Summary of NAEPP's EPR-3: Recommended Medications for Asthma*

Long-Term Control Medications for Children Ages 0-4 Years			
Medication	**Estimated Daily Dose**		
Inhaled Corticosteroid (ICS)	**Low**	**Medium**	**High**
Beclomethasone HFA 40 or 80 mcg/puff	NA		
Budesonide DPI 90, 180, or 200 mcg/inhalation	NA		
Budesonide Inhaled Suspension *for nebulizer*	0.25-0.5 mg	>0.5-1.0 mg	>1.0 mg
Flunisolide 250 mcg/puff	NA		
Flunisolide HFA 80 mcg/puff	NA		
Fluticasone HFA/MDI 44, 110, or 220 mcg/puff	176 mcg	>176-352 mcg	>352 mcg
Fluticasone DPI 50, 100, or 250 mcg/inhalation	NA		
Mometasone 200 mcg/inhalation	NA		
Triamcinolone Acetonide 75 mcg/puff	NA		
Medication	**Usual Doses**		
Long-Acting Beta$_2$ Agonist (LABA) **			
Salmeterol DPI 50 mcg/blister	NA		
Formoterol DPI 12 mcg/single-use capsule	NA		
Combined Medications			
Fluticasone/Salmeterol DPI 100 mcg/50 mcg	NA		
Budesonide/Formoterol HFA MDI 80 mcg/4.5 mcg	NA		
Cromolyn/Nedrocromil			
Cromolyn MDI 0.8mg/puff	NA		
Cromolyn *Nebulizer* 20 mg/ampule	1 ampule QID **(NA for <2 years of age)**		
Nedrocromil MDI 1.75 mg/puff	NA		
Leukotriene Receptor Antagonists (LTRAs)			
Montelukast 4 or 5 mg chewable tablets; 4 mg granule packets	4 mg QHS **(1-5 years of age)**		
Zafirlukast 10 mg tablet	NA		
Methylxanthines			
Theophylline liquids, sustained release tablets, and capsules	Starting dose 10mg/kg/day; Usual maximum: < 1 year of age: 0.2 (age in weeks) + 5 =mg/kg/day ≥ 1 year of age: 16 mg/kg/day		
Oral Systemic Corticosteroids (OSC)			
Methylprednisolone 2, 4, 8, 16, 32 mg tablets	0.25-2.0 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			
Prednisone 1, 2.5, 5, 10, 20, 50 mg tablets; 5 mg/cc, 5 mg/5 cc			

KEY: CFC-chloroflurocarbon, DPI-dry-powdered inhaler; HFA-hydrofluroalkane; MDI-metered-dose inhaler; NA-not available (safety & efficacy not established for this age group, not approved, or no data available)

NOTE: Dosages are provided for those products that have been approved by the U.S. Food and Drug Administration or have sufficient clinical trial safety and efficacy data in the appropriate age ranges to support their use.

The above list is not all inclusive. Check availability and health plan formulary when applicable.

*** See EPR-3 Full Report for full discussion. See reverse side for therapeutic issues.**

****LABA's:** In February 2010 the FDA issued a safety announcement on the use of LABA's. The FDA has concluded that there is an **increased risk for severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients** using LABA's for the treatment of asthma. It is recommended that LABA's only be used in patients whose asthma cannot be adequately controlled on asthma controller medications and should only be used in conjunction with an inhaled corticosteroid. Additional LABA information on reverse side.

Produced by the California Asthma Public Health Initiative (CAPHI). Summarized from the NAEPP EPR-3: www.nhlbi.nih.gov/guidelines/asthma. This summary of NAEPP's recommended stepwise medications for asthma is designed to assist the clinician in the diagnosis and management of asthma and is not intended to replace the clinician's judgment or establish a protocol for all patients with a particular condition. Additional copies of this summary and other asthma resources available at www.betterasthmacare.org. Permission to reprint granted if unaltered. **April 2010**

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Long-Term Control Medications for Children Ages 0-4 Years

General Therapeutic Issues:

- The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy. The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.
- For children <4 years of age: The safety and efficacy of ICSs in children <1 year has not been established. Children <4 years of age generally require delivery of ICS (budesonide and fluticasone HFA) through a face mask that should fit snugly over nose and mouth and avoid nebulizing in the eyes. Wash face after each treatment to prevent local corticosteroid side effects. For budesonide, the dose may be administered 1–3 times daily. Budesonide suspension is compatible with albuterol, ipratropium, and levalbuterol nebulizer solutions in the same nebulizer. Use only jet nebulizers, as ultrasonic nebulizers are ineffective for suspensions.
- Use of a spacer/holding chamber is recommended with the use of an MDI.
- Metered-dose inhaler (MDI) dosages are expressed as the actuator dose (the amount of the drug leaving the actuator and delivered to the patient), which is the labeling required in the United States. This is different from the dosage expressed as the valve dose (the amount of drug leaving the valve, not all of which is available to the patient), which is used in many European countries and in some scientific literature. Dry powder inhaler (DPI) doses are expressed as the amount of drug in the inhaler following activation.
- For fluticasone HFA, the dose should be divided 2 times daily; the low dose for children <4 years is higher than for children 5–11 years of age due to lower dose delivered with face mask and data on efficacy in young children.
- Preparations are not interchangeable on a mcg or a per puff basis. These figures represent estimated daily doses.
- Some doses may be outside package labeling, especially in the high-dose range. Budesonide nebulizer suspension is the only ICS with FDA approved labeling for children <4 years of age.
- Cromolyn & Nedrocromil: 4-6 week trial may be needed to determine maximum benefit. Dose by MDI may be inadequate to affect hyperresponsiveness. One dose before exercise or allergen exposure provides effective prophylaxis for 1-2 hours. Not as effective for EIB as SABA. Once control is achieved, the frequency of dosing may be reduced.
- Montelukast: Exhibits a flat dose-response curve.
- Theophylline: Adjust dosage to achieve serum concentration of 5-15 mcg/mL at steady-state (at least 48 hours on the same dosage). Due to wide interpatient variability in theophylline metabolic clearance, routine serum theophylline level monitoring is important. See full EPR-3 guidelines for factors that affect theophylline levels.
- All three systemic corticosteroids: For long-term treatment of severe persistent asthma, administer single dose in a.m. either daily or on alternate days (alternate-day therapy may produce less adrenal suppression). Short courses or "bursts" are effective for establishing control when initiating therapy or during a period of gradual deterioration. There is no evidence that tapering following improvement prevents relapse. Patients receiving the lower dose (1mg/kg/day) experience fewer behavioral side effects (Kayani and Shannon 2002), and it appears to be equally efficacious (Rachelefsky 2003). For patients unable to tolerate the liquid preparations, dexamethasone syrup at 0.4 mg/kg/day may be an alternative. Studies are limited, however, and the longer duration of activity increases the risk of adrenal suppression (Hendeles 2003).
- Long-Acting Beta2-Agonist (LABA): Potential risk of uncommon, severe, life threatening or fatal exacerbation. Not to be used to treat acute symptoms or exacerbations. Should not be used as monotherapy for long-term control of asthma or as anti-inflammatory therapy. May provide more effective symptom control when added to standard doses of ICS compared to increasing the ICS dosage. See full EPR-3 for additional discussion regarding safety of LABAs. FDA warning on all LABAs. To access the complete FDA Safety Announcement go to: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200776.htm

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