



COMMUNITY HEALTH PLAN
of Washington

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Disease Management Guidelines

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ASTHMA

I. General Goals of Asthma Therapy

1. Prevent chronic asthma symptoms and asthma exacerbations during the day and night.
 - No sleep disruption by asthma
 - No missed school or work days due to asthma
 - Minimal need for emergency visits or hospitalizations
2. Maintain normal activity levels – including exercise and other physical activities.
3. Have normal or near-normal lung function.
4. Be satisfied with asthma care received.
5. Have no or minimal side effects while receiving optimal medications.

STEP THERAPY: The Key to Long-Term Asthma Management

Severity of signs and symptoms must be classified at all visits. Initially & before treatment has been optimized, clinical signs, symptoms & peak flow monitoring or spirometry are used to classify severity.

II. Classification of Asthma Severity: Clinical Features before Treatment

Classifications of asthma severity

Classification	Step	Days with symptoms	Nights with symptoms	For adults and children aged >5 years who can use a spirometer or peak flow meter	
				FEV1 or PEF* % predicted normal	PEF variability (%)
Severe persistent	4	Continual	Frequent	≤60	>30
Moderate persistent	3	Daily	>1/week	>60 - <80	>30
Mild persistent	2	>2/week, but <1 time/day	>2/month	≥80	20 - 30
Mild intermittent	1	≤2/week	<2/month	≥80	<20

*Percentage predicted values for forced expiratory volume in 1 second (FEV1) and percentage of personal best for peak expiratory flow (PEF).

- *Asthma is now recognized primarily as an inflammatory condition, so anti-inflammatory therapy should be the cornerstone of therapy*
 - *Patients with mild, moderate or severe persistent asthma require daily long-term control medication to control their asthma*
 - *All patients need to have a short-acting inhaled beta2-agonist to take as needed for symptoms.*

The following three tables are excerpts from the National Asthma Education and Prevention Program's (NAEPP) *Practical Guide for the Diagnosis and Management of Asthma* (2002), National Heart, Lung and Blood of the National Institutes of Health:

Stepwise Approach for Managing Infants and Young Children (5 Years of Age and Younger) With Acute or Chronic Asthma

Classify Severity: Clinical Features Before Treatment or Adequate Control		Medications Required To Maintain Long-Term Control
	Symptoms/Day Symptoms/Night	Daily Medications
Step 4 Severe Persistent	Continual Frequent	<ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> - High-dose inhaled corticosteroids AND - Long-acting inhaled beta₂-agonists AND, if needed, <ul style="list-style-type: none"> - Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)
Step 3 Moderate Persistent	Daily > 1 night/week	<ul style="list-style-type: none"> ■ Preferred treatments: <ul style="list-style-type: none"> - Low-dose inhaled corticosteroids and long-acting inhaled beta₂-agonists OR - Medium-dose inhaled corticosteroids. ■ Alternative treatment: <ul style="list-style-type: none"> - Low-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline. <p>.....</p> <p>If needed (particularly in patients with recurring severe exacerbations):</p> <ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> - Medium-dose inhaled corticosteroids and long-acting beta₂-agonists. ■ Alternative treatment: <ul style="list-style-type: none"> - Medium-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline.
Step 2 Mild Persistent	> 2/week but < 1x/day > 2 nights/month	<ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> - Low-dose inhaled corticosteroid (with nebulizer or MDI with holding chamber with or without face mask or DPI). ■ Alternative treatment (listed alphabetically): <ul style="list-style-type: none"> - Cromolyn (nebulizer is preferred or MDI with holding chamber) OR leukotriene receptor antagonist.
Step 1 Mild Intermittent	≤ 2 days/week ≤ 2 nights/month	<ul style="list-style-type: none"> ■ No daily medication needed.

<p>Quick Relief All Patients</p>	<ul style="list-style-type: none"> ■ Bronchodilator as needed for symptoms. Intensity of treatment will depend upon severity of exacerbation. <ul style="list-style-type: none"> - Preferred treatment: Short-acting inhaled beta₂-agonists by nebulizer or face mask and spacer/holding chamber - Alternative treatment: Oral beta₂-agonist ■ With viral respiratory infection <ul style="list-style-type: none"> - Bronchodilator q 4–6 hours up to 24 hours (longer with physician consult); in general, repeat no more than once every 6 weeks - Consider systemic corticosteroid if exacerbation is severe or patient has history of previous severe exacerbations ■ Use of short-acting beta₂-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term-control therapy.
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<p>Step down Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.</p> <p>Step up If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.</p>
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Goals of Therapy: Asthma Control	
<ul style="list-style-type: none"> ■ Minimal or no chronic symptoms day or night ■ Minimal or no exacerbations ■ No limitations on activities; no school/parent's work missed 	<ul style="list-style-type: none"> ■ Minimal use of short-acting inhaled beta₂-agonist ■ Minimal or no adverse effects from medications

