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Committee Approvals/Dates:
Respiratory Care Committee (07/14/15)
Clinical Knowledge Management (CKM) Council (07/23/15)
  •  Interim revisions (07/28/2016)

Release Date: July 2016
Expiration Date: July 2017
Executive Summary
Guideline Overview

Key Practice Recommendations & Companion Documents
UW Health supports the following key recommendations summarized from GINA, in addition to those recommendations found within the 2015 GINA quick-reference pocket guides available online (accessed on 5/15/15):
- GINA Pocket Guide for Asthma Management and Prevention (Age 6 or older)
- GINA Pocket Guide for Asthma Management and Prevention (Age 5 or younger)

**WHAT IS ASTHMA?**
Asthma is a chronic inflammatory disorder of the airways which causes symptoms of wheezing, shortness of breath, tightness in the chest, and cough that may vary in frequency and over time.

**ESTABLISHING A DIAGNOSIS**
It is recommended to complete a medical history to establish respiratory symptoms, as well as lung function testing using spirometry or peak expiratory flow (PEF) (see Figure 1). A diagnosis of asthma may be made after consideration of a patient’s history and whether the patient exhibits variable expiratory airflow limitations (i.e., difficulty exhaling due to bronchoconstriction, airway wall thickening, and increased mucus).

*Figure 1. Summary of Diagnostic Steps*

**Common Characteristics of Asthma:**
- Symptoms of wheezing, shortness of breath, chest tightness, or cough
- Symptoms occur or worsen at night
- Symptoms may be triggered by exercise, infection, allergens, changes in weather, or emotions/hormonal changes

**Patient presents with respiratory symptoms**

**Perform detailed medical history/examination**

**Symptoms consistent with asthma?**

**Perform lung function testing** (spirometry or PEF)

**Results support diagnosis of asthma?**

**Asthma diagnosis**

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Contact: CCKM@uwhealth.org  
Last Revised: 09/2016
PROVIDING TREATMENT AND ASSESSMENT
The goals of asthma treatment include:
- Prevention of chronic asthma symptoms and asthma exacerbations;
- Maintenance of normal activity levels;
- Patient satisfaction with asthma care and quality of life (i.e., having normal or near normal lung function, experiencing no or minimal side effects).

Asthma treatment should follow a repeating pattern of assessment of control, adjustment of treatment, and review of response to the treatment.

Assessment
An age-appropriate questionnaire should be used to help determine asthma control and efficacy of the treatment plan. It is recommended to assess asthma control at least annually.

- **Asthma Control Test (ACT)** for patients age 12 years or older.
- **Childhood Asthma Control Test (cACT)** for patients age 6-11 years.
- **Test for Respiratory and Asthma Control in Kids (TRACK)** for patients age 5 years or younger.

Treatment
The age-differentiated **Stepwise Approach to Control** should be used to guide the prescription of asthma medication (controllers and rescue). A full listing of medications available in the United States is summarized in the **Asthma Rescue and Controller Medication Table**, and dosing options for inhaled corticosteroids are available in the **Asthma Medication Dosing Table**.

All patients should have a written asthma action plan, which should include:
- A list of medications and a description of how to use them
- Environmental triggers

**Omalizumab** is FDA approved for patients ≥ 12 years of age. Patients age 18 years or older with uncontrolled severe-persistent asthma, despite use of recommended
therapeutic regimens and referral to an asthma specialist (Step 5) may be candidates for a non-pharmacological intervention of **Bronchial Thermoplasty**.

**Review Response**

It is recommended that patients be seen every 1-3 months after initiating treatment and every 3-12 months thereafter.

Patients should be seen by the provider managing their asthma within 1 week following an exacerbation to re-evaluate the patient compliance and treatment plan efficacy.

**MANAGING ASTHMA EXACERBATIONS**

Asthma exacerbations are acute or subacute episodes of progressively worsening asthma symptoms (i.e., shortness of breath, coughing, wheezing, chest tightness).

Treatment algorithms should be followed to guide exacerbation management within the outpatient, emergency department, and inpatient settings:

- **Asthma Exacerbation- Primary Care Algorithm**
- **Asthma Exacerbation- Emergency Department (Pediatric) Algorithm**
- **Asthma Exacerbation- Inpatient (Pediatric) Algorithm**
- **Asthma Exacerbation- Emergency Department (Adult) Algorithm**
- **Asthma Exacerbation- Inpatient (Adult) Algorithm**

The severity of an asthma exacerbation in pediatric patients (age 12 months to 17 years) presenting in the ED or inpatient setting should be assessed using the modified Pediatric Asthma Severity Score (mPASS) (Figure 2). The mPASS is an internally developed assessment tool based upon the Pediatric Asthma Severity Score (PASS).²

**Figure 2. Modified Pediatric Asthma Severity Score (mPASS)**

<table>
<thead>
<tr>
<th>POINTS</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant (0-1 yr.) &lt; 50</td>
<td>Normal</td>
<td>Above tachypnea threshold</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Child (2-9 yrs.) &lt; 40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adolescent (10-17 yrs.) &lt; 20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessory Muscle Use</td>
<td>None</td>
<td>Suprasternal/sub-costal/intercostal retractions or nasal flaring</td>
<td>Neck or abdominal muscles (belly breathing)</td>
<td></td>
</tr>
<tr>
<td>Air Exchange</td>
<td>Normal</td>
<td>Decreased in single lung field</td>
<td>Decreased in multiple lung fields</td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td>None or end expiratory only</td>
<td>Entire expiration</td>
<td>Expiration &amp; inspiration or if no wheezing heard due to poor air entry</td>
<td></td>
</tr>
<tr>
<td>Expiration</td>
<td>Normal (&lt; 1:2)</td>
<td>Prolonged (≥ 1:3)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Coughing</td>
<td>None</td>
<td>Infrequent (Occasional)</td>
<td>Frequent (Consistent)</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL POINTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Companion Documents
1. GINA Pocket Guide for Asthma Management and Prevention (Age 6 or older)
2. GINA Pocket Guide for Asthma Management and Prevention (Age 5 or younger)
3. GINA Appendices to the Global Strategy for Asthma Management and Prevention

Related UW Health Clinical Practice Guidelines
1. Aerosolized Respiratory Medications – Pediatric/Adult – Inpatient Guideline

Pertinent UW Health Policies & Procedures
1. UWHC Policy 1.53: Respiratory Care Protocol
2. UWHC Policy 2.25: Inhaler Medication Treatment

