



# SMART: Why is it Smart and What are the Challenges?

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# Disclosure

Speaker Regeneron and Sanofi

No conflict.

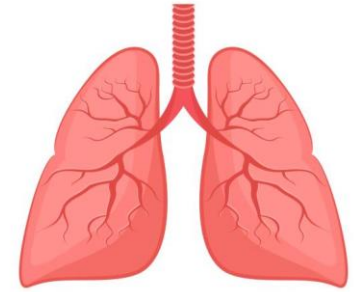
# Objectives

1. Describe the pathophysiology and guideline-based severity classifications of asthma.
2. Define SMART regimen, efficacy and safety, selection of the appropriate candidates and implementation of SMART.
3. Recognize barriers of implementing SMART and what to do when SMART does not work.

“The burden of asthma affects patients with asthma, their families and society in terms of lost work and school, lessened quality of life, and avoidable emergency room visits, hospitalization and deaths.”



# Asthma Statistic



<b>Total number patients with asthma in US</b>	<b>25,257,138</b>	<b>7.8%</b>
Children (Age <18 years)	4,226,659	5.8 %
Adults (Age 18+ years)	21,030,479	8.4 %

2021: 3,517 fatalities

**2020: 4,145 fatalities**

2019: 4.9 million provider office visits

2019: 69,330 hospital admissions

2019: 1.5 million ER visit

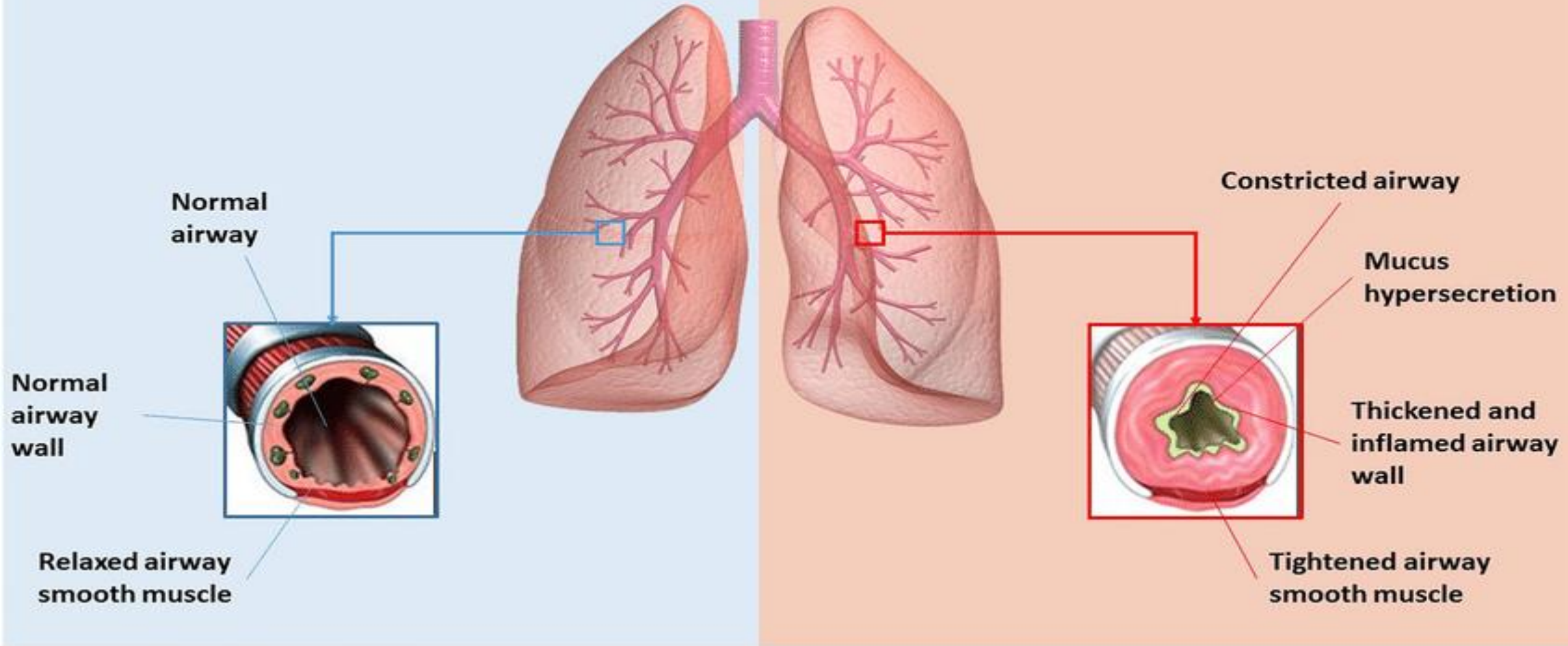


Asthma is a heterogeneous disease,  
generally characterized by  
chronic airway inflammation

- Asthma is defined by the history of respiratory symptoms:
  - Wheeze
  - Shortness of breath
  - chest tightness
  - Cough
- Symptoms vary over time and in intensity with variable expiratory airflow

## Normal lung

## Asthmatic lung







# What is Asthma?

The Global Initiative for Asthma (GINA) defines asthma as:

“a heterogeneous disease, usually characterized by chronic airway inflammation with a severe global impact on quality of life, mortality, economy, and health care utilization.”

GINA, 2022





# Asthma Disparities

Burden of asthma is disproportionately affected by racial and ethnic minority groups and the economically disadvantaged<sup>1</sup>

## 2020 Asthma Prevalence<sup>1,2,3</sup>

Black non-Hispanic individuals.	10.8%
White non-Hispanic individuals	7.6%.
Hispanic	6.4%
Puerto Rican	14.9%
American Indians/Alaska Natives	14.2

1. [NHLBI 2023.  
https://www.nhlbi.nih.gov/education/lmbbba/asthma/asthma-communities](https://www.nhlbi.nih.gov/education/lmbbba/asthma/asthma-communities)
2. J Allergy Clin Immunol Pract 2023;11:737-45
3. <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=60>

# Asthma Disparities

- Hispanic/Latino individuals are twice as likely to visit the emergency room for asthma, compared to non-Hispanic whites<sup>1</sup>
- Black individuals, the observed asthma morbidity and mortality disparities for Black individuals are worse<sup>2</sup>
- Asthma mortality rates are highest for adults, women, and African Americans<sup>1</sup>

1. [NHLBI 2023.  
https://www.nhlbi.nih.gov/education/lmbba/asthma/asthma-communities](https://www.nhlbi.nih.gov/education/lmbba/asthma/asthma-communities)

2. J Allergy Clin Immunol Pract 2023;11:737-45

# Primary Goal of Asthma Management and Treatment

- Achieve the control of symptoms and underlying airway inflammation
- Reduce the risk of asthma exacerbation
- Minimize the risk of medication-related side effects
- Prevent the progression of obstructive lung damage
- Engagement of patients as active partners
- Ongoing asthma education
- Ongoing and comprehensive treatment aimed to reduce the symptom burden



# Evidence-based Practice Guidelines

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• Proud to be celebrating the 30<sup>th</sup> year of GINA •



GLOBAL INITIATIVE FOR ASTHMA

GLOBAL STRATEGY FOR  
ASTHMA MANAGEMENT AND PREVENTION  
NHLBI/WHO WORKSHOP REPORT  
(Based on a March 1993 Meeting)

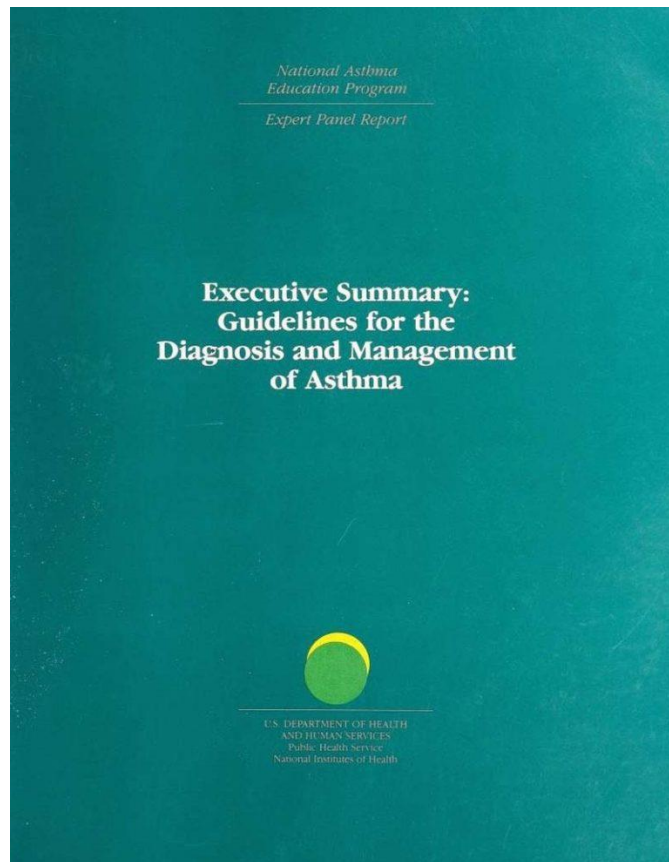


NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute  
Publication Number 95-0007  
January 1995  
Revised May 1996

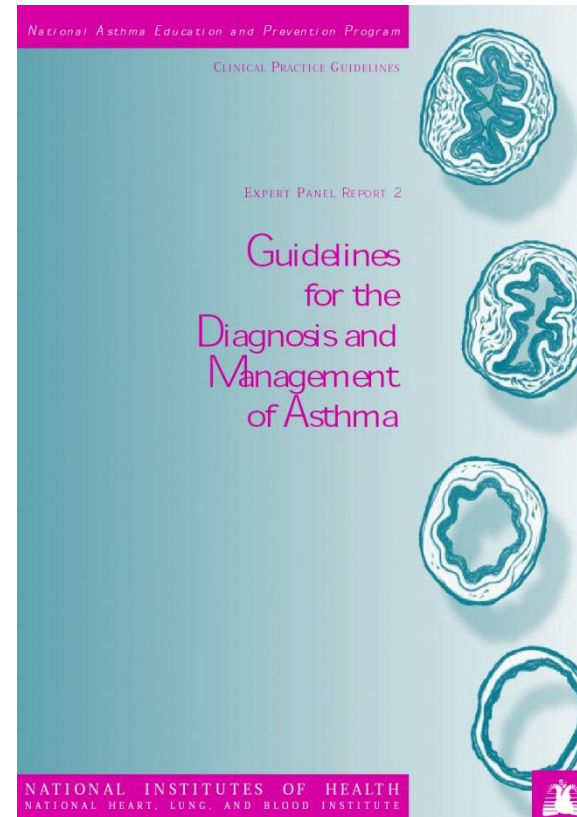


1995

# National Asthma Education & Prevention Program (NAEPP)



1991



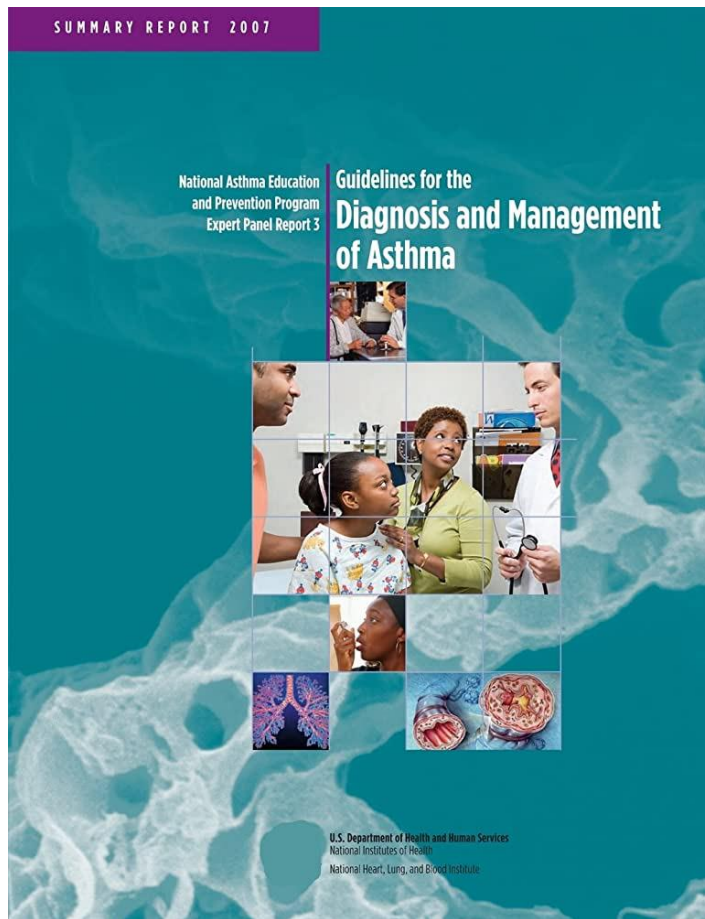
1997



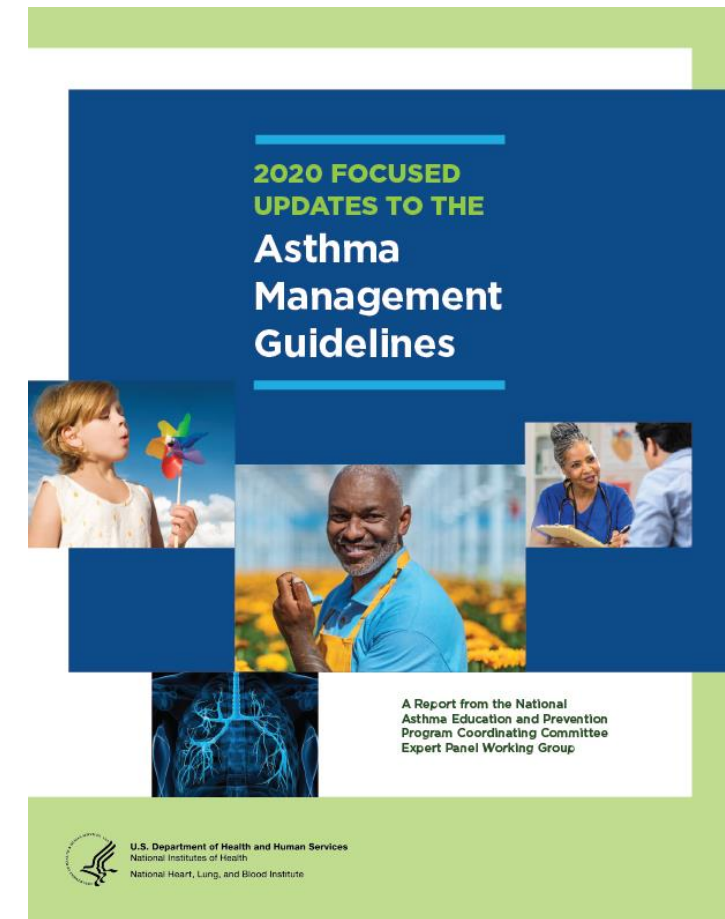
2002



# National Asthma Education & Prevention Program (NAEPP)



2007

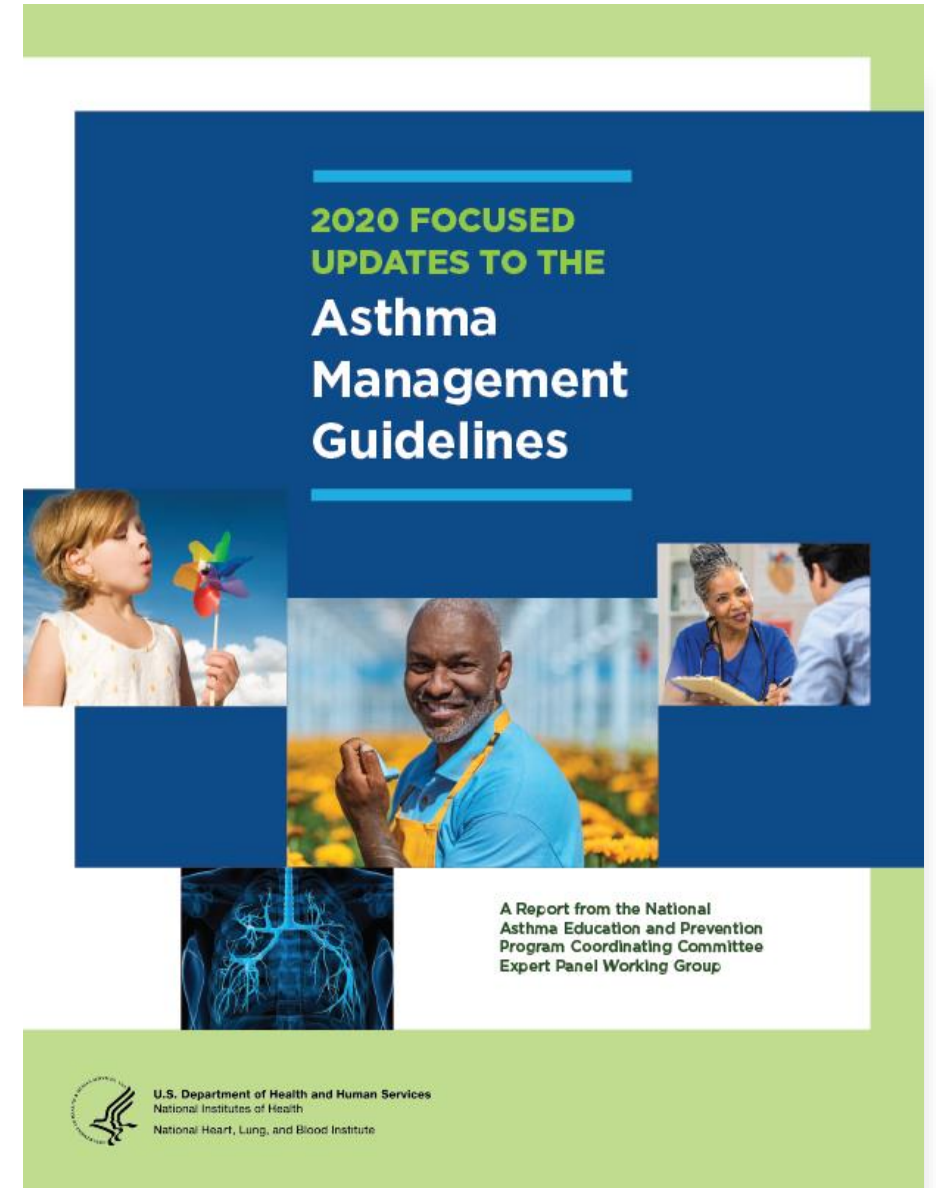


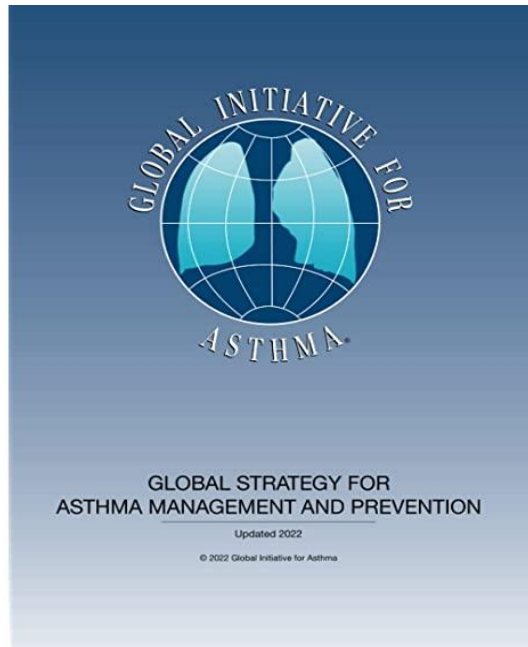
2020



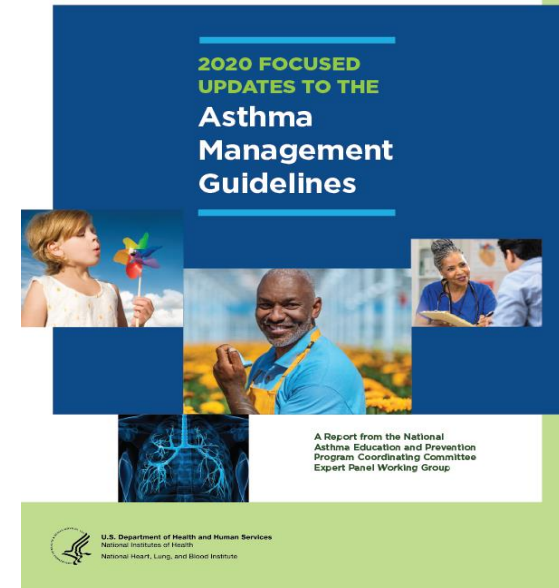
# Six Priority Topics Identified for Systematic Review

1. Fractional exhaled nitric oxide (FENO) in diagnosis, medication selection, and monitoring of treatment response in asthma
2. Remediation of indoor allergens (eg, house-dust mites/pets) in asthma management
3. Adjustable medication dosing in recurrent wheezing and asthma
4. Long-acting antimuscarinic agents in asthma management as add-ons to inhaled corticosteroids (ICSs)
5. Immunotherapy and the management of asthma
6. Bronchial Thermoplasty (BT) in adult severe asthma





GINA report is intended to inform a comprehensive global strategy for various aspects of diagnosis and management of mild to severe asthma, including in low- and middle- income countries



2020 report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group presents focused updates to the previous 2007 asthma management guidelines on 6 priority topics

# Asthma Severity and Control

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## **Asthma severity:**

the intrinsic intensity of disease and is based on the lowest level of therapy that allows the patient's asthma to remain controlled.

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## **Asthma control:**

based on impairment and future exacerbation risk criteria

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## **Impairment:**

patient's/caregiver's recall of symptoms and functioning during the previous 2 to 4 weeks and spirometry finding

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## **Risk:**

number and frequency of exacerbations requiring oral corticosteroids

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**Asthma severity is assigned to the most severe category in which any feature exists**

# SEVERITY

Underlying Intensity of Disease  
Pre-Treatment

## Impairment

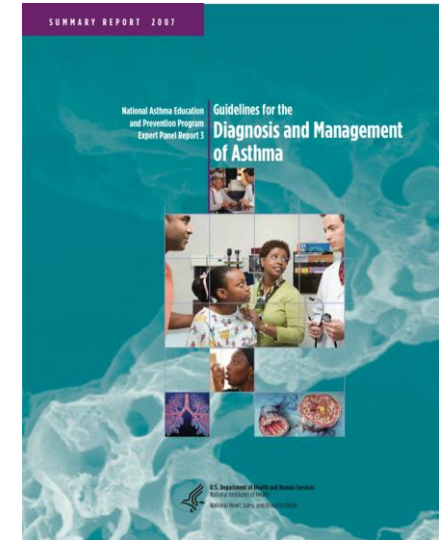
- Frequency of symptoms
- Intensity of symptoms
- Measures of lung function
- Functional limitations
- Impairment currently or recently experienced

## Risk

- Likelihood of future exacerbations or impairment
- History of exacerbations
- Likelihood of progressive lung function decline
- Concomitant diseases

# Classifying Asthma Severity: EPR-3

- Asthma severity is broadly categorized as:
  - intermittent or persistent
- Individuals with intermittent asthma are treated with step 1 therapy
- Individuals with persistent asthma are treated with steps 2 through 6 therapy, depending on whether they have mild, moderate, or severe persistent asthma





# SMART

Single Maintenance and Reliever Therapy



GLOBAL INITIATIVE  
FOR ASTHMA

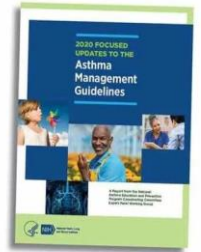
# SMART

THE 2020 FOCUSED UPDATES TO THE  
Asthma Management Guidelines are  
now available on the NHLBI website.

UPDATED TOPICS INCLUDE:

- Use of inhaled corticosteroids
- LAMA use
- Reducing allergens in your home
- Immunotherapy in the treatment of allergic asthma
- FeNO testing
- Bronchial thermoplasty

[nhlbi.nih.gov/AsthmaGuidelines](https://nhlbi.nih.gov/AsthmaGuidelines)



2020 Focused Updates to the Asthma Management Guidelines  
A Report from the National Asthma Education and Prevention Program  
Coordinating Committee Expert Panel Working Group

Use of a single inhaler containing the combination of an inhaled corticosteroid (ICS) and formoterol for both maintenance and quick relief therapy is recommended by the Global Initiative for Asthma and the National Asthma Education and Prevention Program Coordinating Committee in steps 3 and 4 of asthma management



# SMART

SMART provides the option of rapid symptom relief, a single medication, similar daily symptom control, reduced risk for severe exacerbations, and a lower total ICS dose for patients requiring step 3 or 4 therapy

## AGES 12+ YEARS: STEPWISE APPROACH FOR MANAGEMENT OF ASTHMA

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 12+ Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6 <sup>■</sup>
Preferred	PRN SABA	Daily low-dose ICS and PRN SABA or PRN concomitant ICS and SABA <sup>▲</sup>	Daily and PRN combination low-dose ICS-formoterol <sup>▲</sup>	Daily and PRN combination medium-dose ICS-formoterol <sup>▲</sup>	Daily medium-high dose ICS-LABA + LAMA and PRN SABA <sup>▲</sup>	Daily high-dose ICS-LABA + oral systemic corticosteroids + PRN SABA
Alternative		Daily LTRA* and PRN SABA or Cromolyn,* or Nedocromil,* or Zileuton,* or Theophylline,* and PRN SABA	Daily medium-dose ICS and PRN SABA or Daily low-dose ICS-LABA, or daily low-dose ICS + LAMA, <sup>▲</sup> or daily low-dose ICS + LTRA,* and PRN SABA or Daily low-dose ICS + Theophylline* or Zileuton,* and PRN SABA	Daily medium-dose ICS-LABA or daily medium-dose ICS + LAMA, and PRN SABA <sup>▲</sup> or Daily medium-dose ICS + LTRA,* or daily medium-dose ICS + Theophylline,* or daily medium-dose ICS + Zileuton,* and PRN SABA	Daily medium-high dose ICS-LABA or daily high-dose ICS + LTRA,* and PRN SABA	
		Steps 2-4: Conditionally recommend the use of subcutaneous immunotherapy as an adjunct treatment to standard pharmacotherapy in individuals ≥ 5 years of age whose asthma is controlled at the initiation, build up, and maintenance phases of immunotherapy <sup>▲</sup>			Consider adding Asthma Biologics (e.g., anti-IgE, anti-IL5, anti-IL5R, anti-IL4/IL13)**	

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 5-11 Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
<b>Preferred</b>	PRN SABA	Daily low-dose ICS and PRN SABA	Daily and PRN combination low-dose ICS-formoterol ▲	Daily and PRN combination medium-dose ICS-formoterol ▲	Daily high-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA + oral systemic corticosteroid and PRN SABA
<b>Alternative</b>		Daily LTRA,* or Cromolyn,* or Nedocromil,* or Theophylline,* and PRN SABA	Daily medium-dose ICS and PRN SABA or Daily low-dose ICS-LABA, or daily low-dose ICS + LTRA,* or daily low-dose ICS + Theophylline,* and PRN SABA	Daily medium-dose ICS-LABA and PRN SABA or Daily medium-dose ICS + LTRA* or daily medium-dose ICS + Theophylline,* and PRN SABA	Daily high-dose ICS + LTRA* or daily high-dose ICS + Theophylline,* and PRN SABA	Daily high-dose ICS + LTRA* + oral systemic corticosteroid or daily high-dose ICS + Theophylline* + oral systemic corticosteroid, and PRN SABA
		Steps 2-4: Conditionally recommend the use of subcutaneous immunotherapy as an adjunct treatment to standard pharmacotherapy in individuals ≥ 5 years of age whose asthma is controlled at the initiation, build up, and maintenance phases of immunotherapy ▲			Consider Omalizumab** ▲	

#### Assess Control

- First check adherence, inhaler technique, environmental factors, ▲ and comorbid conditions.
- **Step up** if needed; reassess in 2-6 weeks
- **Step down** if possible (if asthma is well controlled for at least 3 consecutive months)

Consult with asthma specialist if Step 4 or higher is required. Consider consultation at Step 3.

Control assessment is a key element of asthma care. This involves both impairment and risk. Use of objective measures, self-reported control, and health care utilization are complementary and should be employed on an ongoing basis, depending on the individual's clinical situation.

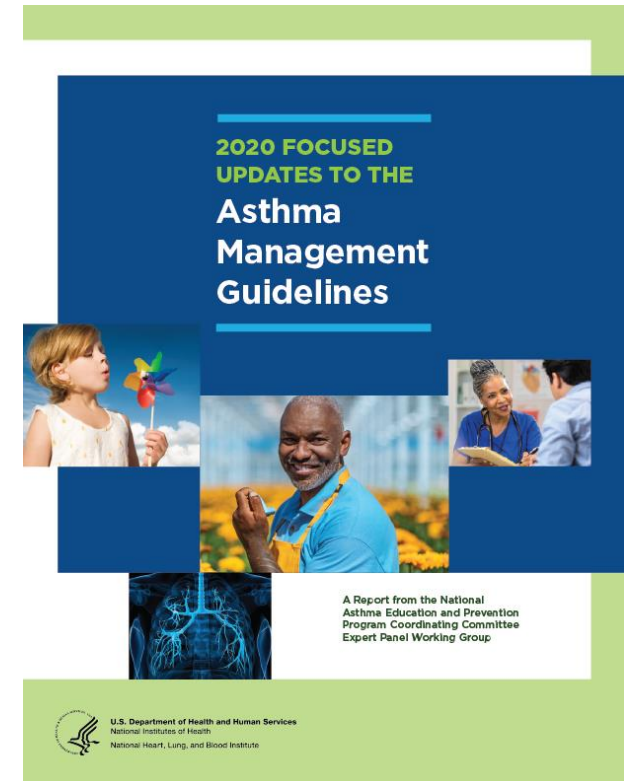
**Abbreviations:** ICS, inhaled corticosteroid; LABA, long-acting beta<sub>2</sub>-agonist; LTRA, leukotriene receptor antagonist; SABA, inhaled short-acting beta<sub>2</sub>-agonist

# SMART: NAEPP 2020

## Expert Panel Recommendation

Ages 4 years and older with moderate to severe persistent asthma

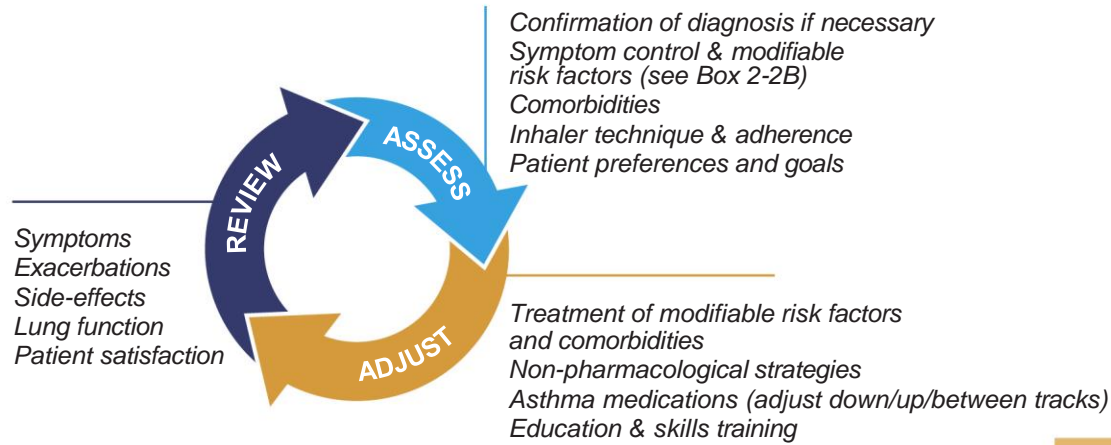
- ICS-formoterol in a single inhaler be used as both daily controller and reliever therapy
  - compared with either a higher-dose ICS daily controller therapy and SABA for quick relief therapy
- **OR**
  - same-dose ICS-LABA as daily controller therapy and SABA for quick-relief therapy
- Strong recommendation with high certainty of evidence for ages 12 years and older
- Moderate certainty of evidence for ages 4- to 11-year-olds



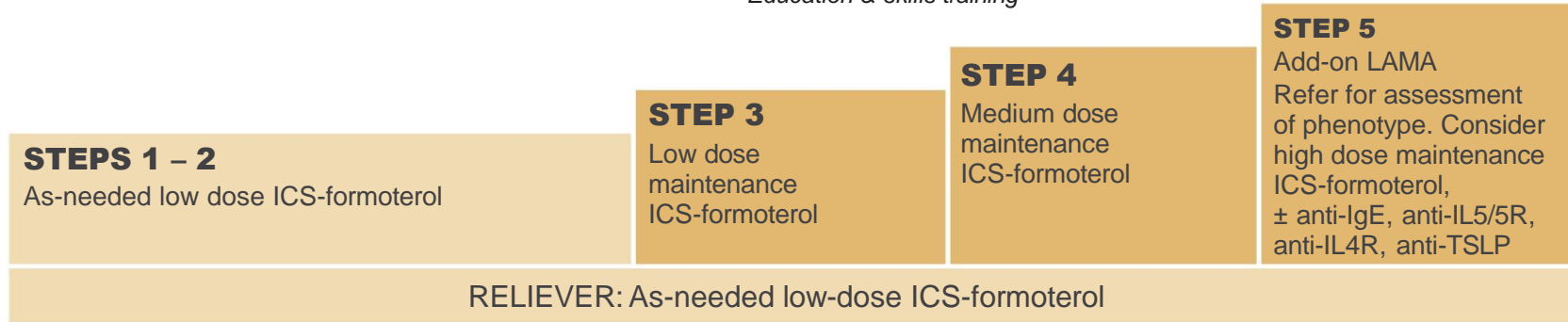
# Adults & adolescents 12+ years

## Personalized asthma management

Assess, Adjust, Review  
for individual patient needs

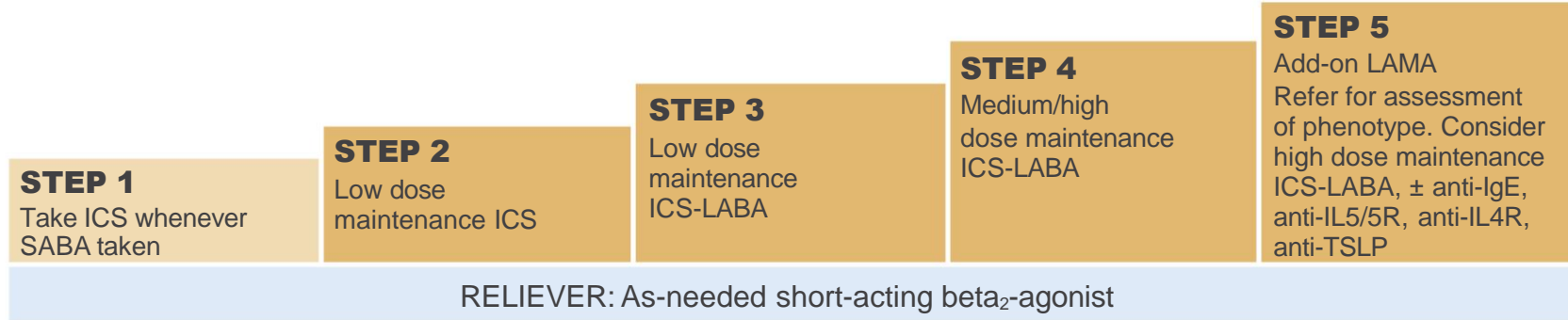


**CONTROLLER** and **PREFERRED RELIEVER** (Track 1). Using ICS-formoterol as reliever reduces the risk of exacerbations compared with using a SABA reliever



See GINA severe asthma guide

**CONTROLLER** and **ALTERNATIVE RELIEVER** (Track 2). Before considering a regimen with SABA reliever, check if the patient is likely to be adherent with daily controller



Other controller options for either track (limited indications, or less evidence for efficacy or safety)

	Low dose ICS whenever SABA taken, or daily LTRA, or add HDM SLIT	Medium dose ICS, or add LTRA, or add HDM SLIT	Add LAMA or LTRA or HDM SLIT, or switch to high dose ICS	Add azithromycin (adults) or LTRA. As last resort consider adding low dose OCS but consider side-effects
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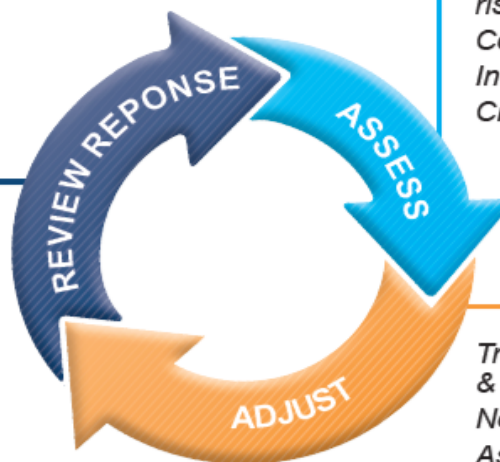
Box 3-5B

# Children 6-11 years

## Personalized asthma management:

Assess, Adjust, Review response

Symptoms  
Exacerbations  
Side-effects  
Lung function  
Child and parent satisfaction



Confirmation of diagnosis if necessary  
Symptom control & modifiable risk factors (including lung function)  
Comorbidities  
Inhaler technique & adherence  
Child and parent preferences and goals

Treatment of modifiable risk factors & comorbidities  
Non-pharmacological strategies  
Asthma medications (adjust down or up)  
Education & skills training

## Asthma medication options:

Adjust treatment up and down for individual child's needs

### PREFERRED CONTROLLER

to prevent exacerbations and control symptoms

Other controller options

### RELIEVER

	<b>STEP 1</b>	<b>STEP 2</b>	<b>STEP 3</b>	<b>STEP 4</b>	<b>STEP 5</b>
	Low dose ICS taken whenever SABA taken*; or daily low dose ICS	Daily low dose inhaled corticosteroid (ICS) (see table of ICS dose ranges for children)	Low dose ICS-LABA or medium dose ICS	Medium dose ICS-LABA Refer for expert advice	Refer for phenotypic assessment ± add-on therapy, e.g. anti-IgE
		Daily leukotriene receptor antagonist (LTRA), or low dose ICS taken whenever SABA taken*	Low dose ICS + LTRA	High dose ICS-LABA, or add-on tiotropium, or add-on LTRA	Add-on anti-IL5, or add-on low dose OCS, but consider side-effects
	As-needed short-acting $\beta_2$ -agonist (SABA)				

\* Separate ICS and SABA inhalers



# NAEPP 2020 Guideline Update

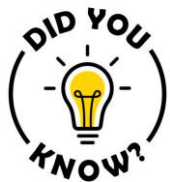
# GINA 2020 Report

Step 1	Step 1 therapy not reviewed as part of NAEPP 2020 guideline update As-needed low-dose ICS-formoterol	As-needed low-dose ICS-formoterol
Step 2*	Conditional recommendation: Daily low-dose ICS and as-needed SABA Daily low-dose ICS and as-needed SABA or or As-needed low-dose ICS-formoterol	Daily low-dose ICS and as-needed SABA or As-needed low-dose ICS-formoterol
Step 3	Strong recommendation: Daily low-dose ICS-formoterol (maintenance and reliever therapy) <sup>†</sup>	Daily low-dose ICS-LABA and as-needed SABA OR Daily low-dose ICS-formoterol (maintenance and reliever therapy)
Step 4	Strong recommendation: Daily medium-dose ICS-formoterol (maintenance and reliever therapy)	Daily medium-dose ICS-LABA and as-needed SABA OR Daily medium-dose ICS-formoterol (maintenance and reliever therapy)
Step 5	Conditional recommendation: Daily medium- to high-dose ICS-LABA 1 LAMA and as-needed SABA	Daily high-dose ICS-LABA AND Refer for phenotypic assessment and add-on therapy (e.g., tiotropium, anti-IgE, anti-IL5/5R, and anti-IL4R)
Step 6	Step 6 therapy not reviewed as part of NAEPP 2020 guideline update	Not applicable in GINA



# SMART

- SMART regimen with budesonide-formoterol is approved for adults and adolescents (aged 12 years) by regulators in more than 120 countries and for children aged 4 to 11 years in a small number of countries<sup>1</sup>
- Over 45 countries have licensed ICS–formoterol for as-needed use in mild asthma and over 120 countries have licensed prescription of SMART (MART) in moderate-to-severe asthma<sup>2</sup>
- **For US clinicians:**<sup>1</sup>
  - Combination of budesonide formoterol is approved for daily use by the US Food and Drug Administration (FDA) for individuals aged 4 years and older
  - SMART regimens are not FDA approved for any age group



Outside the United States, this approach is referred to as maintenance and reliever therapy or MART

# What inhalers are used in SMART?

ICS/formoterol

Currently, this combination is available in:  
budesonide/formoterol (Symbicort®)

Only mometasone/formoterol (Dulera®) 100 mcg/5 mcg

There were NO SMART studies with mometasone/formoterol

Combination inhalers that contain an ICS and **salmeterol** cannot be used for SMART therapy

Advair or Wixela (fluticasone-salmeterol)



# Recommended Doses of budesonide-formoterol for SMART

Based on Published Studies and International Use

		Step 3		Step 4		Step 3 or 4
Age group	Budesonide-formoterol dose	Maintenance dose	As-needed dose	Maintenance dose	As-needed dose	Maximum total daily inhalations
≥ 12 years	160 mcg/4.5 mcg	1 puff twice daily or once daily	1 puff as needed	2 puffs twice daily	1 inhalation as needed	12
4-11 years	80 mcg/4.5 mcg	1 puff once daily	1 puff as needed	1 puff twice daily	1 puff as needed	8

# Why SMART?

- Improves asthma control
- More effective and safer reliever than as-needed SABA
- Reduces the risk for exacerbations compared with ICS plus as needed SABA
- Onset of action of formoterol is as rapid as albuterol, but it has the added advantage of a longer duration of action

# Why SMART?

- A critical mass of data indicate that combining maintenance and rescue therapies offers better asthma control, reducing the number of exacerbations
- The SMART approach augments anti-inflammatory coverage during times of increased symptoms, when airways may be more inflamed
- Using a single inhaler for both maintenance and rescue can also improve adherence
- Eliminates medication confusion for patients who tend to mix up their two inhalers

# SMART: The Evidence

NOTE: All of the reviewed studies used the LABA-formoterol because it has a rapid onset of effect

- SMART approach using formoterol-budesonide is superior in preventing exacerbations when compared to traditional therapy with fixed dose ICS or ICS-LABA combination without any increase in adverse events
- In patients with mild asthma, as-needed ICS–formoterol reduces the risk of severe flare-ups by 60–64% compared with as-needed SABA
- SMART was associated with a 32% reduced exacerbation risk compared with the same dose of ICS-LABA maintenance therapy but with SABA as reliever and with a 23% reduced exacerbation risk compared with a higher-dose ICS-LABA maintenance plus SABA

# SMART: The Evidence

- Randomized clinical trials (RCTs) have provided level 1 evidence that in adolescents and adults with asthma, ICS/formoterol as reliever therapy reduces the risk of severe exacerbations compared with SABA reliever therapy, across the spectrum of asthma severity, when the same baseline maintenance treatment is taken
- Children randomized to very low-dose SMART (budesonide/formoterol 100/ 6 mg once daily plus for relief) had a 60% and 75% reduced risk of asthma exacerbations compared with:
  - moderate-dose ICS (budesonide 320 mg once daily) plus SABA
  - low-dose ICS/ LABA (budesonide/formoterol 100/6 mg once daily) plus SABA



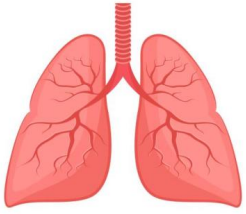


# SMART: The Evidence

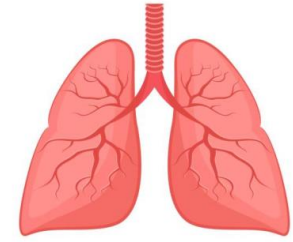
- Cochrane systematic review and meta-analysis (n = 9565), patients with mild asthma treated with as-needed ICS–formoterol had a 55% reduction in severe exacerbations and 65% lower emergency department visits or hospitalizations compared with SABA alone
- Those treated with as-needed ICS–formoterol had 37% lower risk of emergency department visits or hospitalizations than with daily ICS plus as-needed SABA

# Benefits of SMART

- SMART therapy may take away some of the confusion about which inhaler to use and when for many patients
- ICS/formoterol helps to reduce inflammation and airway constriction
- As-needed ICS/formoterol reduces fractional exhaled nitric oxide, an indirect marker of airway inflammation, thereby defining this therapeutic approach as anti-inflammatory reliever therapy
- SMART approach using formoterol-budesonide is superior in preventing exacerbations compared to traditional therapy with fixed dose ICS or ICS-LABA combination without any increase in adverse events



# Benefits of SMART



- Significantly reduces the risk for severe exacerbations
  - emergency room visit, hospitalization, or the need for systemic corticosteroids for 3 or more days compared with maintenance ICS or ICS-LABA regimens with a SABA reliever
- Provides additional anti-inflammatory treatment when asthma and airway inflammation are worsening
- Extra doses of both ICS and formoterol in SMART may contribute to a further reduction in exacerbation risk during this critical period, which may range from 1 day to several days
- Even 1 day of modestly high SABA use heralds an increased risk for an attack in coming days that is reduced if the reliever is formoterol, and it is further reduced if the reliever is budesonide-formoterol



## Barriers to SMART

1. Budesonide-formoterol is not currently approved by the FDA for use in a SMART regimen, and beclometasone-formoterol is not currently available in the United States
2. Many US insurers will cover the cost of only a 30-day supply of maintenance medication at a time
3. Cost: significant difference in the unit price of albuterol compared with ICS-formoterol formulations that may limit the uptake of SMART
4. New concept may be challenging for those relieving symptoms by albuterol



# Can budesonide-formoterol be used before exercise and replace SABA for this indication?

- Pre-exercise formoterol or budesonide-formoterol provides greater protection against exercise-induced bronchoconstriction than does pre-exercise SABA
- Pre-exercise formoterol (alone) is no longer recommended because of concern about the risks of LABA-only treatment.
- Based on available data, it would be reasonable for a patient receiving SMART who needed exercise prophylaxis to take one inhalation of their ICS-formoterol inhaler before exercise.
- ICS-formoterol is unavailable, such as in a school setting, it would be acceptable to use albuterol for pre-exercise prophylaxis

# Budesonide-formoterol Administered Before Exercise

A double blind randomized controlled trial in individuals with mild asthma found that the use of low-dose ICS-formoterol for symptom relief and before exercise reduced exercise-induced bronchoconstriction at 6 weeks to an extent similar to that with regular ICS

# What patients with asthma are candidates for SMART?

- SMART treatment should require maintenance treatment with ICS-LABA 2020 NAEP Asthma Update or GINA 2021 steps 3 or 4
- Main advantage of SMART is the reduction of severe exacerbations, with the associated reduction in potential cumulative adverse effects of oral corticosteroids
- SMART has shown to be beneficial to those with a history of asthma exacerbations
- SMART has not been tested specifically in individuals who are obese or in pregnant women
- Patients who are well controlled on current therapy and they are not having side effects, there is no need for SMART





# Will patients who use SMART reduce adherence to maintenance dosing?

In a 6-month trial of individuals with asthma and a severe exacerbation in the past year, participants randomized to SMART had fewer days without the use of ICS-LABA, or with only one dose of ICS-LABA, based on electronic inhaler monitoring

# How do we teach our patients about SMART?

High patient satisfaction and adherence with treatment are more likely to be achieved through effective communication, education, and shared decision-making

SMART provides the option of rapid symptom relief, a single medication, similar daily symptom control, reduced risk for severe exacerbations, and a lower total ICS dose

The approach to introducing SMART to a patient may differ between those who have newly received a diagnosis of asthma and those who currently use SABA as a reliever

# Can SMART be prescribed with other ICS-LABA combinations?

In patients taking maintenance treatment with ICS-LABA combinations other than ICS-formoterol (fluticasone propionate-salmeterol), the use of ICS-formoterol for quick relief is not recommended by either GINA or the 2020 NAEPP Asthma Update because of the lack of evidence for safety or efficacy with this mixture

# Is SMART safe?

- 2020 NAEPP Asthma Update advises that clinicians should inform patients that studies involving SMART have found “no difference in documented harms between this type of therapy and daily ICS-LABA.”<sup>1</sup>
- This conclusion is supported by a pooled analysis of six randomized double-blind and seven open-label clinical trials comparing SMART with budesonide and formoterol with alternative treatment options in steps 3 and 4<sup>2,3</sup> and a Cochrane review of 13 trials<sup>3,4</sup>

1. J Allergy Clin Immunol 2020;146:1217-70.

3. J Allergy Clin Immunol Pract 2022;10:S31-S8.

2. Respir Med 2009;103:1960-8.

4. Cochrane Database Syst Rev 2013;4:CD007313.

What do we do about  
an Asthma Action Plan?

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(Example of action plan template for budesonide/formoterol.

A similar action plan could be constructed for other ICS/formoterol formulations, e.g. mometasone/formoterol)

# My Asthma Action Plan

For Single Inhaler Maintenance and Reliever Therapy (SMART) with budesonide/formoterol

Name: \_\_\_\_\_ Action plan provided by: \_\_\_\_\_

Date: \_\_\_\_\_ Doctor: \_\_\_\_\_

Usual best PEF: \_\_\_\_\_ L/min Doctor's phone: \_\_\_\_\_  
(if used)

## Normal mode

### My SMART Asthma Treatment is:

- budesonide/formoterol 160/4.5 (12 years or over)
- budesonide/formoterol 80/4.5 (4-11 years)

### My Regular Treatment Every Day:

(Write in or circle the number of doses prescribed for this patient)

Take [ 1, 2 ] inhalation(s) in the morning

and [ 0, 1, 2 ] inhalation(s) in the evening, every day

### Reliever

Use 1 inhalation of budesonide/formoterol whenever needed for relief of my asthma symptoms

I should always carry my budesonide/formoterol inhaler

### My asthma is stable if:

- I can take part in normal physical activity without asthma symptoms

AND

- I do not wake up at night or in the morning because of asthma

### Other Instructions

\_\_\_\_\_  
\_\_\_\_\_

## Asthma Flare-up

### If over a Period of 2-3 Days:

- My asthma symptoms are getting worse **OR NOT** improving **OR**
- I am using more than 6 budesonide/formoterol reliever inhalations a day (if aged 12 years and older) or more than 4 inhalations a day (if 4-11 years)

### I should:

- Continue to use my regular everyday treatment **PLUS** 1 inhalation budesonide/formoterol whenever needed to relieve symptoms
- Start a course of prednisolone
- Contact my doctor

### Course of Prednisolone Tablets:

Take \_\_\_\_\_ mg prednisolone tablets per day for \_\_\_\_\_ days **OR**

\_\_\_\_\_

- If I need more than **12 budesonide/formoterol inhalations (total)** in any day, (or more than 8 inhalations for children 4-11 years) I **MUST** see my doctor or go to the hospital the same day

## Asthma Emergency

### Signs of an Asthma Emergency:

- Symptoms getting worse quickly
- Extreme difficulty breathing or speaking
- Little or no improvement from my budesonide/formoterol reliever inhalations.

If I have any of the above danger signs, I should dial \_\_\_\_\_ for an ambulance and say I am having a severe asthma attack.

### While I am waiting for the ambulance start my asthma first aid plan:

- Sit upright and stay calm
- Take 1 inhalation of budesonide/formoterol. Wait 1-3 minutes. If there is no improvement take another inhalation of budesonide/formoterol (up to a maximum of 6 inhalations on a single occasion)
- If only albuterol is available, take 4 puffs as often as needed until help arrives
- Start a course of prednisolone tablets (as directed) while waiting for the ambulance
- Even if my symptoms appear to settle quickly, I should see my doctor immediately after a serious attack

Modified from Australian action plan with permission from National Asthma Council Australia and AstraZeneca Australia

# Things to Consider

- High patient satisfaction and adherence with asthma treatment regimen are more likely to be achieved through effective communication, education, and shared decision-making
- Prescription of more than one type of inhaler (as may occur with ICS-LABA plus as-needed SABA) is associated with a lower likelihood of adherence<sup>5</sup> and a greater chance of incorrect inhaler technique.
- Willingness and likelihood of adhering to a daily maintenance treatment should be considered, because poor adherence could result in the use of SABA alone
- The provision of a written action plan improves outcomes in asthma and is recommended for all patients
- .The approach to introducing SMART to a patient may differ between those who have newly received a diagnosis of asthma and those who currently use SABA as a reliever



# SMART

SMART might not be a smart choice for everyone such as those whose symptoms are effectively managed by the conventional approach, but SMART offers a simplified approach to asthma management, has shown to reduce asthma exacerbations, medical utilization and oral prednisone requirements



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## AGES 12+ YEARS: STEPWISE APPROACH FOR MANAGEMENT OF ASTHMA

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 12+ Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6 <sup>■</sup>
Preferred	PRN SABA	Daily low-dose ICS and PRN SABA or PRN concomitant ICS and SABA <sup>▲</sup>	Daily and PRN combination low-dose ICS-formoterol <sup>▲</sup>	Daily and PRN combination medium-dose ICS-formoterol <sup>▲</sup>	Daily medium-high dose ICS-LABA + LAMA and PRN SABA <sup>▲</sup>	Daily high-dose ICS-LABA + oral systemic corticosteroids + PRN SABA
Alternative		Daily LTRA* and PRN SABA or Cromolyn,* or Nedocromil,* or Zileuton,* or Theophylline,* and PRN SABA	Daily medium-dose ICS and PRN SABA or Daily low-dose ICS-LABA, or daily low-dose ICS + LAMA, <sup>▲</sup> or daily low-dose ICS + LTRA,* and PRN SABA or Daily low-dose ICS + Theophylline* or Zileuton,* and PRN SABA	Daily medium-dose ICS-LABA or daily medium-dose ICS + LAMA, and PRN SABA <sup>▲</sup> or Daily medium-dose ICS + LTRA,* or daily medium-dose ICS + Theophylline,* or daily medium-dose ICS + Zileuton,* and PRN SABA	Daily medium-high dose ICS-LABA or daily high-dose ICS + LTRA,* and PRN SABA	
		Steps 2-4: Conditionally recommend the use of subcutaneous immunotherapy as an adjunct treatment to standard pharmacotherapy in individuals ≥ 5 years of age whose asthma is controlled at the initiation, build up, and maintenance phases of immunotherapy <sup>▲</sup>			Consider adding Asthma Biologics (e.g., anti-IgE, anti-IL5, anti-IL5R, anti-IL4/IL13)**	

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 5-11 Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
Preferred	PRN SABA	Daily low-dose ICS and PRN SABA	Daily and PRN combination low-dose ICS-formoterol ▲	Daily and PRN combination medium-dose ICS-formoterol ▲	Daily high-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA + oral systemic corticosteroid and PRN SABA
Alternative		Daily LTRA,* or Cromolyn,* or Nedocromil,* or Theophylline,* and PRN SABA	Daily medium-dose ICS and PRN SABA or Daily low-dose ICS-LABA, or daily low-dose ICS + LTRA,* or daily low-dose ICS + Theophylline,* and PRN SABA	Daily medium-dose ICS-LABA and PRN SABA or Daily medium-dose ICS + LTRA* or daily medium-dose ICS + Theophylline,* and PRN SABA	Daily high-dose ICS + LTRA* or daily high-dose ICS + Theophylline,* and PRN SABA	Daily high-dose ICS + LTRA* + oral systemic corticosteroid or daily high-dose ICS + Theophylline* + oral systemic corticosteroid, and PRN SABA
		Steps 2-4: Conditionally recommend the use of subcutaneous immunotherapy as an adjunct treatment to standard pharmacotherapy in individuals ≥ 5 years of age whose asthma is controlled at the initiation, build up, and maintenance phases of immunotherapy ▲			Consider Omalizumab** ▲	

#### Assess Control

- First check adherence, inhaler technique, environmental factors, ▲ and comorbid conditions.
- **Step up** if needed; reassess in 2-6 weeks
- **Step down** if possible (if asthma is well controlled for at least 3 consecutive months)

Consult with asthma specialist if Step 4 or higher is required. Consider consultation at Step 3.

Control assessment is a key element of asthma care. This involves both impairment and risk. Use of objective measures, self-reported control, and health care utilization are complementary and should be employed on an ongoing basis, depending on the individual's clinical situation.

**Abbreviations:** ICS, inhaled corticosteroid; LABA, long-acting beta<sub>2</sub>-agonist; LTRA, leukotriene receptor antagonist; SABA, inhaled short-acting beta<sub>2</sub>-agonist

## AGES 0-4 YEARS: STEPWISE APPROACH FOR MANAGEMENT OF ASTHMA

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 0-4 Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
<b>Preferred</b>	PRN SABA and At the start of RTI: Add short course daily ICS▲	Daily low-dose ICS and PRN SABA	Daily medium-dose ICS and PRN SABA	Daily medium-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA + oral systemic corticosteroid and PRN SABA
<b>Alternative</b>		Daily montelukast* or Cromolyn,* and PRN SABA		Daily medium-dose ICS + montelukast* and PRN SABA	Daily high-dose ICS + montelukast* and PRN SABA	Daily high-dose ICS + montelukast* + oral systemic corticosteroid and PRN SABA
			For children age 4 years only, see Step 3 and Step 4 on Management of Persistent Asthma in Individuals Ages 5-11 Years diagram.			

### Assess Control

- First check adherence, inhaler technique, environmental factors,▲ and comorbid conditions.
- **Step up** if needed; reassess in 4-6 weeks
- **Step down** if possible (if asthma is well controlled for at least 3 consecutive months)

Consult with asthma specialist if Step 3 or higher is required. Consider consultation at Step 2.

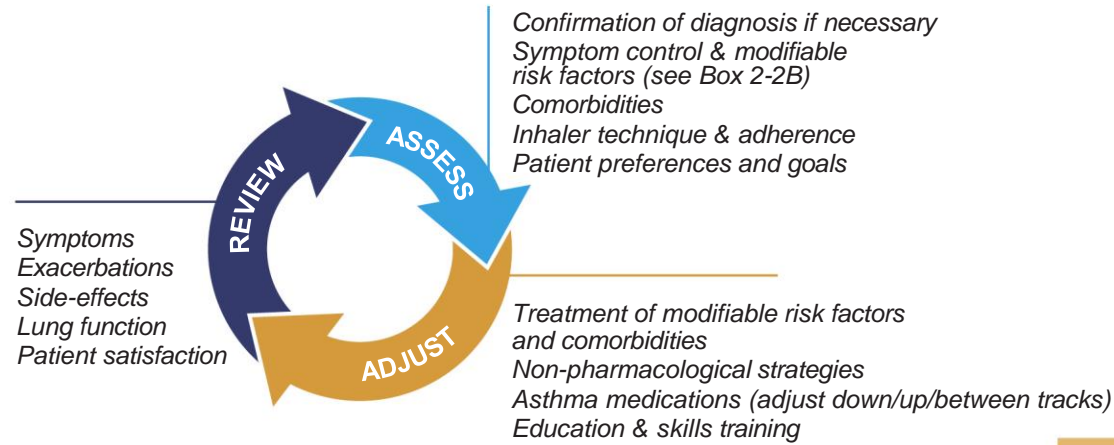
Control assessment is a key element of asthma care. This involves both impairment and risk. Use of objective measures, self-reported control, and health care utilization are complementary and should be employed on an ongoing basis, depending on the individual's clinical situation.

**Abbreviations:** ICS, inhaled corticosteroid; LABA, long-acting beta<sub>2</sub>-agonist; SABA, inhaled short-acting beta<sub>2</sub>-agonist; RTI, respiratory tract infection; PRN, as needed

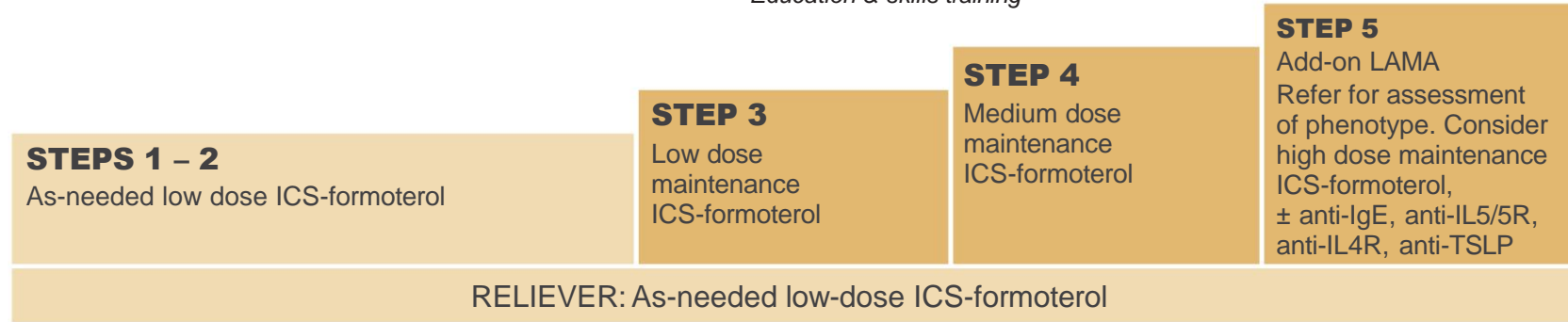
# Adults & adolescents 12+ years

## Personalized asthma management

Assess, Adjust, Review  
for individual patient needs

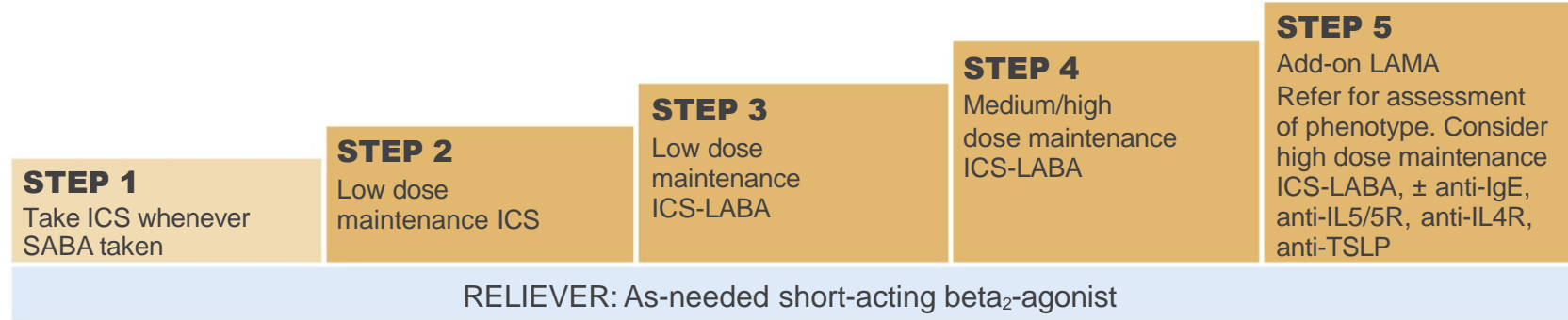


**CONTROLLER** and **PREFERRED RELIEVER** (Track 1). Using ICS-formoterol as reliever reduces the risk of exacerbations compared with using a SABA reliever



See GINA severe asthma guide

**CONTROLLER** and **ALTERNATIVE RELIEVER** (Track 2). Before considering a regimen with SABA reliever, check if the patient is likely to be adherent with daily controller



Other controller options for either track (limited indications, or less evidence for efficacy or safety)

	Low dose ICS whenever SABA taken, or daily LTRA, or add HDM SLIT	Medium dose ICS, or add LTRA, or add HDM SLIT	Add LAMA or LTRA or HDM SLIT, or switch to high dose ICS	Add azithromycin (adults) or LTRA. As last resort consider adding low dose OCS but consider side-effects
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Box 3-5B

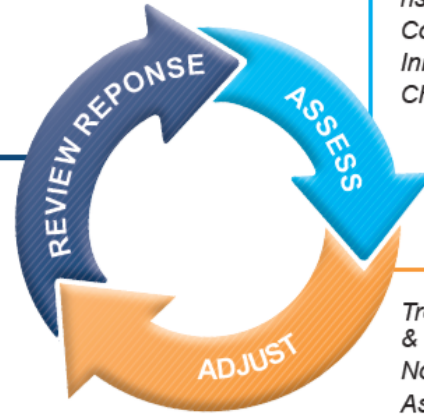
## Children 6-11 years

GINA 2023

### Personalized asthma management:

Assess, Adjust, Review response

Symptoms  
Exacerbations  
Side-effects  
Lung function  
Child and parent satisfaction



Confirmation of diagnosis if necessary  
Symptom control & modifiable risk factors (including lung function)  
Comorbidities  
Inhaler technique & adherence  
Child and parent preferences and goals

Treatment of modifiable risk factors & comorbidities  
Non-pharmacological strategies  
Asthma medications (adjust down or up)  
Education & skills training

### Asthma medication options:

Adjust treatment up and down for individual child's needs

#### PREFERRED CONTROLLER

to prevent exacerbations and control symptoms

Other controller options

#### RELIEVER

	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
<b>PREFERRED CONTROLLER</b>		Daily low dose inhaled corticosteroid (ICS) (see table of ICS dose ranges for children)	Low dose ICS-LABA or medium dose ICS	Medium dose ICS-LABA Refer for expert advice	Refer for phenotypic assessment ± add-on therapy, e.g. anti-IgE
<b>Other controller options</b>	Low dose ICS taken whenever SABA taken*; or daily low dose ICS	Daily leukotriene receptor antagonist (LTRA), or low dose ICS taken whenever SABA taken*	Low dose ICS + LTRA	High dose ICS-LABA, or add-on tiotropium, or add-on LTRA	Add-on anti-IL5, or add-on low dose OCS, but consider side-effects
<b>RELIEVER</b>	As-needed short-acting β <sub>2</sub> -agonist (SABA)				

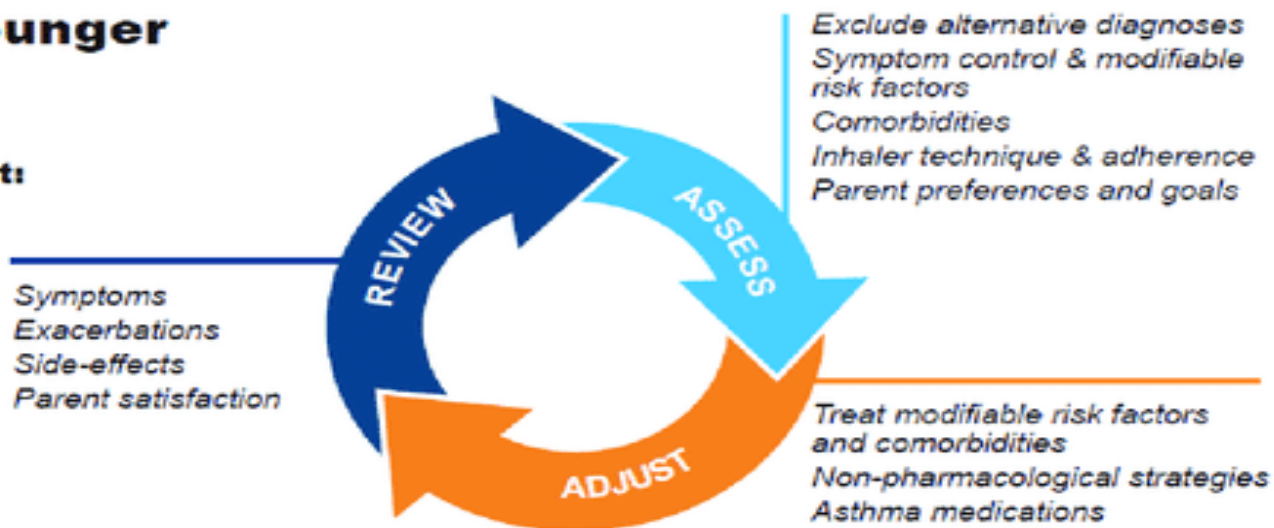
\* Separate ICS and SABA inhalers



## Children 5 years and younger

### Personalized asthma management:

Assess, Adjust, Review response



### Asthma medication options:

Adjust treatment up and down for individual child's needs

#### PREFERRED CONTROLLER CHOICE

	STEP 1	STEP 2	STEP 3	STEP 4
		Daily low dose inhaled corticosteroid (ICS) (see table of ICS dose ranges for pre-school children)	Double 'low dose' ICS	Continue controller & refer for specialist assessment
<i>Other controller options</i>		<i>Daily leukotriene receptor antagonist (LTRA), or intermittent short courses of ICS at onset of respiratory illness</i>	<i>Low dose ICS + LTRA Consider specialist referral</i>	<i>Add LTRA, or increase ICS frequency, or add intermittent ICS</i>

#### RELIEVER

*As-needed short-acting  $\beta_2$ -agonist*

#### CONSIDER THIS STEP FOR CHILDREN WITH:

Infrequent viral wheezing and no or few interval symptoms	Symptom pattern not consistent with asthma but wheezing episodes requiring SABA occur frequently, e.g. $\geq 3$ per year. Give diagnostic trial for 3 months. Consider specialist referral.	Asthma diagnosis, and asthma not well-controlled on low dose ICS	Asthma not well-controlled on double ICS
	Symptom pattern consistent with asthma, and asthma symptoms not well-controlled or $\geq 3$ exacerbations per year.	Before stepping up, check for alternative diagnosis, check inhaler skills, review adherence and exposures	