Note

- The stepwise approach is intended to assist, not replace, the clinical decisionmaking required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs.
- There are very few studies on asthma therapy for infants.
- Gain control as quickly as possible (a course of short systemic corticosteroids may be required); then step down to the least medication necessary to maintain control.
- Minimize use of short-acting inhaled beta₂-agonists. Overreliance on short-acting inhaled beta₂-agonists (e.g., use of approximately one canister a month even if not using it every day) indicates inadequate control of asthma and the need to initiate or intensify long-term-control therapy.
- Provide parent education on asthma management and controlling environmental factors that make asthma worse (e.g., allergies and irritants).
- Consultation with an asthma specialist is recommended for patients with moderate or severe persistent asthma. Consider consultation for patients with mild persistent asthma.

Stepwise Approach for Managing Asthma in Adults and Children Older Than 5 Years of Age: Treatment

Classify Severity: Clinical Features Before Treatment or Adequate Control		Medications Required To Maintain Long-Term Control	
	Symptoms/Day Symptoms/Night	PEF or FEV ₁ PEF Variability	Daily Medications
Step 4 Severe Persistent	Continual Frequent	≤ 60% > 30%	<ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> – High-dose inhaled corticosteroids AND – Long-acting inhaled beta₂-agonists AND, if needed, – Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)
Step 3 Moderate Persistent	Daily > 1 night/week	> 60% – < 80% > 30%	<ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> – Low-to-medium dose inhaled corticosteroids and long-acting inhaled beta₂-agonists. ■ Alternative treatment (listed alphabetically): <ul style="list-style-type: none"> – Increase inhaled corticosteroids within medium-dose range OR – Low-to-medium dose inhaled corticosteroids and either leukotriene modifier or theophylline. <p>If needed (particularly in patients with recurring severe exacerbations):</p> <ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> – Increase inhaled corticosteroids within medium-dose range and add long-acting inhaled beta₂-agonists. ■ Alternative treatment (listed alphabetically): <ul style="list-style-type: none"> – Increase inhaled corticosteroids within medium-dose range and add either leukotriene modifier or theophylline.
Step 2 Mild Persistent	> 2/week but < 1x/day > 2 nights/month	≥ 80% 20–30%	<ul style="list-style-type: none"> ■ Preferred treatment: <ul style="list-style-type: none"> – Low-dose inhaled corticosteroids. ■ Alternative treatment (listed alphabetically): cromolyn, leukotriene modifier, nedocromil, OR sustained-release theophylline to serum concentration of 5–15 mcg/mL.
Step 1 Mild Intermittent	≤ 2 days/week ≤ 2 nights/month	≥ 80% < 20%	<ul style="list-style-type: none"> ■ No daily medication needed. ■ Severe exacerbations may occur, separated by long periods of normal lung function and no symptoms. A course of systemic corticosteroids is recommended.

Quick Relief

All Patients

- Short-acting bronchodilator: 2–4 puffs short-acting inhaled beta₂-agonists as needed for symptoms.
- Intensity of treatment will depend on severity of exacerbation; up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed. Course of systemic corticosteroids may be needed.
- Use of short-acting beta₂-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term-control therapy.



Step down

Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.



Step up

If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.

Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night
- Minimal or no exacerbations
- No limitations on activities; no school/work missed
- Maintain (near) normal pulmonary function
- Minimal use of short-acting inhaled beta₂-agonist
- Minimal or no adverse effects from medications

Note

- The stepwise approach is meant to assist, not replace, the clinical decisionmaking required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs (PEF is % of personal best; FEV₁ is % predicted).
- Gain control as quickly as possible (consider a short course of systemic corticosteroids); then step down to the least medication necessary to maintain control.
- Minimize use of short-acting inhaled beta₂-agonists. Overreliance on short-acting inhaled beta₂-agonists (e.g., use of approximately one canister a month even if not using it every day) indicates inadequate control of asthma and the need to initiate or intensify long-term-control therapy.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g., allergens and irritants).
- Refer to an asthma specialist if there are difficulties controlling asthma or if step 4 care is required. Referral may be considered if step 3 care is required.