Patient Resources
1. HFFY #3028: About Asthma
2. HFFY #3171: Severe Asthma Packet
3. HFFY #6129: Adult and Pediatric Asthma Treatment Plan
4. HFFY #4815: Asthma- How to Use Your Spacer
5. HFFY #5122: Asthma and Pregnancy
6. HFFY #6844: Asthma Controller Medicine (Combined Medicines)
7. HFFY #6657: Asthma Controller Medicine Inhaled Corticosteroids
8. HFFY #6843: Asthma Controller Medicine Inhaled Corticosteroids: Respiratory
9. HFFY #6662: Asthma Controller Medicine Leukotriene Modifiers
10. HFFY #6661: Asthma Medicine Oral Corticosteroids
11. HFFY #6660: Asthma Rescue Medicine
12. HFFY #4506: Exercise-Induced Asthma or Bronchospasm in Children
13. HFFY #5125: How to Manage an Asthma Flare or Attack
14. HFFY #6659: Internet Websites for Allergy/Asthma Information
15. HFFY #4300: What is Asthma?
16. HFFY #5121: What is Asthma?
17. HFFY #5040: Corticosteroids (Inhalation) (with or without Long Acting Beta-Agonist)
18. HFFY #5020: Your Peak Flow Meter
19. Healthwise: Asthma: Adult
20. Healthwise: Asthma: General Info
21. Healthwise: Asthma: Pediatric
22. Healthwise: Asthma: Pediatric: 0 to 4 Years
23. Healthwise: Asthma: Pediatric 5 to 11 Years
24. Healthwise: Asthma: Pediatric: 12 Years and Older
25. Healthwise: Asthma: Teen
26. Healthwise: Asthma Attack
27. Healthwise: Asthma Attack: Pediatric
28. Healthwise: Asthma Triggers: General Info
29. Healthwise: Asthma Triggers: Pediatric: General Info
32. Healthwise: Asthma: Asthma Control
33. Healthwise: Asthma: Asthma Control: Pediatric
34. Healthwise: Asthma: Metered-Dose Inhaler With A Mask Spacer: Pediatric
36. Healthwise: Asthma: Using a Dry Powder Inhaler
37. Healthwise: Asthma: Using a Metered-Dose Inhaler
38. Healthwise: Asthma: Using a Metered-Dose Inhaler: Teen
39. Healthwise: Wheezing or Bronchoconstriction
40. Health Information: Asthma
41. Health Information: Asthma Action Plan
42. Health Information: Asthma Action Plan: Green Zone
43. Health Information: Asthma Action Plan: Yellow Zone
44. Health Information: Asthma Action Plan: Red Zone
45. Health Information: Asthma and GERD
46. Health Information: Asthma and Vocal Cord Problems
47. Health Information: Asthma and Wheezing
48. Health Information: Asthma Attack
49. Health Information: Asthma Diary
50. Health Information: Asthma During Pregnancy
51. Health Information: Asthma in Children
52. Health Information: Asthma in Children: Helping a Child Use A Metered-Dose Inhaler and Mask Spacer
53. Health Information: Asthma in Children: Knowing How Bad an Attack Is
Scope
Disease/Condition(s): Asthma

Clinical Specialty: Pulmonary, Allergy, Family Medicine, Internal Medicine, Pediatrics, Hospitalists, Respiratory Therapy, Emergency Medicine

Intended Users: Physicians, Advanced Practice Providers, Respiratory Therapists, Registered Nurses, Pharmacists, Asthma Educators

CPG objective(s): To provide evidence-based recommendations for the management of asthma across age groups and clinical settings.

Target Population: Any pediatric (0-11 years), adolescent (12-17 years), or adult (18 years or older) patient diagnosed with asthma.

Guideline Metrics:
Inpatient Quality Reporting
CAC-1 Use of Relievers for Inpatient Asthma
CAC-2 Use of Systemic Corticosteroids for Inpatient Asthma
CAC-3 Home Management Plan of Care Given to Patient/Caregiver

CPG-derived
1. Percentage of asthma patients with a completed asthma action plan
2. Percentage of asthma patients with a measurement of control (i.e., ACT score, outpatient use of systemic corticosteroids)
3. Percentage of adult patients with asthma and a lung function test within the last year
4. Attendance rates to follow-up appointments following discharge from the hospital or emergency department.
Methodology
The GINA guideline\(^1\) was produced using the standard methodology of the GINA Science Committee outlined on page vi of the full guideline (http://www.ginasthma.org).

Rating Scheme for the Strength of the Evidence/Recommendations:

<table>
<thead>
<tr>
<th>Sources of evidence</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Randomized controlled trials (RCTs) and meta-analyses. Rich body of data.</td>
</tr>
<tr>
<td></td>
<td>Evidence is from endpoints of well designed RCTs or meta-analyses that provide a consistent pattern of findings in the population for which the recommendation is made. Category A requires substantial numbers of studies involving substantial numbers of patients.</td>
</tr>
<tr>
<td>B</td>
<td>Randomized controlled trials (RCTs) and meta-analyses. Limited body of data.</td>
</tr>
<tr>
<td></td>
<td>Evidence is from endpoints of intervention studies that include only a limited number of patients, post hoc or subgroup analysis of RCTs or meta-analysis of such RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, they were under-taken in a population that differs from the target population of the recommendation, or the results are somewhat inconsistent.</td>
</tr>
<tr>
<td>C</td>
<td>Nonrandomized trials. Observational studies.</td>
</tr>
<tr>
<td></td>
<td>Evidence is from outcomes of uncontrolled or non-randomized trials or from observational studies.</td>
</tr>
<tr>
<td>D</td>
<td>Panel consensus judgement.</td>
</tr>
<tr>
<td></td>
<td>This category is used only in cases where the provision of some guidance was deemed valuable but the clinical literature addressing the subject was insufficient to justify placement in one of the other categories. The Panel Consensus is based on clinical experience or knowledge that does not meet the above listed criteria.</td>
</tr>
</tbody>
</table>

Cost Analysis: An analysis was completed by the UW Health Drug Policy Program to compare the inpatient and emergency department cost for an inhaler vs. nebulized treatment.
- Inhaler (Ventolin): 60 actuations, 90mcg per puff = $16.50
- Neb: 2.5mg/3mL = $0.20 per neb

Introduction
Asthma is a chronic inflammatory disorder of the airways. In susceptible individuals, this inflammation causes recurrent episodes of coughing (particularly at night or early in the morning), wheezing, breathlessness, and chest tightness. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. The goals of asthma therapy are to prevent chronic asthma symptoms and asthma exacerbations, maintain normal activity levels, have normal or near normal lung function, experience no or minimal side effects and have patient satisfaction with asthma care.
Recommendations

UW Health endorses the recommendations outlined within the 2015 GINA Guideline\(^1\) located online at http://www.ginasthma.org/documents/4 (accessed on 5/15/15).


UW Health Implementation

Implementation Plan/Tools

1. Guideline will be housed on U-Connect in a dedicated folder for CPGs and advertised in the CKM Corner of the Best Practice newsletter.
2. Links to this guideline will be updated and/or added in appropriate Health Link or equivalent tools, including:

Order Sets and Smart Sets
- Allergic Rhinitis/Asthma/Conjunctivitis [72]
- Allergy Asthma [3199]
- Asthma ACHC [147]
- Asthma/Wheezing [99]
- Injection- Acute Allergic Reaction/Steroids/Asthma [173]
- Ped Allergy Asthma [3284]
- Ped Pulmonary Asthma [2534]
- IP – Asthma Exacerbation – Pediatric – Admission [997]

Delegation Protocols
- Asthma or Recurrent Wheezing – Pediatric – Inpatient [3]
- Respiratory Therapy Treatment – Adult/Pediatric – Inpatient [70]
- Spirometry Ordering – Adult/Pediatric – Allergy [104]

e-Consults
- Asthma [5655]
- Shortness of Breath [5664]

Disclaimer

CPGs are described to assist clinicians by providing a framework for the evaluation and treatment of patients. This Clinical Practice Guideline outlines the preferred approach for most patients. It is not intended to replace a clinician’s judgment or to establish a protocol for all patients. It is understood that some patients will not fit the clinical condition contemplated by a guideline and that a guideline will rarely establish the only appropriate approach to a problem.

