

Appendix A:

Pediatric Asthma Severity and Control
Ages 0-4 years

Patients aged 0–4 years

To classify asthma severity in patients **not on medications**, see Table 3a.

To assess asthma control in patients **already on medications**, see Table 3b.

Table 3a. Patients aged 0–4 years not on medications: classifying asthma severity				
Assess each component over the last 2–4 weeks. The result is based on the score of the most severe component.				
Impairment	Intermittent asthma	Persistent asthma		
		Mild	Moderate	Severe
Symptoms	Up to 2 days/week	More than 2 days/week	Daily	Throughout the day
Nighttime awakenings	0	1–2x/month	3–4x/month	More than 1x/week
Short-acting beta ₂ agonist use (for rescue, not exercise prophylaxis)	Up to 2 days/week	More than 2 days/week	Daily	Several times a day
Interference with normal activity	None	Minor limitation	Some limitation	Extreme limitation
Lung function: FEV ₁ predicted	N/A	N/A	N/A	N/A
FEV ₁ /FVC	N/A	N/A	N/A	N/A
Risk Exacerbations requiring systemic corticosteroids	Up to 1x/year	2 or more exacerbations in 6 months ¹ or 4 or more wheezing episodes in the year lasting longer than a day and having risk factors for persistent asthma ²		
Therapy recommendation See 0–4 Year Stepwise Chart, pp. 12–13.	Initiate therapy at Step 1 .	Initiate therapy at Step 2 .	Initiate therapy at Step 3 . Consider short course of systemic corticosteroids.	Initiate therapy at Step 3 . Consider short course of systemic corticosteroids.
¹ Patients with 2 or more exacerbations may be considered the same as patients who have persistent asthma, even in the absence of impairment consistent with persistent asthma. ² Initiate daily long-term control therapy for children who had 4 or more episodes of wheezing in the past year that lasted longer than 1 day and affected sleep and who have either: <ul style="list-style-type: none"> • One of the following: parental history of asthma, physician diagnosis of atopic dermatitis, or evidence of sensitizations to inhaled allergens, or • Two of the following: sensitization to foods, blood eosinophilia of 4% or higher, or wheezing apart from colds. 				

Table 3b. Patients aged 0–4 years currently taking medications: assessing asthma control
Assess each component over the last 2–4 weeks. The result is based on the score of the most severe component.

Impairment	Asthma is:		
	<i>Well controlled</i>	<i>Not well controlled</i>	<i>Very poorly controlled</i>
Symptoms	Up to 2 days/week but not more than once a day	More than 2 days/week or multiple times up to 2 days/week	Throughout the day
Nighttime awakenings	Up to 1x/month	More than 1x/month	More than 1x/week
Short-acting beta ₂ agonist use (for rescue, not exercise prophylaxis)	Up to 2 days/week	More than 2 days/week	Several times a day
Interference with normal activity	None	Some limitation	Extreme limitation
Lung function: FEV ₁ predicted	N/A	N/A	N/A
FEV ₁ /FVC	N/A	N/A	N/A
Questionnaire	N/A	N/A	N/A
Risk Exacerbations requiring systemic corticosteroids	0–1x/year	2–3x/year	More than 3x/year
Therapy recommendation See 0–4 Year Stepwise Chart, pp. 12–13.	Maintain therapy at current step. If well controlled for 3 months or longer, consider step down.	Step up 1 step. ¹	Step up 1–2 steps. ¹ Consider short course of systemic corticosteroids.
Follow-up	Every 1–6 months	2–6 weeks	2 weeks

¹ Before stepping up therapy, review adherence to medication, inhaler technique, and environmental control.

Pharmacologic Options: Stepwise Approach to Long-term Asthma Management in Patients Aged 0–4 Years

For notes to this chart, including abbreviations used, see following page.

INTERMITTENT Symptoms	PERSISTENT Symptoms				
Step 1	Step 2	Step 3	Step 4	Step 5 Refer to asthma specialist	Step 6 Refer to asthma specialist
<p>Quick-relief medication (as needed)</p> <p>SABA Albuterol HFA w/spacer 90 mcg/puff 2 puffs every 4–6 hours prn</p>	<p>SABA Albuterol HFA w/spacer 90 mcg/puff 2 puffs every 4–6 hours prn</p>	<p>SABA Albuterol HFA w/spacer 90 mcg/puff 2 puffs every 4–6 hours prn</p>	<p>SABA Albuterol HFA w/spacer 90 mcg/puff 2 puffs every 4–6 hours prn</p>	<p>SABA Albuterol HFA w/spacer 90 mcg/puff 2 puffs every 4–6 hours prn</p>	<p>SABA Albuterol HFA w/spacer 90 mcg/puff 2 puffs every 4–6 hours prn</p>
Long-term control medication—PREFERRED 1,2					
<p>Low-dose ICS <i>1st line</i> Fluticasone (Flovent) HFA/MDI 88 mcg twice daily, delivered with face mask and spacer</p> <p><i>2nd line</i> (age over 12 months) Budesonide (Pulmicort Respules) nebulization suspension 0.25–0.5 mg, divided 1–3x daily</p> <p>Long-term control medication—ALTERNATIVE 2,3</p> <p>LTRA Age 12–23 months: Montelukast (Singulair) oral granules (NF) 4 mg daily at bedtime</p> <p>Age 2–4 years: Montelukast (Singulair) tablet (PA) 4 mg daily at bedtime</p>	<p>Medium-dose ICS <i>1st line</i> Fluticasone (Flovent) HFA/MDI 88–176 mcg twice daily, delivered with face mask and spacer</p> <p><i>2nd line</i> (age over 12 months) Budesonide (Pulmicort Respules) nebulization suspension 0.5–1 mg, divided 1–3x daily</p> <p>and either LTRA (Age 2–4 years) Montelukast (Singulair) tablet (PA) 4 mg daily at bedtime</p> <p>or LABA (Age 4 years) Salmeterol (Serevent) DPI (PA) 50 mcg every 12 hours</p>	<p>Medium-dose ICS <i>1st line</i> Fluticasone (Flovent) HFA/MDI 88–176 mcg twice daily, delivered with face mask and spacer</p> <p><i>2nd line</i> (age over 12 months) Budesonide (Pulmicort Respules) nebulization suspension 0.5–1 mg, divided 1–3x daily</p> <p>and either LTRA (Age 2–4 years) Montelukast (Singulair) tablet (PA) 4 mg daily at bedtime</p> <p>or LABA (Age 4 years) Salmeterol (Serevent) DPI (PA) 50 mcg every 12 hours</p>	<p>Medium-dose ICS <i>1st line</i> Fluticasone (Flovent) HFA/MDI 88–176 mcg twice daily, delivered with face mask and spacer</p> <p><i>2nd line</i> (age over 12 months) Budesonide (Pulmicort Respules) nebulization suspension 0.5–1 mg, divided 1–3x daily</p> <p>and either LTRA (Age 2–4 years) Montelukast (Singulair) tablet (PA) 4 mg daily at bedtime</p> <p>or LABA (Age 4 years) Salmeterol (Serevent) DPI (PA) 50 mcg every 12 hours</p>	<p>High-dose ICS <i>1st line</i> Fluticasone (Flovent) HFA/MDI 176–354 mcg twice daily, delivered with face mask and spacer</p> <p><i>2nd line</i> (age over 12 months) Budesonide (Pulmicort Respules) nebulization suspension Greater than 1 mg, divided 1–3x daily</p> <p>and either LTRA (Age 2–4 years) Montelukast (Singulair) tablet (PA) 4 mg daily at bedtime</p> <p>or LABA (Age 4 years) Salmeterol (Serevent) DPI (PA) 50 mcg every 12 hours</p>	<p>High-dose ICS <i>1st line</i> Fluticasone (Flovent) HFA/MDI 354–710 mcg twice daily, delivered with face mask and spacer</p> <p><i>2nd line</i> (age over 12 months) Budesonide (Pulmicort Respules) nebulization suspension Greater than 1 mg, divided 1–3x daily</p> <p>and either LTRA (Age 2–4 years) Montelukast (Singulair) tablet (PA) 4 mg daily at bedtime</p> <p>or LABA (Age 4 years) Salmeterol (Serevent) DPI (PA) 50 mcg every 12 hours</p> <p>and Oral systemic corticosteroid Prednisone “burst”: 1–2 mg/kg/day. Maximum 60 mg/day for 3–10 days</p>

NOTES to Stepwise Approach, Patients Aged 0–4 Years

Abbreviations

SABA	short-acting beta ₂ agonist
ICS	inhaled corticosteroid
LABA	long-acting beta ₂ agonist
LTRA	leukotriene receptor antagonist
PA	prior authorization required
DPI	dry powder inhaler
MDI	metered-dose inhaler
HFA	hydrofluoroalkane

Notes

1 Inhaled corticosteroids

The safety and efficacy of inhaled corticosteroids aged under 12 months has not been established. Children aged under 4 years generally require delivery of ICS through a face mask that fits snugly over the nose and mouth, avoiding nebulization into the eyes. The child's face should be washed after each treatment to prevent local corticosteroid side effects.

- Fluticasone HFA: The low dose for children up to 4 years of age is higher than that for children 5–11 years of age due to lower dose delivered with face mask and data on efficacy in young children.
- Budesonide: Use only jet nebulizers (Pari), as ultrasonic nebulizers are ineffective for suspension, and use only with a Pari mask (which has no holes that can allow medicine to reach the eyes). Budesonide suspension is compatible with albuterol, ipratropium, and levalbuterol nebulizer solutions in the same nebulizer.

2 Leukotriene receptor antagonist (montelukast) :

- Not covered for allergic rhinitis, sinusitis or atopic dermatitis
- Prior Authorization criteria:

1. Patients aged 12 months or over who have asthma and are unable to use inhaled corticosteroids because of medical contraindications or inability to manipulate the inhaler. In these patients, a clinical response to montelukast must be documented for continued coverage. Rationale: montelukast is less effective than inhaled corticosteroids.
2. For children under 12 years of age with asthma who are able to use inhaled corticosteroids, but not controlled on medium-dose inhaled corticosteroid monotherapy, montelukast can be added to inhaled corticosteroid treatment.
3. For treatment of exercise-induced bronchospasm for athletes and children who do not have indications for inhaled corticosteroids and fall albuterol because they are active for a substantial part of the day or because the time of their activity is not predictable.
4. For individuals who have history of systemic (anaphylactic) reaction to allergy immunotherapy, and poor response to at least one antihistamine pre-treatment (i.e., diphenhydramine, loratadine, fexofenadine, cetirizine), montelukast can be added to antihistamine pre-treatment.

3 Other alternatives

Theophylline:

- Starting dose: 10 mg/kg/day
- Usual maximum for age under 12 months: [0.2 (age in weeks) + 5] = mg/kg/day
- Usual maximum for age 12 months or over: 16 mg/kg/day