



# ROC Breathes Easy Asthma Initiative















ROC Breathes Easy Asthma Initiative

## Community Guidance Deliver a Combination Punch to Asthma!

July 2025

## Relief + Control = The combination punch asthma can't handle!

### Short-Acting Beta-Agonist (SABA) Stewardship:1

- Address SABA over-reliance leading to associated harms.
- Recognize the need to move away from episodic symptom relief with acute management and to embrace a chronic disease model.

SABA reliever monotherapy (albuterol by itself) does not address underlying airway inflammation and should be avoided for the majority of patients with asthma.<sup>2</sup>

Numerous studies show that over-reliance on SABA is associated with increased morbidity and mortality due to asthma, particularly in our most vulnerable patients.<sup>3,4,5</sup> Chronic airway inflammation, a defining characteristic of asthma, is the underlying etiology leading to asthma symptoms, exacerbations requiring systemic steroids, and impaired lung function. Underlying airway inflammation should not be left untreated for any patient with asthma,<sup>6</sup> and most children with asthma should initiate treatment with an inhaled preventive medication at the time of initial asthma diagnosis. All patients, regardless of race/ethnicity, should have their treatment optimized, with the goal of being symptom-free.

For children 6 years of age and older with symptomatic asthma, a <u>single combination</u> <u>inhaler</u> (consisting of an anti-inflammatory inhaled corticosteroid and reliever medication) should be considered as first-line therapy for <u>both</u> rescue and prevention. Studies show that this approach decreases exacerbation risk while minimizing use of medication.<sup>7,8</sup>

For children 6 years of age and older who are symptomatic, the familiar two-inhaler management approach [SABA reliever monotherapy and a separate anti-inflammatory controller] should be avoided, when possible. Children under the age of 6 may utilize an inhaled corticosteroid in conjunction with a separate SABA reliever medication.<sup>9</sup>

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### Oral Corticosteroid (OCS) or Systemic Steroid Stewardship:10,11

- It is time to protect patients with asthma from potential overexposure to oral corticosteroids (OCS) and to recognize OCS overuse for what it often is: a treatment plan failure.
- OCS use is a signal that a patient may need an updated treatment plan or support with adherence concerns.
- OCS or systemic steroid use should not be confused with inhaled corticosteroids (ICS),
   which have fewer risks.

	OCS/Systemic Steroid Health Risks: 10,12,13,14								
Sh	ort Term	Lo	Long Term						
0	Problems with mood, stress, memory and behavior	0	Growth suppression						
0	Sleep disturbance	0	Increase risk of diabetes						
0	Weight gain	0	Glaucoma/Cataracts						
0	Hyperglycemia	0	Hypertension						
0	Gastroesophageal reflux	0	Adrenal Suppression						
0	Thromboembolism	0	Osteoporosis						
0	Infection / Increased risk for Sepsis	0	Dyslipidemia						
		0	Immunosuppression						

#### **Collaborative Recommendations to Curb Overexposure:**

- 1. Educating patients and their caregivers about (1) the risks associated with OCS; (2) the importance of adherence to other asthma medicines; and (3) advanced treatment options. (4) discuss the importance of completing the full prescribed OCS course when appropriate and necessary.
- 2. Supporting healthcare providers (allergists, pulmonologists, and primary care) to develop and adopt OCS–sparing strategies and practice shared decision-making.
- 3. Petitioning payers to adopt OCS-sparing strategies by providing appropriate and timely access to conventional and advanced treatment options based on clinical judgement of the treating HCP in consultation with the patient.