References

## Appendix A. Summary of Interim Revisions

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Interim Revision(s)</th>
<th>Section (Page #)</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/16</td>
<td>Modified pediatric ED and IP asthma exacerbation algorithms</td>
<td>Collateral Tool</td>
</tr>
<tr>
<td></td>
<td>- Added step to allow for escalation of care within IP setting</td>
<td></td>
</tr>
<tr>
<td>07/16</td>
<td>Omalizumab content added as an appendix (formerly a full guideline which was retired by P&amp;T Committee on 07/21/2016)</td>
<td>Collateral Tool</td>
</tr>
</tbody>
</table>
**Stepwise Approach to Asthma Symptom Control**

### ASSESS
- Diagnosis
- Symptom control + risk factors
- Inhaler technique + adherence
- Parent or patient preferences

### REVIEW RESPONSE
- Symptoms and side effects
- Exacerbations
- Parent or patient preferences
- Lung function

### ADJUST TREATMENT
- Asthma medications
- Non-pharmacological interventions
- Treat modifiable risk factors

### CONTROLLER

#### STEP 1
- **Age 0-5 yrs.**
  - Preferred: Low dose ICS
  - Alternatives: LTRA or intermittent ICS
- **All Ages**
  - Preferred: Low dose ICS
  - Alternative: Low dose ICS
  - **Age 6-11 yrs.**
    - Preferred: Medium dose ICS or Low dose ICS + LABA
    - Alternative: Low dose ICS + LTRA
  - **Age > 12 yrs.**
    - Preferred: Low dose ICS + LABA
    - Alternative: Medium dose ICS or Low dose ICS + LTRA + theophylline

#### STEP 2
- **Age 0-5 yrs.**
  - Preferred: Double low dose ICS
  - Alternative: Add LTRA
- **Age 6-11 yrs.**
  - Preferred: Refer to asthma specialist
  - **Age > 12 yrs.**
    - Preferred: Refer to asthma specialist

#### STEP 3
- **Age 0-5 yrs.**
  - Preferred: Refer to asthma specialist
  - **Age 6-11 yrs.**
    - Preferred: Add LTRA or increase ICS frequency or add intermittent ICS
  - **Age > 12 yrs.**
    - Preferred: Refer to asthma specialist

#### STEP 4
- **Age 0-5 yrs.**
  - Preferred: Refer to asthma specialist
- **Age 6-11 yrs.**
  - Preferred: Refer to asthma specialist
  - **Age > 12 yrs.**
    - Preferred: Refer to asthma specialist

#### STEP 5
- **Age 0-5 yrs.**
  - Preferred: Refer to asthma specialist
  - **Age 6-11 yrs.**
    - Preferred: Refer to asthma specialist
    - **Age > 12 yrs.**
    - Preferred: Refer to asthma specialist

### RESCUE
- **All Ages**
  - Preferred: PRN Short-acting Beta₂-agonist (SABA)

---

*For adult patients only. Not indicated or recommended for patients younger than 18 years.*

---

**Consider stepping up if uncontrolled symptoms, exacerbations or risks. Always evaluate diagnosis, inhaler technique, and adherence before making therapy changes.**

**Consider stepping down if symptoms controlled for 3 months and low risk for exacerbations. Ceasing ICS is not advised.**
Asthma Medications- Low, Medium and High Doses of Inhaled Corticosteroids

This table provides an estimate of comparative daily doses for inhaled corticosteroids administered to children and adults with asthma. It may be used in conjunction with the Stepwise Approach to Asthma Symptom Control found within the Asthma Guideline.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily Dose (mcg)</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Child (≤ 5 yrs.)</td>
<td>Child (6-11 yrs.)</td>
<td>Adult (≥ 12 yrs.)</td>
<td>Child (≤ 5 yrs.)</td>
</tr>
<tr>
<td>Beclomethasone HFA</td>
<td>100</td>
<td>50-100</td>
<td>80-240</td>
<td>NA</td>
</tr>
<tr>
<td>Budesonide DPI</td>
<td>200</td>
<td>100-200</td>
<td>180-540</td>
<td>NA</td>
</tr>
<tr>
<td>Budesonide (nebule)</td>
<td>250-500</td>
<td>250-500</td>
<td>NA</td>
<td>&gt;500-1000</td>
</tr>
<tr>
<td>Ciclesonide HFA</td>
<td>160</td>
<td>80</td>
<td>80-160</td>
<td>NA</td>
</tr>
<tr>
<td>Flunisolide HFA</td>
<td>NA</td>
<td>160</td>
<td>320</td>
<td>NA</td>
</tr>
<tr>
<td>Fluticasone HFA</td>
<td>100</td>
<td>100-200</td>
<td>44-264</td>
<td>&gt;100-352</td>
</tr>
<tr>
<td>Fluticasone DPI</td>
<td>NA</td>
<td>100-200</td>
<td>100-300</td>
<td>NA</td>
</tr>
<tr>
<td>Momentasone DPI</td>
<td>NA</td>
<td>110</td>
<td>110-220</td>
<td>NA</td>
</tr>
</tbody>
</table>

Last reviewed/revised: 07/2015
Contact CCKM or Drug Policy Program for revisions.
Asthma – Pediatric/Adult – Inpatient/Ambulatory Guideline

References:
# Table 1. Asthma Medications Chart

NOTE: The following table objectively outlines selected asthma medications available in the United States, and does not provide recommendations for or against their use. The listing does not indicate inclusion on the UWHC formulary. Prescribing providers should refer to specific formulary listings for status of various agents.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Inhaler</th>
<th>Nebulization Solution</th>
<th>Oral (Injectable products where noted)</th>
<th>Purpose</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESCUE Medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Short-acting beta agonists</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albuterol Sulfate</td>
<td>- ProAir® MDI</td>
<td>108 mcg/act</td>
<td>0.63 mg/3 mL</td>
<td>Tablet: 2 mg, 4 mg</td>
<td>Bronchodilation through smooth muscle relaxation</td>
</tr>
<tr>
<td>- Proventil® MDI</td>
<td></td>
<td></td>
<td>1.25 mg/3 mL</td>
<td>Oral Syrup: 2 mg/5 mL</td>
<td></td>
</tr>
<tr>
<td>- Ventolin® MDI</td>
<td></td>
<td></td>
<td>2.5 mg/3 mL</td>
<td>ERT: 4 mg, 8 mg</td>
<td></td>
</tr>
<tr>
<td>- Accuneb® nebulization</td>
<td></td>
<td></td>
<td>5 mg/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- VoSpire® ERT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levalbuterol</td>
<td>- Xopenex® MDI</td>
<td>45 mcg/act</td>
<td>0.31 mg/3 mL</td>
<td>Tablet: 2.5 mg, 5 mg</td>
<td></td>
</tr>
<tr>
<td>- Xopenex® nebulization</td>
<td></td>
<td></td>
<td>0.63 mg/3 mL</td>
<td>Injection: 1 mg/mL</td>
<td></td>
</tr>
<tr>
<td>Terbutaline</td>
<td>- tablet</td>
<td></td>
<td>1.25 mg/3 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- injection</td>
<td></td>
<td></td>
<td>1.25 mg/0.5 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Short-acting anticholinergics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ipratropium Bromide</td>
<td>- Atrovent® MDI</td>
<td>17 mcg/act</td>
<td>0.5 mg/2.5 mL</td>
<td>Bronchodilation through inhibition of muscarinic receptors to reduce intrinsic vagal tone of the airway</td>
<td></td>
</tr>
<tr>
<td>- Atrovent® nebulization</td>
<td></td>
<td></td>
<td></td>
<td>May be an alternative to short-acting beta agonists in patients who cannot tolerate short-acting beta agonists</td>
<td></td>
</tr>
<tr>
<td><strong>Combination short-acting beta agonist and short-acting anticholinergic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albuterol Sulfate/ Ipratropium Bromide</td>
<td>- Combivent Respimat® MDI</td>
<td>100/20 mcg/act</td>
<td>2.5/0.5 mg/3 mL</td>
<td>See individual agents</td>
<td></td>
</tr>
<tr>
<td>- Duoneb® nebulization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Systemic corticosteroids</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisone</td>
<td>- tablet</td>
<td></td>
<td></td>
<td>Tablet: 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg</td>
<td></td>
</tr>
<tr>
<td>- Rayos® delayed-release tablet</td>
<td></td>
<td></td>
<td>Delayed-release tablet: 1 mg, 2 mg, 5 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- solution</td>
<td></td>
<td></td>
<td>Solution: 5 mg/6 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Intensol® concentrated solution</td>
<td></td>
<td></td>
<td>5 mg/1 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylprednisolone</td>
<td>- Medrol® tablet</td>
<td></td>
<td></td>
<td>Tablet: 2 mg, 4 mg, 8 mg, 16 mg, 32 mg</td>
<td></td>
</tr>
<tr>
<td>- Solu-Medrol® injection</td>
<td></td>
<td></td>
<td>Pak: 4 mg tablets x 21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>- Tablet</td>
<td></td>
<td></td>
<td>Tablet: 0.5 mg, 0.75 mg, 1 mg, 1.5 mg, 2 mg, 4 mg, 6 mg</td>
<td></td>
</tr>
<tr>
<td>- Solution</td>
<td></td>
<td></td>
<td>Solution: 0.5 mg/5 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Intensol® concentrated solution</td>
<td></td>
<td></td>
<td>1 mg/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Elixir</td>
<td></td>
<td></td>
<td>Elixir: 0.5 mg/5 mL</td>
<td></td>
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<tr>
<td>- Elixir</td>
<td></td>
<td></td>
<td>Injection: 4 mg/mL, 10 mg/mL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Last reviewed/revised: 07/2015
Contact CCKM or Drug Policy Program for revisions.
Asthma – Pediatric/Adult – Inpatient/Ambulatory Guideline