Usual Dosages for Long-Term-Control Medications

Medication	Dosage Form	Adult Dose	Child Dose*
Inhaled Corticosteroids (See Estimated Comparative Daily Dosages for Inhaled Corticosteroids.)			
Systemic Corticosteroids		(Applies to all three corticosteroids.)	
Methylprednisolone	2, 4, 8, 16, 32 mg tablets	■ 7.5–60 mg daily in a single dose in a.m. or qod as needed for control	■ 0.25–2 mg/kg daily in single dose in a.m. or qod as needed for control
Prednisolone	5 mg tablets, 5 mg/5 cc, 15 mg/5 cc	■ Short-course "burst" to achieve control: 40–60 mg per day as single or 2 divided doses for 3–10 days	■ Short-course "burst": 1–2 mg/kg/day, maximum 60 mg/day for 3–10 days
Prednisone	1, 2.5, 5, 10, 20, 50 mg tablets; 5 mg/cc, 5 mg/5 cc		
Long-Acting Inhaled Beta₂-Agonists (Should not be used for symptom relief or for exacerbations. Use with inhaled corticosteroids.)			
Salmeterol	MDI 21 mcg/puff DPI 50 mcg/blister	2 puffs q 12 hours 1 blister q 12 hours	1–2 puffs q 12 hours 1 blister q 12 hours
Formoterol	DPI 12 mcg/single-use capsule	1 capsule q 12 hours	1 capsule q 12 hours
Combined Medication			
Fluticasone/Salmeterol	DPI 100, 250, or 500 mcg/50 mcg	1 inhalation bid; dose depends on severity of asthma	1 inhalation bid; dose depends on severity of asthma
Cromolyn and Nedocromil			
Cromolyn	MDI 1 mg/puff Nebulizer 20 mg/ampule	2–4 puffs tid-qid 1 ampule tid-qid	1–2 puffs tid-qid 1 ampule tid-qid
Nedocromil	MDI 1.75 mg/puff	2–4 puffs bid-qid	1–2 puffs bid-qid
Leukotriene Modifiers			
Montelukast	4 or 5 mg chewable tablet 10 mg tablet	10 mg qhs	4 mg qhs (2–5 yrs) 5 mg qhs (6–14 yrs) 10 mg qhs (> 14 yrs)
Zafirlukast	10 or 20 mg tablet	40 mg daily (20 mg tablet bid)	20 mg daily (7–11 yrs) (10 mg tablet bid)
Zileuton	300 or 600 mg tablet	2,400 mg daily (give tablets qid)	
Methylxanthines (Serum monitoring is important [serum concentration of 5–15 mcg/mL at steady state].)			
Theophylline	Liquids, sustained-release tablets, and capsules	Starting dose 10 mg/kg/day up to 300 mg max; usual max 800 mg/day	Starting dose 10 mg/kg/day; usual max: ■ < 1 year of age: 0.2 (age in weeks) + 5 = mg/kg/day ■ ≥ 1 year of age: 16 mg/kg/day

Estimated Comparative Daily Dosages for Inhaled Corticosteroids

Drug	Low Daily Dose		Medium Daily Dose		High Daily Dose	
	Adult	Child*	Adult	Child*	Adult	Child*
Beclomethasone CFC 42 or 84 mcg/puff	168–504 mcg	84–336 mcg	504–840 mcg	336–672 mcg	> 840 mcg	> 672 mcg
Beclomethasone HFA 40 or 80 mcg/puff	80–240 mcg	80–160 mcg	240–480 mcg	160–320 mcg	> 480 mcg	> 320 mcg
Budesonide DPI 200 mcg/inhalation	200–600 mcg	200–400 mcg	600–1,200 mcg	400–800 mcg	> 1,200 mcg	> 800 mcg
Inhalation suspension for nebulization (child dose)		0.5 mg		1.0 mg		2.0 mg
Flunisolide 250 mcg/puff	500–1,000 mcg	500–750 mcg	1,000–2,000 mcg	1,000–1,250 mcg	> 2,000 mcg	> 1,250 mcg
Fluticasone MDI: 44, 110, or 220 mcg/puff DPI: 50, 100, or 250 mcg/inhalation	88–264 mcg 100–300 mcg	88–176 mcg 100–200 mcg	264–660 mcg 300–600 mcg	176–440 mcg 200–400 mcg	> 660 mcg > 600 mcg	> 440 mcg > 400 mcg
Triamcinolone acetonide 100 mcg/puff	400–1,000 mcg	400–800 mcg	1,000–2,000 mcg	800–1,200 mcg	> 2,000 mcg	> 1,200 mcg

* Children ≤ 12 years of age

The following two tables are excerpts from the Guidelines for the Diagnosis and Management of Asthma endorsed by the Washington State Department of Health, the Washington State Medical Association, and the American Lung Association of Washington. These guidelines are based largely on the NAEPP's Practical Guide for the Diagnosis and Management of Asthma.