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## **Community Guidance**

July 2025

Management Pathway for ALL Patients with Asthma ≥ 6 Years
Transition to Single Inhaler Management Upon Earliest Opportunity to Treat

Adapted from 2025 GINA Guidelines

#### Asthma treatment is not 'set and forget', and not just medications

Symptoms

Exacerbations

Side-effects

Comorbidities

Lung function

Consider biomarkers

Patient (and parent/caregiver) satisfaction



Confirmation of diagnosis if necessary

Symptom control & modifiable risk factors

Comorbidities

Inhaler technique & adherence

Patient (and parent/caregiver) preferences and goals

Treatment of modifiable risk factors and comorbidities

Non-pharmacological strategies

Asthma medications including ICS

Education & skills training, action plan

#### 1. Primary Care Asthma Follow-Up for ≥ 6 Years of Age:

#### Confirm Asthma Diagnosis [when necessary and/or if possible]

• Children ≥ 6 years of age should strongly be considered for lung function testing (spirometry, exhaled nitric oxide) as objective measures of asthma have been shown to increase diagnostic accuracy.

<u>Include Routine Impairment/Risk Assessment</u> during Visits with the Patient OR as Pre-Visit Screening Tool [Includes Post-Exacerbation Recovery Evaluation, when needed]

How Are Asthma Symptoms? Please select YES or NO for each question.		Well Controlled	Partly Controlled	Uncontrolled
IMPAIRMENT/SYMPTOMS In the past 4 WEEKS, have you/your child had:		NONE of these	1-2 of these	3-5 of these
Daytime asthma symptoms more than twice a week?	Yes □ No□	No change or	Consider	
ANY night waking due to asthma?	Yes □ No□	consider step down: lower	stepping up, after review	stepping up [1-2 steps],
SABA# reliever for symptoms more than twice a week?	Yes □ No□	daily ICS dose, but caution with	and assess*	after review
ANY activity limitation due to asthma?	Yes □ No□	stopping ICS		and assess
RISK		altogether		
In the past YEAR, have you/your child had:				
ANY flare-up or exacerbation requiring oral/systemic steroids, ED visit, OR hospitalization?	Yes □ No□			

<sup>\*</sup>BEFORE stepping-up, REVIEW inhaler (spacer) TECHNIQUE and ADHERENCE. CONFIRM diagnosis.

ASSESS: Modifiable risk factors and comorbidities. SHARED decision-making regarding PREFERENCES/GOALS.

<sup>\*</sup>Only for patients using SABA reliever (not ICS-formoterol reliever). Do not include SABA taken before exercise.

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## **Community Guidance**

Management Pathway for ALL Patients with Asthma ≥ 6 Years
Transition to Single Inhaler Management Upon Earliest Opportunity to Treat

Adapted from 2025 GINA Guidelines

#### **1a.** Urgent Care/ED/Acute Encounter for Exacerbation/Flare-up for ≥ 6 Years of Age:

#### [POSSIBLE INITIAL TOUCHPOINT: May occur BEFORE Primary Care Asthma Follow-Up]

May require treatment with nebulized albuterol, OCS, etc. in acute setting

#### Treatment (minimum) Before Acute Discharge:

- REPLACE SABA with PRN Anti-Inflammatory Reliever (AIR) therapy, a reliever inhaler that contains both a low-dose ICS and a rapid-onset long-acting bronchodilator (see Appendix for prescribing examples)
  - Prescribe/Refill PRN ICS-formoterol 80-4.5 mcg [Symbicort® or Breyna®]
  - o ICS-formoterol also be taken every 12 hours post-exacerbation until primary care follow-up occurs.
    - Maximum Daily Dose:
      - 8 puffs/24 hours for children 6-11
      - 12 puffs/24 hours for 12 years of age and older
- Prescribe/dispense spacer/holding chamber
- Follow-Up Plan [from Acute Care Setting]:
  - Schedule a post-exacerbation follow-up and preventive asthma care review/update appointment for within 1-2 working days (children) and within 2-7 days (adults), whenever possible

\*Currently working with insurance to improve availability/dose and quantity limits. At times this may require a PA or review the plans formulary.