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<table>
<thead>
<tr>
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<th>Oral (Injectable products where noted)</th>
<th>Purpose</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Long-acting beta agonists</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formoterol Fumarate</td>
<td>12 mcg/inh</td>
<td>20 mcg/2 mL</td>
<td></td>
<td>Bronchodilation</td>
<td>Should be used in combination with an inhaled corticosteroid</td>
</tr>
<tr>
<td>- Foradil Aerolizer® DPI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Perforomist® nebulization</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Salmeterol Xinafoate</td>
<td>50 mcg/inh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Serevent Diskus® DPI</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Inhaled corticosteroids</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beclomethasone Dipropionate</td>
<td>40 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Qvar® MDI</td>
<td>80 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budesonide</td>
<td>90 mcg/inh</td>
<td>0.25 mg/2 mL</td>
<td>0.5 mg/2 mL</td>
<td>1 mg/2 mL</td>
<td>Reduce airway hyperresponsiveness, inhibit inflammatory cell migration and activation, and block late phase reaction to allergen</td>
</tr>
<tr>
<td>- Pulmicort Flexhaler® DPI</td>
<td>180 mcg/inh</td>
<td></td>
<td></td>
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<tr>
<td>- Pulmicort® nebulization</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ciclesonide</td>
<td>80 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Alvesco® MDI</td>
<td>160 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flunisolide</td>
<td>80 mcg/act</td>
<td></td>
<td></td>
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<tr>
<td>- Aerospan® MDI</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fluticasone Furoate</td>
<td>100 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Arnuity Elipta® MDI</td>
<td>200 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluticasone Propionate</td>
<td>DPI: 50 mcg/inh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Flovent Diskus® DPI</td>
<td>100 mcg/inh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Flovent® MDI</td>
<td>250 mcg/inh</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>- MDI: 44 mcg/act</td>
<td>110 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 220 mcg/act</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mometasone Furoate</td>
<td>DPI: 110 mcg/inh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Asmanex® DPI</td>
<td>220 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Asmanex® MDI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- MDI: 100 mcg/act</td>
<td>200 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Combination long-acting beta agonists and corticosteroid</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budesonide/Formoterol Fumarate</td>
<td>80/4.5 mcg/act</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>- Symbicort® MDI</td>
<td>160/4.5 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mometasone Furoate/Formoterol Fumarate</td>
<td>100/5 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Dulera® MDI</td>
<td>200/5 mcg/act</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Fluticasone Propionate/Salmeterol Xinafoate</td>
<td>DPI: 100/50 mcg/inh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Advair Diskus® DPI</td>
<td>250/50 mcg/inh</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Advair® MDI</td>
<td>500/20 mcg/inh</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>- MDI: 45/21 mcg/act</td>
<td>115/21 mcg/act</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 230/21 mcg/act</td>
<td></td>
<td></td>
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<tr>
<td><strong>Long-acting anticholinergics</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Tiotropium</td>
<td>DPI: 18 mcg/inh</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>- Spiriva® Handihaler DPI</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>- Spiriva® Respimat MDI</td>
<td>MDI: 2.5 mcg/act</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

MDI: metered dose inhaler  
inh: inhalation  
DPI: dry powder inhaler  
act: actuation  
ERT: extended-release tablet

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Last Revised: 09/2016
<table>
<thead>
<tr>
<th>Medication</th>
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<th>Oral (Injectable products where noted)</th>
<th>Purpose</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mast cell stabilizers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cromolyn</td>
<td></td>
<td>20 mg/2 mL</td>
<td></td>
<td>Stabilize mast cells</td>
<td></td>
</tr>
<tr>
<td>- nebulization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Methylxanthines</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aminophylline</td>
<td></td>
<td></td>
<td>Injection: 25 mg/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theophylline</td>
<td></td>
<td></td>
<td>12-hour ERT: 100 mg, 200 mg, 300 mg, 450 mg</td>
<td>Bronchodilation through smooth muscle relaxation and the suppression of airway response to stimuli</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>24-hour ERT: 400 mg, 600 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>24-hour ER capsule: 100 mg, 200 mg, 300 mg, 400 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Solution and Elixir: 80 mg/15 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Injection: 0.8 mg/mL, 1.6 mg/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Leukotriene Modifiers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Montelukast</td>
<td></td>
<td></td>
<td>Tablet: 10 mg</td>
<td></td>
<td>Interfere with the pathway of leukotriene mediators, which are released from mast cells, eosinophils, and basophils.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chewable tablet: 4 mg, 5 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Packet: 4 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zafirlukast</td>
<td></td>
<td></td>
<td>Tablet: 10 mg, 20 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tablet: 600 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zileuton</td>
<td></td>
<td></td>
<td>12-hour ERT: 600 mg</td>
<td></td>
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<td></td>
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<tr>
<td><strong>Immunomodulators</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Omalizumab</td>
<td></td>
<td></td>
<td>Injection: 150 mg vial</td>
<td></td>
<td>Prevents binding of IgE to the high-affinity receptors on basophils and mast cells</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

**Controller Medications**

MDI: metered dose inhaler
DPI: dry powder inhaler
ERT: extended-release tablet

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See Policy 8.30 Management of Clinic Administered Medications with Internal Pharmacy Prior Authorization and Omalizumab Clinical Practice Guideline

Last Revised: 09/2016
Omalizumab Clinical considerations, Administration, and Monitoring

Introduction
Omalizumab is a recombinant DNA monoclonal antibody that selectively binds to human immunoglobulin E (IgE) and is FDA approved for the treatment of moderate to severe persistent allergic asthma in adult and adolescent patients inadequately controlled with inhaled corticosteroids (ICS) and treatment of chronic idiopathic urticaria in patients who are still symptomatic despite H1 antihistamine therapy.\(^1\) Due to its relative novel mechanism of action, potential for anaphylaxis, its unique prescribing complexity, and cost, this appendix to the “UW Health Diagnosis and Management of Asthma Guidelines” is designed to guide the use of omalizumab at the UW Health clinics for treatment of asthma. For P&T approved restrictions, please refer to Lexicomp\(^6\).