Pharmacotherapy

PRESCRIBE MEDICATIONS ACCORDING TO SEVERITY

- I. Current evidence indicates that daily long-term control medications are necessary for all patients with persistent asthma.
- II. Inhaled corticosteroids are the preferred long-term controllers.

Medications used in different levels of asthma severity*

Classification	Step	Daily Medication	Quick relief medication
Severe persistent	4	High-dose inhaled steroids (ICS) and long-acting inhaled β 2-agonist If needed, add oral steroids	Short-acting inhaled β 2-agonist, as needed; oral steroids may be required
Moderate persistent	3	Low-to-medium-dose ICS and long-acting β 2-agonist (preferred) or for children <5, low dose ICS plus long-acting β 2-agonist or medium-dose ICS Or Low-to-medium-dose ICS and either leukotriene modifier or theophylline	Short-acting inhaled β 2-agonist, as needed; oral steroids may be required
Mild persistent	2	Low-dose inhaled steroids (preferred) Or Cromolyn, leukotriene modifier, or (except for children aged <5 years) nedocromil or sustained release theophylline to serum concentration of 5-15 μ g/mL	Short-acting inhaled β 2-agonist, as needed; oral steroids may be required
Mild Intermittent	1	No daily medicine needed	Short-acting inhaled β 2-agonist, as needed; oral steroids may be required

* The medications listed here are appropriate for treating asthma at different levels of severity. The preferred treatments, dosage, and type of medication recommended vary for adults and children and are detailed in the EPR-Update 2002 stepwise approach to therapy. The stepwise approach emphasizes that therapy should be stepped up as necessary and stepped down when possible to identify the least amount of medication required to achieve goals of therapy. The stepwise approach to care is intended to assist, not replace, the clinical decision making required to meet individual patient needs.

Pharmacotherapy

KEY POINTS

- I. All patients with persistent (mild, moderate or severe) asthma should take daily long-term controller medications.
- II. Inhaled corticosteroids are the preferred long-term controllers.
- III. Other agents can be used for mild persistent but none (cromolyn, leukotriene modifiers, nedocromil and sustained released theophylline) has been demonstrated to be as effective as inhaled corticosteroids.
- IV. Patients with moderate and severe persistent asthma frequently require a second controller medication.
 - A. In adults and patients 5 and older the addition of a long-acting inhaled beta agonist (LABA) to the low-to-medium dose inhaled corticosteroids is the preferred agent. Other controllers can be added instead of a LABA but none has been shown to be as effective.
 - B. In patients <5 either: 1) The addition of a LABA to a low dose of inhaled corticosteroids, or 2) medium dose corticosteroids as monotherapy
- V. All patients should be strongly advised not to use a LABA on a daily basis unless they are on an inhaled steroid.
- VI. All patients require a short-acting bronchodilator for managing acute symptoms when they occur.
- VII. Severe exacerbations require the addition of systemic (oral) corticosteroids.
- VIII. Once treatment goals are achieved a gradual reduction in treatment should be carefully performed to identify the minimum dose required to maintain control.

MONITOR USE OF BETA-AGONIST DRUGS

- I. Beta-agonist use should be reviewed at every patient visit. This should include:
 - A. Patient's understanding of dosage instructions.
 - B. Inhaler technique.
 - C. Reasons for increased use.
- II. More than 1 canister of short acting beta-agonist per month is always a sign of inadequate control. Use of more than 2 canisters per year is a sign of inadequate control.
- III. Routine use of more than 1 puff per day of short-acting beta-agonist should result in increased use of daily long-term controller therapy. A long-acting beta-agonist should not be used without also being on a long-acting controller – preferably an inhaled corticosteroid.

III. Tips for Stepping Up and Down in Therapy

- **STEP DOWN:** Review treatment every 1 to 6 months. Follow up visits should be scheduled within 1 month of initial diagnosis; routine follow up thereafter should be every 1-6 months depending on the severity of asthma and ability to maintain control of symptoms. Gradually decrease the treatment to the least medication necessary to maintain control.
- **STEP UP:** If control is not maintained, consider a step up. Inadequate control is indicated by increased use of short-acting beta₂-agonists and in step 1 when patient uses a short-acting beta₂-agonist more than two times a week or in, steps 2 and 3 when patient uses short-acting beta₂-agonist on a daily basis or more than 3-4 times in one day.

BUT BEFORE STEPPING UP: Review patient inhaler technique, compliance, and environmental control (avoidance of allergens or other precipitant factors).

- A course of oral steroids may be needed at any time and at any step.
- Patients with exercise-induced bronchospasm should use an inhaled beta2-agonist 5 to 60 minutes before exercise.
- Referral to an asthma specialist for consultation or co-management is recommended if there is difficulty maintaining control or if the patient requires step 4 care. Referral may be considered for step 3 care.

VI. Asthma Education

Living with any chronic disease is challenging. Clinic staff members are in an ideal position to provide necessary education and support for families and patients with asthma. Patient education and individualized self-care plans play a central role in good asthma management. The following is a list of various components of asthma education which can be covered over time. The use of a WRITTEN ASTHMA ACTION (MANAGEMENT) PLAN to guide patient self-management of exacerbations at home, especially for patients with moderate-to-severe persistent asthma and any patient with a history of severe exacerbations is useful as a team building tool and gives your patients something to refer to asthma flares up. The clinic, patient, family, and school should each have a copy of the plan, which should be reviewed at each visit. Common discussion items:

1. Cultural and family beliefs which may affect asthma care
2. Disease processes (especially inflammation)
3. Goals for treatment
4. Signs and symptoms of exacerbation and respiratory distress
5. Signs and symptoms of worsening condition
 - Increasing waking up at night
 - Increasing medication use
 - Decreased activity tolerance
6. When and who to call for help
7. Trigger avoidance, including active and passive smoking
8. Environmental modification, tailored to patient
9. Current medication (rescue vs. controller; side effects)
10. Peak flow meters
11. Home nebulizer use/care
12. Inhaler use/care
13. Spacer use/care

Educating patients to recognize and treat exacerbations early is the best strategy

REFERENCES:

- National Asthma Education and Prevention Program (2002). *Practical Guide for the Diagnosis and Management of Asthma*. National Heart, Lung, and Blood Institute of the National Institutes of Health: Bethesda, Maryland.
- American Academy of Allergy, Asthma & Immunology (1999). *Pediatric Asthma: Promoting Best Practice*. Milwaukee, Wisconsin.
- Effective 2001. Reviewed and Updated Jan 2002, Dec 2002, Dec 2004, Jan 2005, March 2006.

DEPRESSION

1. Background:

The treatment of Major Depressive Disorder (MDD) is divided into 3 phases:

- **ACUTE PHASE** (typically lasts 3 months): The goal of the acute phase is to put the patient's symptoms into "remission."
- **CONTINUATION PHASE** (usually 6-12 months following the acute phase): During this period, remission is preserved.
- **MAINTENANCE PHASE** (long term): During this phase, the patient is protected from having a recurrence of his MDD. This phase may last for years if the patient is at high risk of recurrence (e.g., has had 3 or more previous MDD episodes, has a pre-existing dysthymia, has a family history of MDD, etc.)

There are primarily 3 therapeutic options when treating MDD:

- Medication
- Psychotherapy
- Electroconvulsive therapy (ECT).

(selection of treatment depends upon the severity of depression and the patient's preference)

- In general, mild MDD (the patient has no vegetative symptoms, suicidal ideation, or significant functional impairment) may be treated with either medication or **psychotherapy**. Moderate to severe MDD (characterized by significant neurovegetative symptoms, hopelessness, or suicidal ideation) requires both medication and psychotherapy, and perhaps ECT.

2. Medication:

Several classes of pharmacotherapy are available. The effectiveness of the medication is comparable within and between therapeutic classes. (However, MAOIs tend to be less effective than TCAs in treating severe MDD.)

- **Tricyclics and tetracyclics antidepressants (TCA)**
Amitriptyline, Clomipramine, Doxepin, Imipramine, Trimipramine, Desipramine, Nortriptyline, Protriptyline, Amoxapine, and Maprotiline.
- **Selective serotonin reuptake inhibitors (SSRI)**
Citalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline
- **Dopamine-norepinephrine reuptake inhibitors**
Bupropion, Bupropion (sustained release)
- **Serotonin-norepinephrine reuptake inhibitors**
Venlafaxine, Venlafaxine (sustained release)
- **Serotonin modulators**

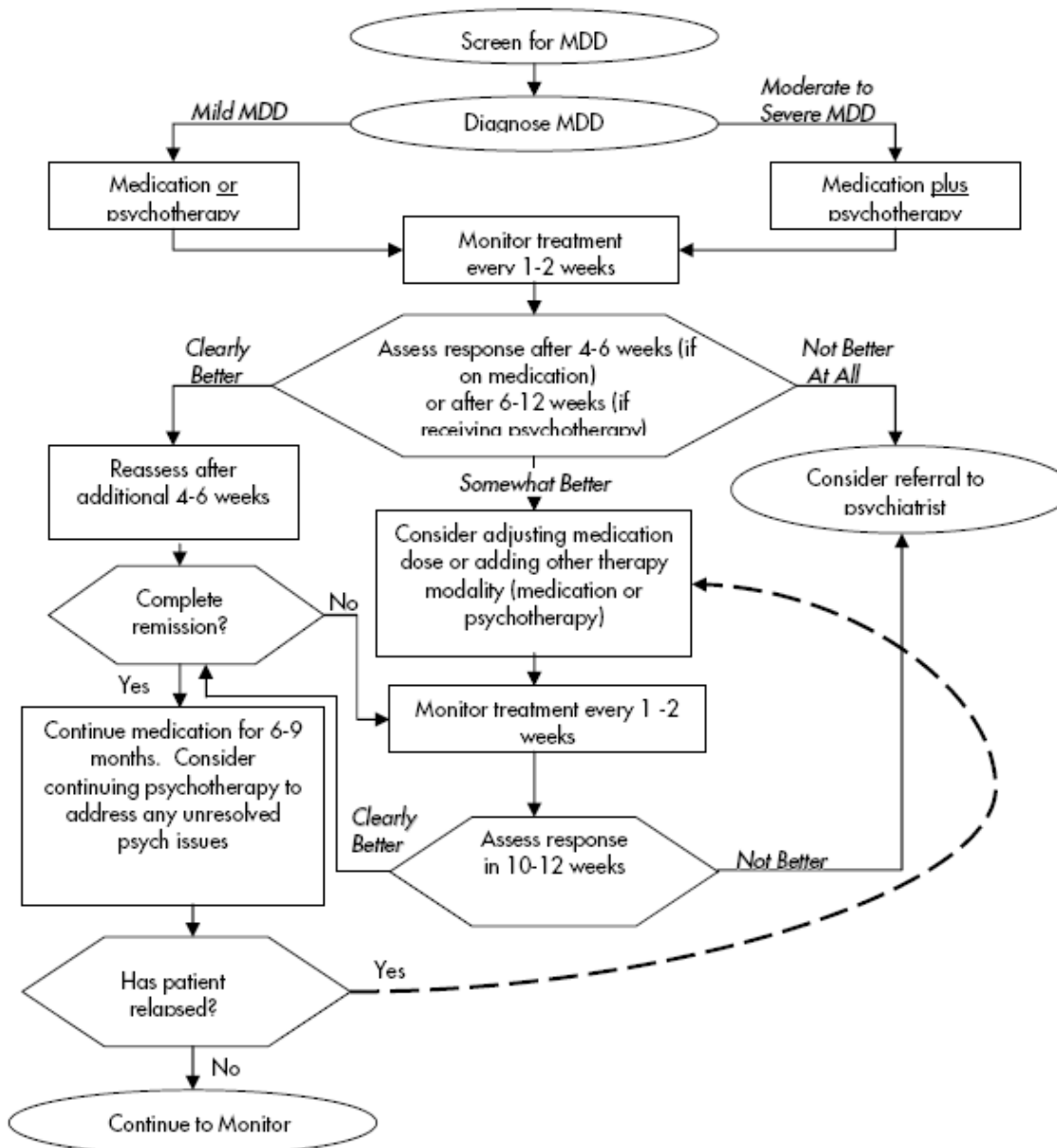
Nefazodone, Trazodone

- **Norepinephrine-serotonin modulator**
Mirtazapine
- **Monoamine oxidase inhibitors (MAOI)**
Phenelzine, Tranylcypromine, Moclobemide
- **Selective noradrenaline reuptake inhibitor**
Reboxetine

Most providers select either a TCA or an SSRI as first line therapy, and most patients (between 65%-70%) respond to their first antidepressant.

3. Treatment Overview:

Major Depressive Disorder (MDD) Treatment Overview



4. FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released. Source: The National Guideline Clearinghouse

- On December 8, 2005, the U.S. Food and Drug Administration (FDA) determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the **WARNINGS** section of paroxetine's prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician. See the www.fda.gov for more information.

- On September 27, 2005, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Pregnancy/PRECAUTIONS section of the Prescribing Information for Paxil and Paxil CR Controlled-Release Tablets to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall major congenital malformations for paroxetine as compared to other antidepressants [OR 2.2; 95% confidence interval, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients. See the www.fda.gov for more information.
- On July 1, 2005, in response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to update patients and healthcare providers with the latest information on this subject. Even before the publication of these recent reports, FDA had already begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population

taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete. See the www.fda.gov for more information.

References:

- American Psychiatric Association Pocket Guideline for the Assessment and Treatment of Major Depressive Disorder. ISBN 0890423849. (January 2006)
- Group Health Cooperative of Puget Sound Adult Depression Guideline (1996/1997)
- Institute for Clinical Systems Improvement, Health Care Guideline: "Major Depression in Primary Care. (Released 5/2004) " www.icsi.org
- National Guideline Clearinghouse, "Depression" American Medical Directors Association. (2003). NGC:003520 <http://www.guideline.gov>
- National Guideline Clearinghouse, "Depression" University of Michigan Health System - Academic Institution. Jun 1998 (revised 2005 Oct). NGC:004662 <http://www.guideline.gov>
- Food and Drug Administration. Questions and Answers on Antidepressant Use in Children and Adolescents (March 2004)
www.fda.gov/cder/drug/antidepressants/Q&A_antidepressants.htm

DIABETES MELLITUS

Diagnostic testing for Diabetes Mellitus is indicated through blood glucose testing for any one of the following:

- Signs or symptoms of diabetes are present
- Every 3 years, for adult, when any one of the following risk factors is present:
 - Personal history of either impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)
 - Female with history of gestational diabetes or of delivering babies >9 pounds
 - Obesity
 - Hypertension, Dyslipidemia, Macrovascular disease, Ischemic heart disease, Peripheral vascular disease, or Cerebrovascular disease
 - Race or ethnicity associated with high prevalence of diabetes (i.e., African Americans, Hispanic Americans, Native Americans, Asian Americans, or Pacific Islanders)

The American Diabetes Association (ADA) Clinical Practice Guidelines are based on a complete review of the relevant literature by a diverse group of highly trained clinicians. These guidelines are revised on a regular basis by the ADA Executive Committee. The following table is an excerpt from the ADA Diagnosis and Classification of Diabetes Mellitus.

Table 2— Criteria for the diagnosis of diabetes mellitus

- | |
|---|
| <ol style="list-style-type: none">1. Symptoms of diabetes plus casual plasma glucose concentration 200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss. <p>OR</p> <ol style="list-style-type: none">2. FPG 126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h. <p>OR</p> <ol style="list-style-type: none">3. 2-h postload glucose 200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water |
|---|

In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day. The third measure (OGTT) is not recommended for routine clinical use.

Diagnosis of glucose intolerance

- Impaired fasting glucose (IFG) is a fasting plasma glucose ≥ 110 mg/dL but < 126 mg/dL.
- Impaired glucose tolerance (IGT) is an OGTT 2-hour plasma glucose ≥ 140 mg/dL and < 200 mg/dL.

KEY TESTS/EXAMS*

Test	Frequency	Value
Glycosylated Hemoglobin (HbA1c) (%)	Quarterly Twice yearly if stable	Normal: <6% Goal: <7% Action suggested: >8%
Dilated Retinal Exam by Ophthalmologist/Optomtrist	Yearly	
Dental Exam	Yearly	
Foot Exam	Yearly More often in high-risk patients	Previously Normal: Monofilament and vascular exam Previously Abnormal: Feet exam at each clinic visit
Lipid Profile	Baseline fasting lipid profile: if abnormal, test and treat as clinically indicated; if normal, test biannually if previous results established low risk (eg, LDL<100 mg/dl)**	Goals (for nonpregnant adults) Lipids (mg/dl) Cholesterol <200 LDL-C <100 HDL-C >45 Triglycerides <200
Microalbumin	Baseline and yearly If abnormal, treat with ACE inhibitor	Abnormal is defined by 2-3 positive tests in 3-6 months where microalbumin is > 50 mg. If patient is on ACE inhibitor, test may be unnecessary***
Blood Pressure	Each visit; treat to reach recommended goals	Blood Pressure (mm Hg) Systolic <130 Diastolic <80***
Weight (BMI)	Each visit	Nutritional counseling as appropriate to achieve or maintain reasonable weight. Even small decreases in weight (5-10%) may significantly improve outcome
Self Monitoring of Blood Glucose	As recommended to reach blood glucose goals	Fasting/preprandial Glucose (mg/dL) Normal: <110 Goal: 80-120 Action Suggested: <80 or >120 Bedtime Glucose (md/dL) Normal: <120 Goal: 100-140 Action Suggested: <100 or >160
* May be postponed if clinically indicated - these key tests/exams are to be used as screening exams to assess when a patient's condition requires further evaluation and/or therapy.		
** Frequency of testing is higher because of increased atherogenic risk of diabetic population.		
*** Research trials underway to assess optimal ACE inhibitor dosage adjustments; BP control appears to be an essential component.		

General principles of diabetic pharmacologic management

- When secondary failure of oral hypoglycemic agents occurs in type 2 diabetics, add new drugs to existing medication rather than switching to a new agent.
- All diabetic patients need regular reassessment and appropriate adjustment of their therapeutic regimen.

GENERAL RECOMMENDATIONS

- Focus on prevention of type 2 diabetes by screening high-risk individuals, as appropriate and providing education about exercise and weight loss as preventive measures.
- Focus on cardiovascular risk reduction (blood pressure control (antihypertensive), statin use, ASA, beta-blocker, and tobacco cessation).
- Aspirin: Start patients without contraindications on low dose aspirin therapy (81-325mg daily) for cardiovascular and stroke prophylaxis. Some concerns have been raised regarding the use of an ACE and aspirin together; however, the available scientific evidence suggests that low dose ASA would not significantly affect an ACE Inhibitor's BP control.
- The A1C goal for patients in general is <7%. The A1C goal for individual patients is an A1C as close to normal (<6%) without significant hypoglycemia. HbA1c of less than 7% often requires frequent drug intensification and use of combination therapy.
- Aggressive blood pressure control is just as important as glycemic control. Systolic blood pressure level should be the major factor for detection, evaluation, and treatment of hypertension. The use of two or more blood pressure lowering agents is often required to meet blood pressure goal.
- Pneumococcal vaccine for all adult patients, at a minimum at diagnosis and at age 65. Revaccinate adults patients >64 year of age previously vaccinated >5 years ago or patients who develop nephritic syndrome, chronic renal disease, or post organ transplantation.
- Prevent microvascular complications through annual eye exams, foot risk assessments and foot care counseling, and annual screening for proteinuria.
- Annual influenza vaccine: 6 months of age and older, except for those with egg allergies.
- Smoking cessation counseling.
- Regular exercise - 30 minutes of moderate exercise daily.
- Self-management support is necessary for people with diabetes to manage their disease. Integrated self-management support by patient care team should include consistent message by all team members.
- Diabetic education by trained individual to include nutrition, exercise, prevention of acute complications, prevention of chronic complications, monitoring, and medication.
- When a patient does not show reasonable improvement within 6-weeks to 3-months of intervention with diet and exercise, pharmacotherapy should be added to the treatment plan.

References:

- American Diabetes Association: clinical practice recommendations 2006. *Diabetes Care* 2006; 29 (1 Suppl):S1-116.
- Duckworth WC. Diabetes mellitus in adults. In: Rakel RE, Bope ET, editors. *Conn's Current Therapy* 2003. Philadelphia, PA: Saunders; 2003:621-9.
- Standards of medical care in diabetes. *Diabetes Care* 2006; 29 (1 Suppl):S15-35.



DISEASE MANAGEMENT REFERRAL FORM

To request Disease Management services, please complete the information below and

Fax this form to (206) 613-8873

(for internal referral, please submit to the DM Assistant)

- Urgent (within 1 business day)
- Routine (within 5 business days)

PATIENT INFORMATION

Last Name: _____

First Name: _____

Patient ID (if unknown, Member No.): _____

Date of Birth: _____

(If member is under age 14, Parent or Guardian First and Last Name): _____

Primary Contact No: _____

LOB: BHP HO SCHIP MA GAU

City: _____

HEALTH CARE TEAM INFORMATION

Referral Date: _____

Referred by: _____

Phone No: _____

PCP: _____

Phone No(s): _____

Fax No(s): _____

1. Reason for referral: _____

2. Diagnosis: _____

3. History of present condition: _____

 Current services (if known): _____

 Comments: _____



SUBMITTING A DISEASE MANAGEMENT REFERRAL:

Please fax this referral form, and any additional clinical information that may assist the Disease Case Manager in providing services to your patient, to Community Health Plan at (206) 613-8873. For internal referrals, please submit to the Disease Management Assistant.

DISEASE MANAGEMENT – GENERAL INFORMATION:

CHP provides Disease Case Management (DM) services for patients who:

1. Have diabetes
2. Have asthma

Upon referral, the Disease Management department will assess the patient's needs and communicate with the appropriate providers of care. Based on need, pertinent supportive or educational interventions will be implemented in conjunction with the providers of care.