 1 mg of nicotine
1 dip chewing tobacco = 3-4 mg of nicotine
1 cigar = 10-20 mg of nicotine
1 bidi or kretek = 2-3 mg of nicotine

NRT and Concomitant Medical Conditions:

NRT is not an independent risk factor for acute myocardial events. It may be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris. Caution should also be used in the following conditions: coronary artery disease, pregnancy, hyperthyroidism, peptic ulcer, insulin-dependent diabetes mellitus, peripheral vascular disease, and temporomandibular joint syndrome (nicotine gum)

NRT Drug-Drug Interactions:

- A decrease in drug dose may be required at cessation of tobacco for theophylline, tacrine, TCAs, haloperidol, and fluphenazine
- A decrease in insulin dose may be needed due to an increase in subcutaneous absorption of insulin upon tobacco cessation. Patients should monitor serum glucose carefully and watch for signs and symptoms of hypoglycemia.

Nicotine Replacement Therapy – Transdermal Patch[4]:

- Transdermal systems are best suited for those patients that smoke "around the clock".
- The anticipated duration of NRT transdermal therapy is 8-12 weeks
- Patients smoking > 10 cigarettes daily should be started on the 21 mg patch and tapered:

Step 1	Week 1 to 6	21mg/24hr patch
Step 2	Week 7 to 8	14mg/24hr patch
Step 3	Week 9 to 10	7mg/24hr patch

- Patients smoking < 10 cigarettes daily (although little research is available on the use of NRT with light smokers) should be started on the 14 mg patch and tapered:

Step 2	Week 1 to 6	14mg/24hr patch
Step 3	Week 7 to 8	7mg/24hr patch

- In special circumstances, very heavy smokers (>1 pack per day) may require doses higher than 21mg/24hr to reduce cravings and minimize slips or relapse. When necessary, 28mg/24hr may be prescribed by Tobacco Cessation ZPharmacists. Patients will be tapered accordingly over 8-12 weeks. Patients must be monitored closely for signs or symptoms of nicotine toxicity.
- When appropriate, HIGH DOSE nicotine replacement therapy for heavy smokers may be prescribed with the authorization of the primary provider or the supervising/consultant physician. The dose could be as much as a milligram per milligram replacement. For example, for a heavy smoker that smokes 3 packs a day = 60 cigarettes = 60mg of nicotine. This patient could be started on a similar nicotine replacement dose (such as 63mg = 21mg patch x 3). These patients must be closely monitored for signs or symptoms of toxicity
- Patients experiencing significant nicotine withdrawal symptoms when switched to a lower dose patch can be switched back to the higher dose.
- If patients experience signs of nicotine toxicity, such as nausea, vomiting, dizziness, weakness, or tachycardia, a lower dose patch may be required.
- If cardiovascular, significant CNS, or toxicity side effects are reported by the patient, the patient should be referred to see a physician in urgent care or the emergency room for evaluation.
- Patients reporting regular use of the NRT patches and still smoking will be counseled to decrease daily cigarette use. The patient's blood pressure should be monitored for elevations. Additional behavioral counseling should be provided and a higher dose patch may be considered.

- Pharmacy providers may use individual patient factors and clinical judgment to make adjustments to therapy at any time.

Additional counseling/use information for NRT Transdermal patches

- Do not remove the patch from its sealed protective pouch until ready for use.
- Starting on the quit day, remove the adhesive and apply patch to an area of skin that is clean, dry and hairless. Patches may be applied to any area of the body, but areas near joints should be avoided. Hold for approximately 10 seconds to help the patch adhere to the skin. Do not use on skin that is burned, broken, cut or irritated in any way. Avoid applying moisturizing lotions or using moisturizing washes in the area of patch application to maximize the adhesive hold.
- Rotate patch site every day and do not use same site more than once a week.
- Leave patch on for 24 hours a day unless the patient experiences nightmares or other sleep disturbances, then the patch should be removed before sleep. It can be worn while showering, bathing, or swimming.
- Up to 50% of patients using the nicotine patch will experience a local skin reaction. Skin reactions are usually mild and self-limiting, but occasionally worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions.

Nicotine Patch *(Transdermal Nicotine System)*	
The nicotine patch was approved by the FDA in 1991 and became available without a prescription in 1996. A person will need to stop using tobacco completely before using the nicotine patch.	
Dosage	The type and strength of the patch should be selected according to individual patient characteristics, such as previous experience with the nicotine patch, body weight, number of cigarettes smoked per day, and medical history. **16 hour** » 15-mg x 6 wks, 10-mg x 2 wks, 5-mg x 2wks » Remove before sleeping » Only releases nicotine for 16 hours **24 hour** » 21-mg x 6 wks, 14-mg x 2 wks, 7-mg x 2wks » 22-mg x 4 wks, 11-mg x 4 wks » May remove CQ patch after 16 hours
Duration	The nicotine patch may be used for 10 weeks. After approximately 6 weeks of treatment, the patient may begin using a lower strength patch and then taper off by reducing the dosage every 2 weeks until the patch is discontinued completely..
Efficacy	Use of nicotine patch doubles the odds of quitting as compared to placebo (Fiore et al., 2008). There is no difference in efficacy between 16-hour and 24-hour patches.
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using the nicotine patch. » Extensive skin disease » Hypersensitivity to patch adhesive » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat.
Side Effects	» Cutaneous hypersensitivity » Headache » Sleep disturbances/insomnia/abnormal dreams (w/24-hr use) » Approximately 50% of patients using the nicotine patch will experience local skin irritation. Rotate patch sites to reduce skin irritation. Less than 5% of patients using the nicotine patch must discontinue use as a result of skin irritation.
Instructions for Use	» After waking up on quit day, apply patch to relatively hairless area between waist and neck. » Apply new patch at start of each day » Rotate patch site to minimize local skin irritation » If sleep disturbance occurs with 24-hour patch, remove patch at bedtime or try 16-hour patch.

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nicotine Replacement Therapy – Nicotine Gum

- Patients will be offered nicotine gum in addition to other tobacco cessation medications, when appropriate.
- The gum may be dosed regularly or used as needed for cravings.
- Patient should use the chew and park method.
- Patients should not swallow gum.
- Patients should not eat or drink 15 mins before and during chewing gum due to acidic beverages interfering with buccal absorption of nicotine.

Nicotine Gum *(Nicotine Polacrilex)*	
Nicotine gum was first approved by the FDA in 1984 and became available without a prescription in 1996. A person will need to stop using tobacco completely before using the nicotine gum.	
Dosage	The gum is available in 2 mg and 4 mg (per piece) strengths. The recommended dosages are: » < 25 cigarettes/day: 2-mg » ≥ 25 cigarettes/day: 4-mg » Weeks 1-6: 1 piece every 1-2 hours » Weeks 7-9: 1 piece every 2-4 hours » Weeks 10-12: 1 piece every 4-8 hours » No more than 24 pieces/day
Duration	Nicotine gum should be used on a fixed schedule (at least one piece every 1 to 2 hours) for 6 to 12 weeks, then tapered off.
Efficacy	Use of nicotine gum increases the odds of quitting by 80% as compared to placebo (Fiore et al., 2008).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using nicotine gum. » Extensive dental work/dentures » TMJ disease » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat.
Side Effects	» Mouth soreness » Jaw ache » Hiccups » Nausea/vomiting » Headache » Indigestion Side effects usually transient and mild, often relieved by correcting chewing technique. These effects are generally mild, subside over time, and often can be alleviated by correcting the chewing technique.
Instructions for Use	» Chew until peppery or minty taste released, "park" between cheek and gum 1-5 minutes, then repeat » Park in different areas of the mouth » Use one piece no longer than 30 minutes » No eating or drinking 15 minutes before and during use (decreases nicotine absorption) » Fixed dosing for 1-3 months may be more useful than ad libitum

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nicotine Replacement Therapy – Nicotine Lozenge

- Patient may use the lozenge in addition to other tobacco cessation medications, when appropriate.
- Patient may use the nicotine lozenge if they have failed or have contraindications to the nicotine gum.
- The lozenge may be dosed regularly or used as needed for cravings.
- The lozenge should be dissolved in the mouth, not chewing or swallowing it.
- Patient should not eat or drink 15 mins before or during the use of lozenge due to acidic beverages interfering with buccal absorption of nicotine.

Nicotine Lozenge *(Nicotine Polacrilex)*	
The nicotine lozenge was first approved by the FDA in 2002. A person will need to stop using tobacco completely before using the nicotine lozenge.	
Dosage	» If smoke>30 mins after waking: 2-mg » If smoke<30 mins after waking: 4-mg » Weeks 1-6: 1 lozenge every 1-2 hours » Weeks 7-9: 1 lozenge every 2-4 hours » Weeks 10-12: 1 lozenge every 4-8 hours » Do not use more than 5 lozenges in 6 hours. » Do not use more than 20 lozenges per day
Duration	The patient should follow a 12-week schedule (lozenges should not be used for more than 12 weeks).
Efficacy	Use of the nicotine lozenge doubles the odds of quitting as compared to placebo (Shiffman et al., 2002).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using the nicotine lozenge. » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat. » Contains phenylalanine 3.4-mg per lozenge
Side Effects	» Insomnia » Nausea » Hiccups » Coughing » Headache » Heartburn These effects are generally mild and self-limiting. If side effects do not subside, or if they increase in severity, patients should discontinue use and consult a physician.
Instructions for Use	» Suck lozenge until fully dissolved (20-30 minutes). There may be a warm tingling sensation. The lozenge should be occasionally moved from one side of the mouth to the other until dissolved completely. » Consume only one lozenge at a time » No eating or drinking 15 minutes before and during use (decreases nicotine absorption)

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

***First Line* Non-Nicotine Medications - Bupropion SR**

- Initiate with 150mg SR daily for 3 days then increase to 150mg SR twice daily for 3-6 months, preferably 1 week prior to the patient's quit date.
- Approximately 90%+ of smokers have been determined to have a component of depression within the overall addiction disease. This component may require medication during and beyond smoking cessation therapy.
- Monitor for treatment-emergent hypertension.

- Lower doses of bupropion may be required for some patients, and doses may need to be empirically reduced for certain drug-drug interactions that increase the plasma concentrations of bupropion (e.g. protease inhibitors)
- Patients should be alerted of the Black Box Warning that accompanies bupropion use and a medication guide should be supplied with each prescription.

Bupropion and Concomitant Medical Conditions:

- ABSOLUTE CONTRAINDICATION in patients with seizure disorder
- Contraindicated in anorexia, or bulimia, and in patients who are receiving or have received monoamine oxidase inhibitors (MAOIs) within the last 14 days.
- Use with caution in patients already receiving a noradrenergic antidepressant agent, patients with hepatic dysfunction or end stage cirrhosis, and patients with medical conditions that may predispose them to seizures.
- Dosing may require adjustment in patients with HIV taking interacting medications, such as protease inhibitors.
- Caution should be used in patients taking concomitant behavioral health medications. The primary provider, behavioral health provider, or Tobacco Clinic consultant/supervising physician should be contacted for guidance when necessary.

Bupropion Drug-Drug Interactions*:

Antipsychotics -increased haloperidol and risperidone concentration
MAOI -increased blood pressure
Warfarin -increased PT
Grapefruit juice -increased bupropion concentration
Carbamazepine, phenobarbital, phenytoin -decreased levels of bupropion
Levodopa – possible increased incidence of adverse events
Use cautiously with drugs with a narrow therapeutic index (TCAs and Type 1C antiarrythmics)
Use cautiously with other drugs known to lower seizure threshold (neuroleptics, other antidepressants, theophylline, systemic steroids, abrupt withdrawal of benzodiazepine)
HIV medications – ritonavir, efavirenz, lopinavir, nelfinavir, tipranavir
Zolpidem – increased chance for hallucinations
SSRIs – increased plasma levels of sertraline, citalopram, paroxetine
Tamoxifen - decreased efficacy of tamoxifen

*This list has a majority of major clinical interactions, but does not include all interactions. It would be prudent to complete a drug interaction review before prescribing.

Bupropion SR (Zyban®)	
Bupropion SR is the first non-nicotine replacement drug approved by the FDA for smoking cessation (1997). It is available by prescription only. Mechanism of action is presumed to be mediated through dopaminergic and/or noradrenergic mechanisms.	
Dosage	The recommended dose is 150 mg once daily for 3 days. Dosage then increases to 150 mg twice a day for 4 days (after which the patient should stop all tobacco use) and continue at this level for the remainder of the treatment.
Duration	Treatment with bupropion SR is recommended for 7 to 12 weeks.
Efficacy	Use of bupropion SR doubles the odds of quitting as compared to placebo (Fiore et al., 2008).
Precautions	» Tobacco users in any of the special circumstances groups should consult with

Second Line Non-Nicotine Medication – Varenicline (Chantix)

- Initiate approximately 1-2 weeks before the quit date. Patients can smoke during this initiation phase, but should be instructed to set a firm quit date. Some people need to take varenicline for several weeks for it to work.
- When prescribing varenicline, patients should need to be carefully screened and monitored for underlining depressed mood, agitation, changes in behavior, and suicidal ideation (2008 FDA Black Box Warning).
- Patients should be warned of the FDA MedWatch communication regarding potential increased risk of cardiovascular events and symptoms while using varenicline
- Patients should be alerted of the Black Box Warning and Warnings and Precautions that accompany varenicline use and a medication guide should be supplied with each prescription.
- Varenicline comes as a white tablet (0.5 mg) and a blue tablet (1 mg).
- Lower doses of varenicline may be required for some patients, and doses may need to be empirically reduced to reduce side effects.
- Most common side effects are nausea and/or insomnia. To reduce nausea, take on a full stomach. To reduce insomnia, the evening dose may be taken earlier in evening instead of at bedtime.
- Patients should be seen approximately every 2 weeks to maintain adequate follow-up.

Varenicline and Concomitant Medical Conditions:

- Caution should be used in patients taking concomitant behavioral health medications or with behavior health disorders. The primary provider, behavioral health provider, or Tobacco Clinic consultant/supervising physician should be contacted for guidance when necessary. This includes a thorough evaluation prior to initiating therapy with the medication and upon subsequent visits.
- Patients should not take varenicline if patients have had a serious allergic or skin reaction to varenicline (including angioedema, Stevens-Johnson, and/or erythema multiforme).

- Varenicline is not recommended for use in combination with NRT because of its nicotine antagonist properties. Varenicline is almost entirely eliminated through the kidneys, it should be used with caution for patients with CrCl < 30 ml/min. Dose should be reduced by 50%.

Drug-Drug Interactions:

- There are no known significant drug interactions with varenicline. However, pharmacy providers should always perform medication reconciliation and monitor current medications.

Varenicline (Chantix™)	
Varenicline is a partial nicotinic acetylcholine receptor agonist. It was designed to bind to nicotine receptors in the brain and ease withdrawal symptoms in adult tobacco users. Varenicline blocks the effects of nicotine from cigarettes if the patient resumes smoking.	
Dosage	» Day 1 to Day 3: white tablet (0.5-mg), 1 tablet each day » Day 4 to Day 7: white tablet (0.5-mg), twice a day (1 in the morning and 1 in the evening) » Day 8 to end of treatment: blue tablet (1-mg), twice a day (1 in the morning and 1 in the evening) » Varenicline should be taken after eating with a full glass (8 ounces) of water.
Duration	Treatment with varenicline is recommended for 12 weeks. For patients who have quit smoking at 12 weeks, an additional 12 weeks of varenicline is recommended to further increase the likelihood of long-term abstinence (Tonstad et al., 2006).
Efficacy	Use of varenicline 3 times to nearly 4 times greater compared to placebo depending on which time point abstinence is assessed (Gonzales et al., 2006; Jorenby et al., 2006).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using varenicline. » History of kidney problems or kidney failure » History of psychiatric illness » Advise patients and caregivers that the patient should stop taking varenicline and contact a healthcare provider immediately if agitation, depressed mood, or changes in behavior that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior. *Note:* Safety and efficacy not established in patients with serious psychiatric Illness.
Side Effects	» Nausea » Changes in dreaming » Constipation, Gas » Vomiting *Note:* Nausea was reported by approximately 30% of patients treated with varenicline 1 mg twice a day, with approximately a 3% discontinuation rate during 12 weeks of treatment. Nausea was generally described as mild or moderate and often transient. Patients who cannot tolerate nausea may have the dose lowered temporarily or permanently.
Instructions for Use	» Start varenicline treatment one week before quit date » Varenicline should be taken after eating with a full glass (8 ouces) of water

Adapted from Fiore et al. 2008; Physicians' Desk Reference [PDR], 2007; PDR, 2008

***Second Line* Non-Nicotine Medications - Nortriptyline**

- May be prescribed by the pharmacy provider after discussion with the primary or behavioral health provider or Tobacco Clinic Consultant/Supervising Physician.
- See full prescribing information to assess appropriateness of medication, assess drug interactions, side effects and monitoring required.

Nortriptyline	
Nortriptyline is appropriate as a second-line treatment for smoking cessation. Nortriptyline is not approved by the FDA for the treatment of tobacco dependence.	
Dosage	» Dosage begins 10–28 days before the quit date. » Initiate treatment at 25 mg/day, gradually increasing to 75–100 mg/day. Blood levels of nortriptyline may be monitored.
Duration	Duration of treatment in smoking cessation is approximately 12 weeks.
Efficacy	Use of nortriptyline triples the odds of quitting as compared to placebo.
Precautions	Use with extreme caution in patients with cardiovascular disease.
Side Effects	The most commonly reported side effects are sedation, urinary retention, light-headedness, dry mouth, blurred vision, and hand tremor.
Instructions for Use	Patients should begin taking nortriptyline 10–28 days before the quit date to allow the medication to reach a steady state in the blood.

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Second Line Non-Nicotine Medications - Clonidine

- May be prescribed by the pharmacy provider after discussion with the primary or behavioral health provider or Tobacco Clinic Consultant/Supervising Physician.
- See full prescribing information to assess appropriateness of medication, assess drug interactions, side effects and monitoring required.

Clonidine	
Clonidine is appropriate as a second-line treatment for smoking cessation. Clonidine is not approved by the FDA for the treatment of tobacco dependence.	
Dosage	Doses used in various clinical trials have varied from 0.15–0.75 mg/day orally to 0.10–0.20 mg/day transdermal patch, without a clear dose-response relation to cessation.
Duration	Patients should begin taking clonidine shortly (3 days) prior to or on the quit date. Duration of treatment ranges from 3 to 10 weeks.
Efficacy	The use of clonidine doubles the odds of quitting as compared to placebo.
Precautions	» As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Monitoring blood pressure is therefore recommended during treatment. » Failure to gradually reduce dosage over 2–4 days before discontinuation may result in rebound hypertension.
Side Effects	The most commonly reported side effects of clonidine are dry mouth, drowsiness, dizziness, sedation, and constipation.
Instructions for Use	Initial dosing is typically 0.10 mg twice daily orally, or 0.10 mg/day transdermal patch. Increase by 0.10 mg/day per week as needed.

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Incidental Medications/Supplies

Hydrocortisone Cream 1%

In the instance of mild topical irritation due to the nicotine transdermal patch, hydrocortisone cream 1% may be supplied to the patient for self-management of the local skin reaction. The primary provider or

consultant/supervising physician should be contacted if the local irritation does not improve or requires additional intervention.

Tegaderm/Hypafix Tape

If a patient is having difficulty with the patch adhering for the full 24 hours, the patient may be sent to the [ ] Central Supply or obtain the tegaderm patches or hypafix tape from pharmacy to be placed over the nicotine patch. Patients would also be counseled to avoid application of lotions or oils in the area of patch application.

Special Populations

[ ] pharmacy providers may consult with a patient's primary provider and assist with tobacco cessation counseling for special populations, including pregnant or breastfeeding women, adolescents, and patients with serious medical conditions (including recent myocardial infarction, unstable angina, arrhythmia, or uncontrolled hypertension). Pharmacy may provide guidance and assist with monitoring of therapy, however, any tobacco cessation medications must be approved by a physician.

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Revision Date: [Month/Year]

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Pharmacy Clinic Director

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Pharmacy Clinic Co-Director

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[Name/Credentials] Date
Consultant/Supervising Physician
Tobacco Cessation Clinic
[ ] Behavior Health Services

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[Name/Credentials] Date
[ ] Chief of Pharmacy

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[Name/Credentials] Date
Chief of Clinical Operations