Recommendations

**Moderate to Severe Allergic Persistent Asthma – Not Well Controlled or Very Poorly Controlled**

1. Consider vocal cord dysfunction as a cause of breathing symptoms that do not respond to asthma treatment prior to initiating omalizumab.\(^1,2\) If clinically indicated consult otolaryngology to rule out vocal cord dysfunction. (*UW Health Strong Recommendation, Very Low Quality of Evidence*)

2. Patients should have positive skin test or in vitro reactivity to perennial aeroallergen documented in the medical record or positive skin test or in vitro reactivity to perennial aeroallergen from another health care facility.\(^1,2\) (*UW Health Strong Recommendation, High Quality of Evidence*)

3. Omalizumab is FDA approved for patients ≥12 years.\(^1,3\) (Class I, Level A)
   3.1. Omalizumab has been evaluated in pediatric patients from 6-12 years of age.\(^4-6\) (*UW Health Strong Recommendation, High Quality of Evidence*)
   3.1.1. Patients outside the age criteria will be considered on a case-by-case basis. Safety and effectiveness in pediatric patients under the age of 12 have not been established as per package label; however, studies have evaluated therapy in pediatric patients from 6-12 years of age and for up to 52 weeks.\(^4-6\) In trials using omalizumab in children 6 to 11 years of age followed for a minimum of 28 weeks both the side effect profile and serious adverse events were similar between omalizumab and placebo.\(^6\)

4. Omalizumab is indicated as adjunctive therapy in patients with moderate or severe allergic asthma whose symptoms are uncontrolled with a combination of a medium- to high-dose inhaled corticosteroid and a long-acting beta\(_2\)-agonist (Global Initiative for Asthma step 5).\(^2\)
   4.1. At least one of the following should exist:\(^1,2\)
   4.1.1. Requirement for systemic corticosteroids episodically
   4.1.2. Inadequate control after at least 3 months of high-dose inhaled corticosteroids in combination with a long-acting beta\(_2\) agonist. Inadequate control is defined as at least one of the following:
   4.1.2.1. Asthma symptoms more than 2 days per week
   4.1.2.2. Nocturnal waking more than two times per month
   4.1.2.3. Limitation of normal activity (work, school, etc.) due to asthma
   4.1.2.4. Short acting beta agonist use more than 2 days/week or multiple times per day
   4.1.2.5. FEV\(_1\) < 80% predicted or personal best
   4.1.2.6. Asthma Therapy Assessment Questionnaire (ATAQ) ≥ 1; Asthma Control Questionnaire (ACQ) ≥ 1.5; ACT (Asthma Control Test) < 20
   4.1.2.7. Asthma exacerbations requiring oral steroids at least twice in past year

4.2. Exceptions based on adverse effects from ICS or long term risks of adverse effects from ICS or oral corticosteroids will be considered on a case-by-case basis. (*UW Health Strong Recommendation, High Quality of Evidence*)
   4.2.1. Cataracts in patients 40 years and older
   4.2.1.1. Case control studies of patients receiving ICS (for the treatment of COPD and asthma) demonstrate a dose related increased incidence of cataracts in patients 40 years and older.\(^7-11\)

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Last Revised: 09/2016
4.2.2. Glaucoma

4.2.2.1. An insurance database review of patients 65 years or older using a nested case-control format of 13,445 control subjects followed for a mean of 4 years did not demonstrate increased risk of glaucoma event with high doses. An earlier study of patients 66 years and older receiving either ICS or nasal glucocorticoids demonstrated an increased risk of ocular hypertension for only high doses of inhaled corticosteroids. However, almost half of the cases of increased ocular pressure did not require treatment.

4.2.3. Recurrent oral candidiasis

4.2.4. Dysphonia

4.2.5. Growth inhibition as evaluated by the Endocrine Service

4.2.6. Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis therapy.

4.2.6.1. A cohort follow up study of children with mild-to-moderate asthma were evaluated with serial scans of the lumbar spine for bone mineral density. A mean follow up of 7 years demonstrated no increased risk for osteopenia, but a decrease in small bone mineral accretion for boys. Risk factors for osteoporosis should be modified (if possible) in all patients on ICS. Meta-analyses evaluating bone mineral density in asthmatic adult patients on ICS are conflicting.

4.2.6.2. A trial comparing budesonide 400 mcg to nedrocromil 16 mg daily or placebo demonstrated a reduction in adult height of 1.2 centimeters (95% CI, -1.9 to -0.5) for budesonide compared to placebo. A systematic review of randomized, placebo controlled studies evaluating ICS in children reports a linear growth decline of approximately 1 centimeter in the first year of ICS, but full adult height is reached.

5. The omalizumab dose for severe allergic asthma is determined by the patient's pre-treatment serum IgE level and actual patient weight. (UW Health Strong Recommendation, Low Quality of Evidence)

5.1. Doses of more than 150 mg should be divided so as to deliver no more than 150 mg per site. (UW Health Strong Recommendation, Very Low Quality of Evidence)

5.2. Administration may require 5 to 10 seconds to administer due to the high viscosity of the reconstituted solution. (UW Health Strong Recommendation, Very Low Quality of Evidence)

5.3. For patients over 150 kg administer the maximum dose recommended by patient IgE concentration. (UW Health Strong Recommendation, Very Low Quality of Evidence)

6. Clinical improvement with omalizumab is indicated by at least one of the following and should be documented in the electronic medical record. These criteria will be reviewed for approval of continuation in patients who have already received omalizumab for 12 months: (UW Health Strong Recommendation, Very Low Quality of Evidence)

6.1. Decreased dose of corticosteroid use to treat or prevent an exacerbation.

6.2. Decreased frequency of unscheduled clinic, urgent care or emergency department visits.

6.3. Increase in percent predicted FEV1 from pre-treatment baseline.

6.4. Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal waking, wheezing, sustained improvement in ACT scores.

6.5. Reduction in use of ICS, leukotriene or beta agonist therapy.

Administration and Monitoring of Omalizumab

7. Medications for clinic administration should be purchased and supplied by the UW Health Pharmacy Department to ensure product integrity. (UW Health Strong Recommendation, Very Low Quality of Evidence)

8. Administer in a supervised medical facility after assessment of existing health status. (UW Health Strong Recommendation, Very Low Quality of Evidence)

9. Monitor patients for anaphylaxis with close observation in the clinic after injection of omalizumab. The recommended time for observation in asthma patients is 2 hours after the first three injections and then 30 minutes after each subsequent injection. (UW Health Strong Recommendation, Very Low Quality of Evidence)

9.1. Anaphylaxis occurs in up to 0.2% of patients receiving omalizumab and most often within 2 hours of administration of the first three doses.
Reference: Asthma – Adult/Pediatric – Inpatient/Ambulatory Guideline

10. Prescribe an epinephrine autoinjector for all patients along with instructions to have readily available at all times on treatment days, due to the possibility of delayed anaphylaxis.\(^{(10)}\) (UW Health Strong Recommendation, Very Low Quality of Evidence)

10.1. The onset of delayed anaphylaxis is 2 to 24 hours or longer after receiving omalizumab therapy and can occur even in the absence of reaction with the first dose. Patient education (such as the Medication Guide in the product labeling) should be supplied to patients prior to administration of the first dose.

11. Serum total IgE levels obtained less than 1 year following discontinuation of omalizumab therapy may not reflect steady state free IgE levels and should not be used to assess therapy. If therapy has been interrupted for 1 year or more, total IgE levels may be reevaluated for dosage determination. (UW Health Weak/Conditional Recommendation, Very Low Quality of Evidence)

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**Evidence Grading Scheme**

*Figure 1. GRADE Methodology adapted by UW Health*

**GRADE Ranking of Evidence**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>We are confident that the effect in the study reflects the actual effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>We are quite confident that the effect in the study is close to the true effect, but it is also possible it is substantially different.</td>
</tr>
<tr>
<td>Low</td>
<td>The true effect may differ significantly from the estimate.</td>
</tr>
<tr>
<td>Very Low</td>
<td>The true effect is likely to be substantially different from the estimated effect.</td>
</tr>
</tbody>
</table>

**GRADE Ratings for Recommendations For or Against Practice**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>The net benefit of the treatment is clear, patient values and circumstances are unlikely to affect the decision.</td>
</tr>
<tr>
<td>Weak/conditional</td>
<td>Recommendation may be conditional upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented.</td>
</tr>
</tbody>
</table>
References

3. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; December 2015.
Bronchial Thermoplasty Summary for Primary Care Providers

Overview: Bronchial Thermoplasty (BT) is an innovative procedure for the treatment of severe persistent asthma. This procedure is performed in an outpatient setting under moderate sedation, and is accomplished in three separate bronchoscopic sessions scheduled approximately 3 weeks apart. In the first procedure, airways under direct vision and reachable by the bronchoscope in the right lower lobe are treated. During the second procedure, targeted airways in the left lower lobe are treated, and in the third and final procedure, targeted airways in both upper lobes are treated.1,2

Target Population: A potential treatment option for highly-selected patients aged 18 years and older with uncontrolled asthma, despite use of recommended therapeutic regimens and referral to an asthma specialist (Step 5).3 (GINA Evidence B)

Technology Assessment Review: Alair™ BT has been reviewed multiple times by the UW Health Technology Assessment Committee since 2010. In that time, the reimbursement picture has become clearer and the long term clinical and safety benefits have been maintained. In January 2015, the committee recommended adoption of Alair Thermoplasty for use at UW Health.4 Insurance prior authorization was suggested and once in use, the program’s performance will be reviewed after one year (or 12 patients).