#### 2. RISK Factor Screen/Assessment [Required Post-Exacerbation] for ≥ 6 Years of Age:

Document Aspects of Future Risk, Include Modifiable Factors to Guide Preventive Interventions and Management

- Factors [examples] that increase RISK of exacerbations even if patient has FEW asthma symptoms:
  - o **SABA over-use:** ≥3 x 200 dose canisters/year; ≥1 canister/month
  - o Inadequate ICS: No ICS: poor adherence/inhaler technique
  - o **Environmental exposures:** Smoke; air pollution; allergens (if sensitized)
  - Poverty status: Economic instability; public (or no) health insurance; substandard housing
  - o Exacerbation history: Severe flare-up in prior year; ever intubated or in ICU for asthma
- Address MODIFIABLE Factors [include/document steps taken]
- Assess and Manage Comorbidities
- Consider Referral to an Asthma Specialist

#### 3. Preventive Asthma Care Review: Update/Adjust Management Plan for ≥ 6 Years of Age:

- For ALL Patients with RISK OR requiring STEP 3 or 4 care:
  - Strongly consider updating management to (Single) Maintenance And Reliever Therapy [(S)MART] approach
  - Recommend referral to an Asthma Specialist
- For ALL others (those Well Controlled<sup>6</sup> AND NOT at RISK), consider transition to <u>Single Inhaler PRN Anti-Inflammatory Reliever [AIR]</u> therapy [see Appendix for prescribing examples and <u>1a. Acute Encounter for Exacerbation</u>, above]
- Discontinue PRN SABA [albuterol] whenever possible for patients transitioned to AIR or (S)MART approach
- Update Asthma Action Plan for distribution to patient/family/school and/or daycare.

#### **Appendix: GINA References<sup>6</sup> and Supporting Materials for ≥6 Years of Age**

#### **Examples of (S)MART and AIR Recommended Products**













Age	Inhaled Medication Unit Dose	Step (Dose)	Schedule and Frequency	Maximum Daily Dose#	
6-11	budesonide-formoterol 80/4.5 mcg [Symbicort® HFA or Breyna® HFA]	Step 3 (Low)	(S)MART: 1 inhalation ONCE daily plus 1 as needed	8 inhalations	
years		Step 4 (Medium)	(S)MART: 1 inhalation TWICE daily plus 1 as needed	in 24 hours	
	budesonide-formoterol 160/4.5 mcg [Symbicort® HFA or Breyna® HFA]	Steps 1-2	AIR-only: 1 inhalation as needed	12 inhalations in 24 hours	
≥12 years		Step 3 (Low)	(S)MART: 1 inhalation TWICE (or ONCE) daily plus 1 as needed		
		Steps 4-5 (Medium)	(S)MART: 2 inhalations TWICE daily plus 1 as needed		
≥18	beclometasone-formoterol 100/5 mcg [Dulera® HFA]	Steps 1-2	AIR-only: 1 inhalation as needed	12 inhalations in 24 hours	
years		Step 3 (Low)	(S)MART: 1 inhalation TWICE (or ONCE) daily plus 1 as needed		
		Steps 4-5 (Medium)	(S)MART: 2 inhalations TWICE daily plus 1 as needed		

#### **Recommended Prescription Language**<sup>6</sup>

#### **Examples of (S)MART budesonide-formoterol medication prescription language:**

For ≥ 12 years: "Inhale 2 puffs using spacer TWICE daily [MORNING and EVENING]; May also inhale 1 puff as NEEDED for symptom relief [Maximum: 12 puffs/24hrs]; Shake well before, rinse mouth after use"

For 6-11 years: "Inhale 1 puff using spacer TWICE daily [MORNING and EVENING]; May also inhale 1 puff as NEEDED for symptom relief [Maximum: 8 puffs/24hrs]; Shake well before, rinse mouth after use"

#### **Notes to pharmacy:**

- Initial TWO inhalers for 30 DAY supply, home/school daily+PRN use. Symbicort or Breyna per insurance. (S)MART per GINA, <a href="https://bit.ly/3WirMe9">https://bit.ly/3WirMe9</a>
- For refills, home/school daily+PRN use. Symbicort or Breyna per insurance. (S)MART per GINA, https://bit.ly/3WirMe9

#### **Example of PRN Anti-Inflammatory Reliever [AIR] therapy (ICS-formoterol) prescription language:**

For ≥ 12 years: "Inhale 1 puff using spacer as NEEDED for symptom relief [Maximum: 12 puffs/24hrs]; Shake well before, rinse mouth after use"

#### **Examples of School Medication Order Language:**15

## PRN component of (S)MART approach or PRN Anti-Inflammatory Reliever [AIR] therapy (same for both) with budesonide-formoterol:

For ≥ 12 years: "Inhale 1 puff using spacer as NEEDED for persistent symptoms, may administer up to 2 inhalations every 20 minutes for 3 doses, the need for more frequent dosing suggest an incomplete response and may require further medical attention, [Maximum: 12 puffs/24hrs]; Shake well before, rinse mouth after use"

#### PRN component of (S)MART approach with budesonide-formoterol:

For 6-11 years: "Inhale 1 puff using spacer as NEEDED for persistent symptoms, may administer up to 2 inhalations every 20 minutes for 3 doses, the need for more frequent dosing suggest an incomplete response and may require further medical attention, [Maximum: 8 puffs/24hrs]; Shake well before, rinse mouth after use"

#### **Select References:**

NAEPP 2020 Focused Updates to the Asthma Management Guidelines

2025 Global Initiative for Asthma Strategy for Management and Prevention

Asthma Disparities in America, 2020: a Roadmap to Reduce Burden on Racial and Ethnic Minorities

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- <sup>2</sup> Reddel HK, et al. <u>GINA 2019</u>: a fundamental change in asthma management: <u>Treatment of asthma with short-acting</u> bronchodilators alone is no longer recommended for adults and adolescents. Eur Respir J. 2019 Jun 27;53(6):1901046.
- <sup>3</sup> Nwaru BI, et al. Overuse of short-acting  $\beta_2$ -agonists in asthma is associated with increased risk of exacerbation and mortality: a nationwide cohort study of the global SABINA programme. Eur Respir J. 2020 Apr 16;55(4):1901872.
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- <sup>5</sup> Rayner DG, Ferri DM, Guyatt GH, et al. <u>Inhaled Reliever Therapies for Asthma: A Systematic Review and Meta-Analysis.</u> JAMA. 2025;333(2):143-152.
- <sup>6</sup> Global Initiative for Asthma. Global Strategy for Management and Prevention, 2025.
- <sup>7</sup> Krings JG, Gerald JK, Blake KV, et al. <u>A Call for the United States to Accelerate the Implementation of Reliever Combination Inhaled Corticosteroid-Formoterol Inhalers in Asthma.</u> Am J Respir Crit Care Med. 2023 Feb 15;207(4):390-405.
- <sup>8</sup> Jonkers RE, Bantje TA, Aalbers R. <u>Onset of relief of dyspnoea with budesonide/formoterol or salbutamol following methacholine-induced severe bronchoconstriction in adults with asthma: a double-blind, placebo-controlled study.</u> Respir Res. 2006;7(1):141.
- <sup>9</sup> 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group.
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- <sup>11</sup> Patrawala S, Ramsey A, Mustafa SS. <u>Steroid stewardship in allergy/immunology: An opportunity for improved clinical outcomes</u>. Ann Allergy Asthma Immunol. 2025 Feb;134(2):133-134.
- <sup>12</sup> Global Initiative for Asthma. <u>Summary Guide for Asthma Management and Prevention</u>, 2024.
- <sup>13</sup> Waljee AK, Rogers MA, Lin P, Singal AG, Stein JD, Marks RM, Ayanian JZ, Nallamothu BK. <u>Short term use of oral corticosteroids and related harms among adults in the United States: population based cohort study.</u> BMJ. 2017 Apr 12;357:j1415.
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- <sup>15</sup> <u>Usual dosing of anti-inflammatory reliever (AIR) therapy in adolescents and adults.</u> Retrieved from <u>UpToDate</u>, 5/22/2025.