Outcomes: Bronchial thermoplasty has been studied in four clinical studies in patients with asthma; three of which were randomized controlled clinical trials and the results for which have been published in peer-reviewed journals. Most notably, published data from the Asthma Intervention Research 2 (AIR2) clinical trial demonstrates that bronchial thermoplasty continues to show benefits in adult patients with severe uncontrolled asthma out to at least five years.4 Bronchial thermoplasty was shown to provide long term asthma control, demonstrated by a sustained reduction in the rate of severe exacerbations (asthma attacks) and emergency room (ER) visits over a five year period after treatment.5

Risk assessment: The most common side effect found in the clinical studies was an expected transient increase in the frequency and worsening of respiratory-related symptoms, including asthma (multiple symptoms), respiratory tract infections, wheezing, dyspnea, and chest pain. Long-term follow-up out to 5 years has been completed in 4 studies: the safety profile for the BT treated patients has demonstrated consistency over time based on the percent of subjects reporting respiratory adverse events, the number of respiratory adverse events per subject, and the number of hospitalizations and emergency room visits due to respiratory symptoms per subject.

Pre-Approval Needs: While non-coverage policies exist, there is a need to request pre-approval to the insurer by submitting documentation that supports a severe asthma diagnosis. This documentation is inclusive of differentiating other respiratory-related disorders (i.e., COPD, bronchiectasis, vocal cord dysfunction, obstructive sleep apnea), management of comorbidities (i.e., allergic rhinitis, sinusitis, GERD), and observations of compliance and/or attempts to manage their asthma with current standard medications (i.e., minimum of ICS+LABA) over at least a 3 month period yet still demonstrating evidence of exacerbations, activity limitation and/or risk of future exacerbations. As coverage policies get implemented, a shorter, more specific pre-authorization form may be required.

* Note: Acquisition of the technology is considered separately in the capital budgeting process.

References:
2. ECRH. Bronchial Thermoplasty for Treating Adult Patients with Severe Persistent Asthma. 2013.
Management of Asthma Exacerbation in Primary Care (Age 2 years or older)

Patient presentation with acute or sub-acute asthma exacerbation

Assess the Patient
- Is it asthma?
- What is the exacerbation severity?
- Does the patient exhibit risk factors for asthma-related death?*

Mild or Moderate Exacerbation

Initiate Treatment
- Short-acting beta₂-agonist (SABA) by pMDI with spacer or nebulizer
- Administer O₂ to maintain SpO₂ > 90%

Assess Response
- Have symptoms improved (not needing SABA)?
- Is O₂ saturation (on room air) > 90%?
- Are resources at home adequate?

Severe Exacerbation

TRANSFER TO ED

While waiting, give dual therapy (SABA + ipratropium bromide), administer O₂, and/or oral corticosteroid (OCS)

Continue Treatment
- Administer Short-acting beta₂-agonist (SABA) as needed
- If no resolution after initial treatment, give dual therapy (SABA + ipratropium bromide)
- Consider oral corticosteroid (OCS)

Assess Response
- Symptoms Resolved?
  - Yes
  - No

Follow-up within 2-7 days to assess stabilization
- Rescue Medication: reduce to as-needed
- Controller Medication: continue higher dose for short term (1-2 weeks) or long term (3 months), depending on background to exacerbation
- Continue oral corticosteroid (OCS) as needed (5-7 days in adults; 3-5 days in pediatrics)
- Risk factors for exacerbation: provide patient education, including inhaler technique/adherence
- Print and review Asthma Action Plan (Note: If pediatric patient, print 2 copies for home/school)

*Determine Exacerbation Severity

<table>
<thead>
<tr>
<th>Mild/Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral characteristics</td>
<td>Talks in phrases, prefers sitting to lying, not agitated</td>
</tr>
<tr>
<td>Talks in words, sits hunched forwards, agitated</td>
<td></td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>Increased</td>
</tr>
<tr>
<td>Accessory muscle use</td>
<td>Not in use</td>
</tr>
<tr>
<td>O₂ saturation (on room air)</td>
<td>90-95%*</td>
</tr>
<tr>
<td>Heart rate</td>
<td>100-120bpm*</td>
</tr>
</tbody>
</table>

*Values listed in table are for patients age 6 yrs. or older. Patients age ≤ 5 yrs. exhibit slightly different vital signs:
- O₂ saturation: > 90% (mild); < 92% (severe)
- Heart rate: < 100bpm (mild); > 200bpm (severe 0-3 yrs.); > 180bpm (4-5 yrs.)

*Risk Factors for Asthma-related Death
- History of near-fatal asthma requiring intubation and mechanical ventilation
- Hospitalization or emergency care visit for asthma in the past year
- Currently using or recently stopped using oral corticosteroids
- Not currently using inhaled corticosteroids
- Over-use of SABAs, especially use of more than one canister of monthly
- A history of psychiatric disease or psychosocial problems
- Poor adherence with asthma medications and/or poor adherence with (or lack of) a written asthma action plan
- Food allergy in a patient with asthma

Medications

<table>
<thead>
<tr>
<th>Medications</th>
<th>Dose &amp; Frequency</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-acting Beta₂-agonist (SABA)</td>
<td>(age ≤ 18 yrs.) 0.6 mg/kg per dose 36-48 hrs. apart; max 16 mg/dose</td>
<td>Oral</td>
</tr>
<tr>
<td>Ipratropium</td>
<td>(age ≤ 18 yrs.) 500 mcg Q20min x3</td>
<td>pMDI + spacer</td>
</tr>
<tr>
<td>Oral Corticosteroid (OCS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>methylprednisolone</td>
<td>(age &lt; 12 yrs.) 1-2 mg/kg in 2 divided doses, max 60 mg per day</td>
<td>Oral</td>
</tr>
<tr>
<td>prednisolone</td>
<td>(age ≥ 12 yrs.) 1 mg/kg/day PO in 1-2 divided doses; max 50 mg/day</td>
<td>Oral</td>
</tr>
</tbody>
</table>

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Contact: CCKM@uwhealth.org
Last Revised: 09/2016
Pediatric Emergency Dept. Asthma Exacerbation Algorithm (Age 12 months to 17 years)

mPASS assessments should be completed before and after each tx.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Rate</td>
<td>Normal</td>
<td>Above tachypnea threshold</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Accessory Muscle Use</td>
<td>None</td>
<td>Suprasternal/subcostal retractions or nostril</td>
<td>Neck or abdominal muscles (buck breathing)</td>
<td>NA</td>
</tr>
<tr>
<td>Air Exchange</td>
<td>Normal</td>
<td>Decreased in single lung field</td>
<td>Decreased in multiple lung fields</td>
<td>NA</td>
</tr>
<tr>
<td>Wheezing</td>
<td>None or end expiratory</td>
<td>Diaphragm</td>
<td>Insufficient expiratory effort or wheeze heard due to poor air entry</td>
<td>NA</td>
</tr>
<tr>
<td>Expiration</td>
<td>Normal (&lt; 12)</td>
<td>Prolonged (&gt; 15)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Coughing</td>
<td>None</td>
<td>Frequent (Occasional)</td>
<td>Frequent (Constant)</td>
<td>NA</td>
</tr>
</tbody>
</table>

TOTAL POINTS

RT perform mPASS assessment and spirometry (if patient able)

Does patient have any of the following?

- FEV1 < 40% or unable to perform spirometry due to work of breathing?
- mPASS score ≥ 2, breathless at rest/agitated confused?
- Diffuse wheezes or poor air movement without wheezes?
- In need of O2 to keep SpO2 > 92%?

Yes

Moderate or Severe Exacerbation

HIGH DOSE THERAPY

- RT order and give A&A treatment:
  - Albuterol 2.5 mg Q20 min (age < 12 yrs.) or 5 mg Q20 min (age ≥ 12 yrs.) via nebulizer x3 in 1st hour OR continuous at 10 mg/hour over 1 hour (up to 15 mg/hour)
  - Ipratropium bromide 500 mcg Q20 min x3 via nebulizer or add to continuous albuterol nebulizer
  - Administer O2 to maintain SpO2 ≥ 90%
  - Oral or IV corticosteroids per ED provider
  - IVF per ED provider if dehydration, impending respiratory failure, or shock
  - Consider 1:1000 epinephrine 0.01 mg/kg IM (max 0.3 mg) per ED provider
  - Consider EtCO2 or venous blood gas per ED provider

- RT assess response to intervention (including mPASS and post spirometry)

- RT give albuterol continuous at 10 mg/hour over 1 hour (up to 15 mg/hour)

- RT assess response to intervention (including mPASS and post spirometry)

- RT notify ED provider to consider PICU consult

Mild Exacerbation

STANDARD DOSE THERAPY

- RT order and give A&A treatment:
  - Albuterol 2.5 mg Q20 min (age < 12 yrs.) or 5 mg Q20 min (age ≥ 12 yrs.) via nebulizer x1-3.
  - Ipratropium bromide 250 mcg Q20 min (age < 5 yrs.) or 500 mcg Q20 min (age ≥ 5 yrs.) via nebulizer x1 (if using albuterol at home > q2-4 hours).
  - Administer O2 to maintain SpO2 ≥ 90%
  - Oral corticosteroids per ED provider

- RT assess response to intervention (including mPASS and post spirometry)

- RT give albuterol continuous at 10 mg/hour over 1 hour (up to 15 mg/hour)

- RT assess response to intervention (including mPASS and post spirometry)

- RT notify ED provider

Intervention Response

Patient exhibits at least one of the following:

Good
- FEV1 ≥ 70%
- mPASS score < 2
- SpO2 > 90% on room air (initial tx) OR > 95% on room air (secondary tx)

Incomplete
- FEV1 ≥ 70%
- mPASS score ≥ 2
- SpO2 < 95% on room air
- Continued symptoms
- PCO2 > 42 mmHg

Initiate Discharge Planning

Good Response

- RT notify ED provider

Observe for 60 min. RT repeat mPASS.

mPASS score < 2 and SpO2 > 90% on room air?

Yes

Admit to General Care Floor

No

Incomplete Response

- RT notify ED provider

Observe for 60 min. and RT repeat mPASS.

mPASS score < 2 and SpO2 > 90% on room air?

Yes

Admit to PICU

No

Admit to General Care Floor

Requiring albuterol > Q2 hours?

Yes

Continue Reassessment and Admission Planning

No

Continue albuterol per ED provider. ED provider to consider adjunctive therapies:
- Heliox (if FiO2 < 50%)
- BiPAP, HFNC
- Terbutaline 2-10 mcg/kg IV bolus then 0.08-0.4 mcg/kg/min IV titrated to effect (max 1 mcg/kg/min)
- Magnesium sulfate 50-75 mg/kg IV (max 2 g) over 20 min

Reference: Asthma – Pediatric/Adult – Inpatient/Ambulatory Guideline

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Contact: CCKM@uwhealth.org

Last Revised: 09/2016
**Pediatric Inpatient Asthma Exacerbation Algorithm (Age 12 months to 17 years)**

**Inclusion Criteria:**
1. Diagnosis of asthma or history of recurrent wheezing
2. Patients with first time wheezing that have demonstrated responsiveness to albuterol suggesting initial presentation of reactive airway disease
3. FiO2 < 50%
4. Exhibits one of the following symptoms:
   - Persistent cough
   - Dyspnea
   - Chest pain
   - Wheezing

**Exclusion Criteria:**
1. Any patient on adjunctive therapies
2. FiO2 > 50%
3. Concomitant diagnosis including:
   - Cystic fibrosis or other chronic lung disease
   - Congenital or acquired cardiovascular disease
   - Bronchopulmonary dysplasia
   - Immunodeficiency syndromes

**Treatment Bundle:**
1. mPASS Assessment
2. If mPASS score ≥ 2, give initial dose of 4 puffs albuterol
3. Repeat mPASS Assessment
4. If mPASS score continues to be ≥ 2, repeat 4 puffs albuterol
5. Repeat mPASS Assessment
6. Senior Resident to notify Attending MD if mPASS score not improved

*May repeat steps 1-5 up to three times in the 1st hour (equals 24 puffs).*

**Notification of Resident MD by RT**
- Initiation of or increasing requirement of supplemental O2
- Worsening or increasing respiratory distress
- Increasing frequency of bronchodilator therapy
- mPASS score ≥ 2 after Treatment Bundle
- Unable to wean from q2 hour bronchodilator therapy after receiving therapy for 6 hours (exclusion of ED protocol)

**Notification of Attending MD by Resident**
- Patient requires q2 hour bronchodilator therapy for > 8-12 hours
- Concern for patient condition or escalation of care

**MDI is preferred delivery method per provider.**

---

**Last reviewed: 07/2016**

Reference: Asthma Guideline

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Contact: CCKM@uwhealth.org

Last Revised: 09/2016
Adult patient presentation to ED with asthma exacerbation
RT perform spirometry (if patient able)

Does patient have any of the following?*
- FEV1 or PEF < 40% or unable to perform spirometry due to work of breathing?
- Diffuse wheezes or poor air movement without wheezes?
- Breathless at rest/agitated or confused?
- In need of O2 to keep SpO2 > 92%?

No
Mild Exacerbation
STANDARD DOSE THERAPY
- RT order and give albuterol 5 mg via nebulizer x1.
- RT order and give ipratropium bromide 500 mcg via nebulizer x1 (if using albuterol at home > q2-4 hours).
- Administer O2 to maintain SpO2 ≥ 92%
- Oral corticosteroids per ED provider

RT assess response to intervention (including spirometry)

Good Response
Patient exhibits at least one of the following:
- FEV1 or PEF > 70%
- No distress, normal exam
- Response sustained for > 60 min.

Initiate Discharge Planning

RT notify ED provider

Incomplete Response
Patient exhibits at least one of the following:
- FEV1 or PEF = 40-69%
- Mild or moderate symptoms*

RT order and give albuterol via MDI with spacer x8 puffs or 5 mg Q20 min. x2 via nebulizer.
MDI therapy is the preferred delivery method. If the patient is unable to perform MDI therapy adequately, give treatments via nebulizer.

RT assess response to intervention (including spirometry)

Good Response
Patient exhibits at least one of the following:
- FEV1 or PEF > 70%
- No distress, normal exam
- Response sustained for > 60 min.

RT notify ED provider

Incomplete or Poor Response
Patient exhibits at least one of the following:
- FEV1 or PEF < 70%
- PCO2 > 42 mmHg
- Mild, moderate, or severe symptoms*
- Significant distress

RT notify ED provider

Moderate or Severe Exacerbation
HIGH DOSE THERAPY
- RT order and give albuterol 5 mg Q20 min x3 in 1st hour via nebulizer
- RT order and give ipratropium bromide 500 mcg Q20 min x3 via nebulizer
- Administer O2 to maintain SpO2 ≥ 92%
- Oral corticosteroids per ED provider
- Consider EtCO2 or arterial blood gas per ED provider

RT assess response to intervention (including spirometry)

Good Response
Patient exhibits at least one of the following:
- FEV1 or PEF > 70%
- No distress, normal exam
- Response sustained for > 60 min.

RT notify ED provider

Incomplete or Poor Response
Patient exhibits at least one of the following:
- FEV1 or PEF < 70%
- PCO2 > 42 mmHg
- Mild, moderate, or severe symptoms*
- Significant distress

RT notify ED provider

Poor Response
Patient exhibits at least one of the following:
- FEV1 or PEF < 40%
- PCO2 > 42 mmHg
- Severe symptoms*
- Significant distress

RT notify ED provider

RT order and give albuterol continuous at 0.5 mg/kg over 1 hour (up to 15 mg/hour) via nebulizer

RT notify ED provider

Continue Reassessment and Admission Planning
RT notify ED provider
Admit to Hospital

Last reviewed/revised: 07/2015
Contact CCKM for revisions.
Asthma – Pediatric/Adult – Inpatient/Ambulatory Guideline

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Contact: CCKM@uwhealth.org
Last Revised: 09/2016
Adult patient admitted to general care floor

Was patient admitted from ED?

Yes → RT perform assessment (including spirometry)

No → RT perform assessment (including spirometry)

Does patient have any of the following?*
- FEV1 or PEF < 40% or unable to perform spirometry due to work of breathing?
- Diffuse wheezes or poor air movement without wheezes?
- Breathless at rest/agitated or confused?
- In need of O₂ to keep SpO₂ > 92%?

Yes

- Moderate or Severe Exacerbation
  - RT order and give albuterol 5 mg Q20 min x3 in 1st hour via nebulizer
  - RT order and give ipratropium bromide 500 mcg Q20 min x3 via nebulizer
  - Administer O₂ to maintain SpO₂ > 92%
  - RT contact physician to consider non-invasive ventilation and moving patient to ICU/IMC

No

- Mild Exacerbation
  - RT order and give albuterol 5 mg via nebulizer x1
  - RT order and give ipratropium bromide 500 mcg via nebulizer x1 (if using albuterol at home > q2-4 hours)
  - Administer O₂ to maintain SpO₂ > 92%

RT assess response to intervention (including spirometry)

Does patient have any of the following?
- Subjective improvement of their shortness of breath?
- Decreased use of accessory muscles?
- Improved breath sounds?

Yes

- Refer to Bronchodilator Follow-up Algorithm and assess patient for self-administration if indicated
- RT contact physician to consider:
  - Moving patient to an ICU and starting continuous bronchodilator therapy
  - Starting adjunct therapies such as BiPAP, Heliox, or inhaled corticosteroids

No

- RT assess patient’s compliance and ability to self-administer all inhaled medications. RT notify provider of patient compliance via progress note and verbal communication.
- RT initiate peak flow monitoring (CS# 3330773) twice daily 10 minutes after bronchodilator therapy.

---

* MDI is the preferred delivery method. If the patient is unable to perform MDI therapy adequately, give treatments via nebulizer. If the patient has an artificial airway, refer to Bronchodilator via Artificial Airway Algorithm.

---

<table>
<thead>
<tr>
<th>Bronchodilator Frequency</th>
<th>Triage Score</th>
<th>Re-assessment Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 &amp; PRN</td>
<td>1</td>
<td>Q24 hours</td>
</tr>
<tr>
<td>Q6 &amp; PRN</td>
<td>2</td>
<td>Q24 hours</td>
</tr>
<tr>
<td>4x Daily &amp; PRN</td>
<td>3</td>
<td>Q24 hours</td>
</tr>
<tr>
<td>3x Daily and/or PRN</td>
<td>4</td>
<td>Q24 hours</td>
</tr>
<tr>
<td>MVC, S/A, or PRN</td>
<td>N/A</td>
<td>The patient will be reassessed once 25 hours after the therapy changed to check their respiratory status and therapy technique. If no changes are needed the reassessment schedule then changes to PRN.</td>
</tr>
</tbody>
</table>

Reference: UWHC Policy 1.53: Respiratory Care Protocol

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Contact: CCKM@uwhealth.org
Last Revised: 09/2016
Asthma – Pediatric/Adult - Discharge Check List
Emergency Department to Home

Note: This checklist does not replace individual clinical judgement and/or consideration for patient tolerance of specific medications or therapies.

## Discharge Criteria

<table>
<thead>
<tr>
<th>Patients who meet the following criteria may be discharged:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• On room air</td>
</tr>
<tr>
<td>• Receiving albuterol treatments (Q4 hours with no increasing frequency)</td>
</tr>
</tbody>
</table>

- Print the Asthma Action Plan in Health Link
  *(GINA Evidence B- patients 6 years or older; GINA Evidence D- patients 5 years or younger)*
  - Note: For pediatric patients, print two color copies (home and school).

- Prescribe oral corticosteroids, inclusive of doses given during admission (pediatric patients: 1-2 mg/kg once daily or divided BID with max dose 60 mg/day).
  - Common options:
    - 4-7 additional days of prednisolone
    - 1 additional dose of dexamethasone to be given 36-48 hours after discharge

- Prescribe inhaled corticosteroid (controller medication) via pMDI with spacer

- Prescribe bronchodilator (rescue medication) via pMDI with spacer

- Schedule Follow-up Appointment (within 2-7 days of discharge) *(GINA Evidence B)*
  - UW Health recommends scheduling an appointment with the PCP within 2-7 days.
  - An appointment with the Allergy or Pulmonary Clinic may be made within 2-3 weeks (if indicated).

- Provide Patient Education *(GINA Evidence B)* which includes:
  - Basics of asthma pathophysiology
  - Triggers and signs and symptoms
  - Rescue vs. controller medications
  - Review what to do in an emergency
  - Inhaler technique
  - Review Asthma Action Plan with patient and family.

Last revised/reviewed: 07/2015 | Contact CCKM for revisions.
UW Health Asthma – Pediatric/Adult – Inpatient/Ambulatory Guideline

References:
Asthma – Pediatric/Adult - Discharge Check List
Inpatient to Home

Note: This checklist does not replace individual clinical judgement and/or consideration for patient tolerance of specific medications or therapies.

Discharge Criteria

Patients who meet the following criteria may be discharged:
- On room air
- Receiving albuterol treatments (Q4 hours with no increasing frequency)

☐ Print the Asthma Action Plan in Health Link
   (GINA Evidence B- patients 6 years or older; GINA Evidence D- patients 5 years or younger)
   - For pediatric patients, print two color copies (home and school).
   - Consider stepping up the Green Zone maintenance therapy for 4-6 weeks after discharge.

☐ Prescribe a total of 5-7 days of oral corticosteroids, inclusive of doses given during admission
  (pediatric patients: 1-2 mg/kg once daily or divided BID with max dose 60 mg/day)

☐ Schedule Follow-up Appointment (within 2-7 days of discharge) (GINA Evidence B)
  - UW Health recommends scheduling an appointment with the PCP within 2-7 days.
  - An appointment with the Allergy or Pulmonary Clinic may be made within 2-3 weeks (if indicated).

☐ Provide Patient Education (GINA Evidence B) which includes:
  - Basics of asthma pathophysiology
  - Triggers and signs and symptoms (i.e., environmental triggers)
  - Rescue vs. controller medications
  - Review what to do in an emergency (i.e., yellow and red zones)
  - Inhaler technique (i.e., mask and spacer)
  - PEF meter technique (if used)
  - Review Asthma Action Plan with patient and family.

Last revised/reviewed: 07/2015 | Contact CCKM for revisions.

UW Health Asthma – Pediatric/Adult – Inpatient/Ambulatory Guideline

References: