Identifying and Addressing the Hidden Risks of Mild Asthma

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doi:10.12788/fp.0638

KEY TAKEAWAYS

- Contrary to common perceptions, mild asthma is associated with a substantial disease burden in the form of severe exacerbations, steroid exposure, and healthcare system costs.
- While patients and clinicians may refer to asthma as being mild, the lack of a clinically useful definition causes confusion and misperceptions about disease morbidity, disease severity, and appropriate management.
- Diagnosing mild asthma is often challenging, but by focusing on objective criteria, clinicians can improve the accuracy of an asthma diagnosis.
- Managing patients with mild asthma is complex, as disease severity can fluctuate over time and seasonally, due to triggers that increase inflammation, worsen symptoms and control, and lead to exacerbations.
- New treatment paradigms for mild asthma, including intermittent and mild persistent disease, emphasize the use of inhaled corticosteroid (ICS)-containing rescue therapy regimens and avoidance of short-acting beta$_2$-agonist (SABA)-only rescue regimens.
- Use of SABA-only as rescue with maintenance ICS is a treatment option for patients with mild asthma but may not be the optimal choice, as considerable evidence exists that adherence is very poor in people with intermittent symptoms.

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ACKNOWLEDGMENT

Editorial support was provided by Austin Ulrich, PharmD, BCACP at Primary Care Education Consortium.

DISCLOSURES

Dr. Falk serves as a member of the speakers bureau of AstraZeneca. Dr. Wright serves as consultant and a member of the speakers bureau of AstraZeneca.

SUPPORT

This activity is sponsored by Primary Care Education Consortium and Primary Care Respiratory Group and is funded by a grant from AstraZeneca.

INTRODUCTION

Asthma is a chronic, heterogeneous disease with substantial national and global impact. The Global Initiative for Asthma (GINA) classifies asthma severities into mild, moderate, and severe disease categories, based on a retrospective definition—the treatment that is required to achieve optimal asthma control and reduce/prevent exacerbations.[1,2] Although the stepwise treatment approach advocated in the GINA report (updated annually) and the National Asthma Education and Prevention Program (NAEPP; last updated in 2020) may suggest clear demarcations between asthma severities, in clinical practice there is often overlap between symptoms and manifestations.[2,3] Notably, NAEPP classifications also include lung function and risk domains, beyond symptoms and impairment.[3] Unlike GINA, NAEPP further subdivides mild asthma into intermittent and mild persistent categories.[1,3] Mild asthma may be viewed by patients and clinicians as a low-risk disease with low symptom burden; however, evidence suggests a wide heterogeneity in outcomes and symptoms.[4] While many individuals with mild asthma are not constantly affected by their disease, certain characteristics increase the risk of adverse outcomes (**TABLE**).[2] Additionally, exacerbations are unpredictable and can even be fatal.

Despite the substantial impact of mild asthma, present definitions are limited in their clinical usefulness.[2] Furthermore, the approach to treating mild asthma has changed significantly in recent years. Current evidence-based approaches to treatment of mild asthma incorporate certain fundamental principles, such as[2]:

- Avoiding short-acting beta$_2$-agonist (SABA)-only rescue therapy and initiating therapy with an anti-inflammatory rescue (or anti-inflammatory reliever) instead
- Assessing asthma symptoms and future risk of exacerbations as 2 separate domains to guide treatment[5]

Mild asthma is of particular importance to primary care practitioners (PCPs), as most patients with mild asthma are managed in primary care settings—up to 90% of patients with asthma seen in community or primary care settings have mild or moderate asthma.[2] Recent data indicate that high symptom burden and exposure to systemic corticosteroids (SCS) are also characteristics of patients treated for mild-to-moderate asthma, not only those with severe asthma.[6] Patients with mild asthma are rarely referred to specialists;

TABLE. Factors associated with increased risk of adverse outcomes in mild asthma.[2]

Factor	Outcome
Previous or current higher treatment requirements for adequate control	Increased exacerbations
Comorbid diagnosis of COPD	Increased exacerbations Reduced quality of life
Low eosinophil count	Suboptimal response to ICS
Current smoking	Poor response to ICS Increased exacerbation risk Increased risk of lung function decline
Female	Increased exacerbations Premenstrual exacerbations Postmenopausal persistence
Obesity (BMI >30 kg/m^2)	Greater risk of persistence
Comorbidities, especially allergic rhinitis, gastroesophageal reflux, or depression	Worse symptom control
Socioeconomic determinants of health	More frequent exacerbations Avoidable but frequent courses of systemic steroids
Older age (adults)	Underrecognized disease severity Undertreatment Worse airflow limitation Poor reversibility
Inappropriate use of SABA: • >2 puffs/wk in the absence of ICS use in the first year of asthma diagnosis • 9 or more canisters of SABA per year, <100 µg of ICS daily in a maintenance regimen during the year	Progression of disease to higher treatment requirements More frequent exacerbations
Undertreatment with anti-inflammatory medications	More persistent symptoms and airflow limitation More frequent exacerbations
Recurrent wheezing or abnormal lung function early in life	More persistent airflow limitation
Occupational exposures	Worse asthma control More persistent disease
Psychosocial factors, anxiety, and depression	Worse asthma control

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; SABA, short-acting beta$_2$-agonist.

therefore, PCPs are uniquely positioned to have a significant impact on reducing morbidity and adverse health outcomes related to mild asthma.

THE MISNOMER OF "MILD ASTHMA"

Even after decades of asthma research, there is no widely accepted or uniformly applied definition for mild asthma, leading to limited utility of this term in clinical settings.[1,2,5,7] GINA recommends that the term "mild asthma" should usually be avoided in clinical practice—or if it is used, it should be accompanied with a caution that infrequent symptoms can still result in serious health outcomes, including death.[1,2] In community and primary care settings, the designation of mild asthma often refers to the frequency or severity of symptoms or exacerbations—if patients do not have daily symptoms or if symptoms are quickly relieved.[1] In clinical trials and epidemiologic studies, mild asthma is designated based on the prescribed treatment, rather than the level of asthma control. This approach assumes that the treatment was appropriate for the patient's needs, but asthma is often under-treated or over-treated.[1] The NAEPP guidelines assign mild asthma severity based on symptoms and the frequency of SABA use and delineate "mild persistent" and "intermittent" asthma, but this historical distinction was arbitrary and not evidence based.[1,3] Since NAEPP guidelines have not been updated since 2020, discussion and recommendations in this article will be focused on the GINA report, which is updated annually.

Patients may perceive their asthma as mild if their symptoms are infrequent or easily relieved by SABA; patients often interpret "mild asthma" as meaning that there is a low risk of severe exacerbations and that inhaled corticosteroids (ICS) are not necessary for disease management.[1] As a retrospective definition aligned with GINA, asthma could be classified as mild only after several months of ICS-containing treatment and only if asthma is well controlled on low-dose ICS or as-needed ICS with a rapid-acting bronchodilator. The definition could not be applied to those with partially controlled or uncontrolled symptoms taking SABA only.[1]

It has now been well established that patients with occasional or "intermittent" asthma symptoms can have severe or fatal exacerbations, and that the risk is substantially reduced by ICS-containing treatment compared with SABA alone.[1,8,9] Up to 30% of asthma exacerbations and deaths occur in people with infrequent symptoms, including patients with symptoms that occur less than weekly or only with strenuous exercise.[1] The most urgent problem with the term "mild asthma," regardless of how it is defined, is that it encourages complacency, since both patients and clinicians often interpret "mild asthma" to mean that the patient is at low risk and does not need ICS-containing treatment.[1]

CASE STUDY

A 59-year-old woman presents to her primary care clinic for an asthma follow-up visit. She is treated with SABA-only rescue therapy and has a diagnosis of mild asthma. She has had several exacerbations over the past 5 years, requiring oral corticosteroids and/or a visit to the emergency department, based on clinical records. When asked about her asthma control, the patient responds that most days she doesn't even know she has asthma, but she uses her rescue inhaler about twice a month on "really bad days," usually after visiting her company's manufacturing plant. She says she knows that her disease is mild, so she doesn't see a need to change anything and asks for a refill of her SABA inhaler. Her disease control, as reflected by current symptom impairment and risk from prior-year exacerbation history, is assessed with the Asthma Impairment and Risk Questionnaire (AIRQ [www.airqscore.com])[10,11] and she scores a 2 (not well controlled).

This patient is at risk for severe exacerbations and adverse asthma outcomes, even though her symptoms do not occur often. She has several factors that increase her risk of worse outcomes, including the use of SABA-only rescue therapy with no anti-inflammatory treatment, an AIRQ score of 2, and previous need for SCS.[12,13] She has received 3 courses of SCS for 3 exacerbations in the past 5 years, which represents a cumulative SCS exposure that increases her risk of steroid-associated adverse effects.[10,14] The patient's perspective of her disease seems to indicate a lack of understanding that she is at risk for severe exacerbations. The PCP should consider discussing an asthma action plan to educate the patient about the risks of SABA-only therapy, and the need for and benefits of ICS inclusion in her rescue treatment.[12]

DISEASE BURDEN OF MILD ASTHMA

Although most patients with asthma may be considered to have "mild" disease, less emphasis has historically been placed on disease burden for this population.[7,15] In recent years, multiple studies have demonstrated the significant disease burden of mild asthma, which is often in contrast to common perspectives of clinicians and patients.[7,15,16] Mild asthma is the most common form of asthma and can lead to severe exacerbations—up to 40% of exacerbations requiring emergency care are patients with mild asthma.[17] Additionally, 15% to 20% of fatal asthma attacks occur in patients reporting symptoms less than weekly or only with exertion in the previous 3 months.[18]

A high proportion of patients with mild asthma (50% to 65%) experience exacerbation events, and increasing SABA refills are associated with increases in total exacerbations and asthma-related costs of care.[8,19] Based on population-level data in the United States, about one-third of patients treated for mild-to-moderate asthma have claims for ≥2 SCS courses and/or ≥3 SABA refills per year.[6] This illustrates that a high proportion of those with mild or moderate asthma have uncontrolled disease.[4] Notably, in this US-based data, including approximately 4.5 million patients, 85.6% were treated for mild or moderate disease. Of the study population, 80.9% of all uncontrolled asthma observed was in patients presumed to have less severe disease.[6]

Regardless of the high burden of uncontrolled asthma in patients with less severe disease (ie, mild asthma), many patients with asthma have historically been and currently are prescribed SABA-only rescue therapy.[9,19] This results in a high burden of disease, risk of exacerbation, and risk of asthma-related mortality. An estimated 10% of patients with mild asthma transition to more severe disease over 10 years; older age at onset and inappropriate use of rescue medications are associated with higher likelihood of severe disease.[20]

While SCS can be used to treat asthma exacerbations, even occasional use of SCS leads to short- and long-term adverse effects from cumulative exposure. Adverse effects resulting from short-term (<30 day) SCS use include increases in risk of venous thromboembolism, fracture, and sepsis.[21] Higher lifetime cumulative doses of SCS (starting at 0.5 g of prednisone or equivalent, with a clear risk threshold of 1 g of prednisone or equivalent) may contribute to increases in cardiovascular disease, cerebrovascular disease, osteoporosis, pneumonia, type 2 diabetes, renal impairment, cataracts, weight gain, sleep apnea, anxiety, and depression.[14,22] In contrast, the addition of ICS to rescue therapy regimens is unlikely to be associated with the risks of systemic steroid exposure.[23]

ASSESSING AND DIAGNOSING MILD ASTHMA

Regardless of the lack of clarity in defining mild asthma, the heterogeneity of symptoms, the risk of adverse outcomes, and differing perspectives on the management of mild asthma, patients with less severe disease and/or occasional symptoms still need optimal, evidence-based care. Assessing and diagnosing patients with less severe disease can be particularly difficult due to these factors.[1,5]

Clinical diagnoses of asthma alone may be inadequate, highlighting the importance of spirometry in assessing and diagnosing asthma.[24] However, patients with less severe disease or occasional symptoms may not be experiencing symptoms when tests like spirometry are administered, which can result in normal results. Recently, the American Thoracic Society (ATS) produced updated guidance regarding the use of spirometry to diagnose asthma. Notably, spirometry does not need to demonstrate 12% reversibility for an asthma diagnosis, as previously recommended. Rather, bronchodilator responsiveness testing is recommended to determine whether there is any change in spirometric lung function

in response to bronchodilators.[25] A reasonable response (based on clinical judgment) to bronchodilators should still be observed to support an asthma diagnosis, in careful consideration with other clinical factors. Additionally, clinicians should be aware of and seek to minimize disparities in spirometry testing; specifically, members of minority groups (especially Black patients) are more likely to be underdiagnosed.[26-28] In addition to traditional spirometric criteria for asthma diagnosis (increase in forced expiratory volume in 1 second of ≥12% and ≥200 mL from baseline after bronchodilator administration), GINA now also recommends a trial of ICS treatment if there is a strong suspicion of asthma despite no evidence of variable airflow obstruction and other diagnoses are unlikely.[1]

Practical tips for accurately diagnosing mild asthma in primary care include:

- Complete a comprehensive history and physical examination
- Perform spirometry (note limitations as discussed above)
- Conduct additional testing as needed to rule out differential diagnoses
    - Fractional exhaled nitric oxide
    - Referral for exercise spirometry
    - Referral for methacholine or other challenge testing

Prioritizing the objective diagnosis of asthma will help to increase accuracy of the diagnosis and ensure patients receive appropriate treatment.

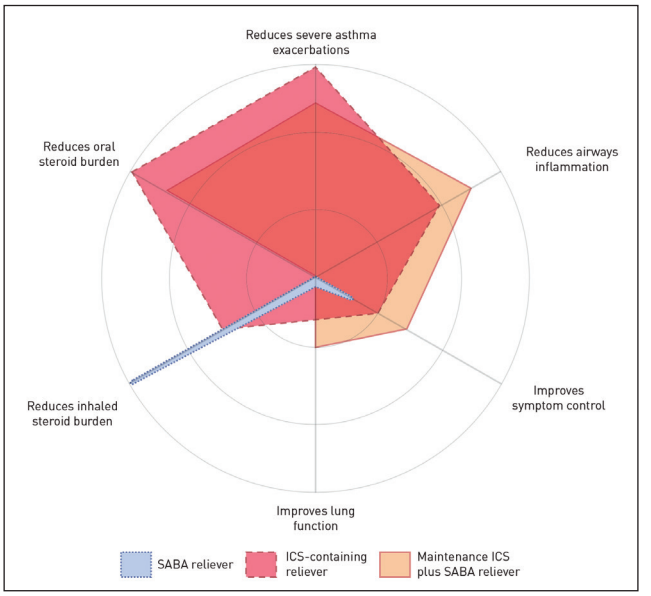
HOW TO TREAT MILD ASTHMA—ADOPTING THE NEW TREATMENT PARADIGM

With increasing evidence that SABA-only treatment is associated with worse asthma outcomes, new treatment paradigms for rescue therapy that include ICS are warranted, and these approaches are becoming widely recommended.[1,8] However, implementing this in clinical practice will require continued patient and clinician education. GINA has recommended against SABA-only rescue therapy in asthma for several years, and the European Respiratory Society guidelines also recommend against SABA-only rescue therapy.[1,29] The most recent (2020) NAEPP guidelines offer SABA-only rescue therapy as an option, although this recommendation was based on limited data available at the time.[3] NAEPP does offer an equal preference for as-needed concomitant ICS-SABA vs daily low-dose ICS with as-needed SABA as Step 2 treatment.[3] Additionally, recent studies have confirmed the risks of SABA-only rescue therapy and the benefits of adding ICS.[30,31] A conceptual comparison of the benefits of 3 treatment options for mild asthma highlights the limitations of SABA-only rescue therapy and supports the use of ICS-based regimens (**FIGURE 1**).[32]

Many patients (up to 70% with intermittent/mild-persistent asthma) in the United States refill SABA-only prescriptions without ICS.[33] Alternatives for clinicians and patients, according to product labeling, include the use of 2 separate inhalers (ICS and SABA) taken together for a rescue dose, or a SABA-ICS combination (albuterol-budesonide), which was approved by the US Food and Drug Administration (FDA) in 2023 for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma who are 18 years of age and older.[34] Prescribing SABA as a rescue option in the absence of concurrent use of a daily ICS inhaler for patients with intermittent or mild symptoms can be risky because these individuals are unlikely to be adherent to daily ICS.[33] Such patients are at increased exacerbation risk if SABA-only rescue therapy is all that they are using, especially when increasing airway inflammation is triggering symptoms and need for a rescue therapy.

The GINA report recommends including ICS in rescue regimens for patients with mild asthma, based on current evidence.[1] For patients with a new diagnosis of asthma who

FIGURE 1. Conceptual comparison of the relative benefits of 3 treatment regimens for asthma.[32]



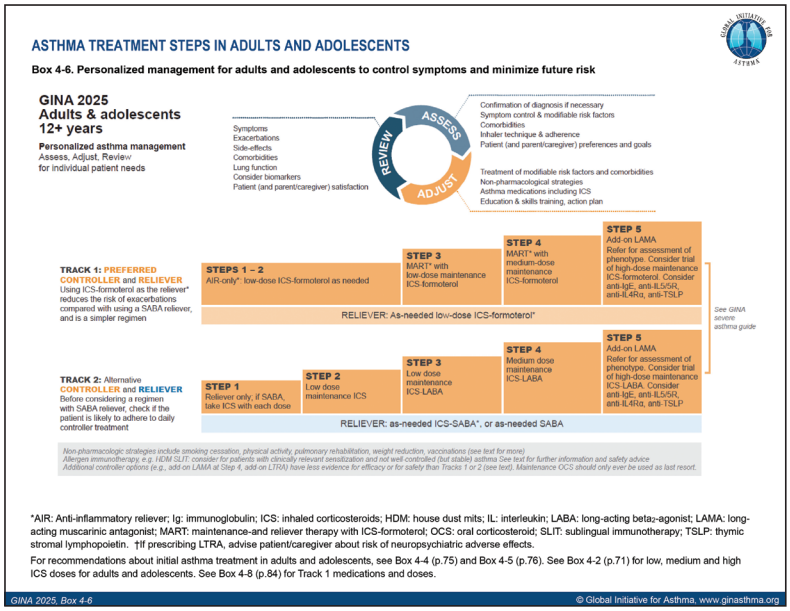
A conceptual comparison of the relative benefits of 3 treatment regimens for asthma: SABA reliever, combination ICS/fast-onset β_2-agonist reliever, and maintenance ICS plus SABA reliever.

While a SABA reliever may reduce inhaled steroid burden because it does not contain ICS, data show that lower use of ICS in asthma rescue therapy leads to adverse outcomes. While ICS-containing rescue/reliever therapy and maintenance ICS plus SABA rescue/reliever therapy have many overlapping benefits, ICS-containing rescue/reliever therapy exhibits the largest overall benefit of the 3 regimens shown in the figure, depicted by the largest area covered.

Source: Reproduced with permission of the © ERS 2025. O'Byrne PM, Reddel HK, Beasley R. The management of mild asthma. *Eur Respir J*. 2021;57:2003051. doi:10.1183/13993003.03051-2020

have symptoms on fewer than 3 to 5 days a week with normal or mildly reduced lung function, GINA recommends ICS + fast-acting bronchodilator (formoterol) as the preferred rescue/reliever therapy (**FIGURE 2**).[1] Notably, in the United States, no ICS-formoterol combination products are currently approved for as-needed use in rescue therapy. Based on current evidence and recommendations, no patient should be prescribed a SABA without also being prescribed an ICS. However, many patients are filling SABA prescriptions for asthma without an ICS, highlighting opportunities to better align current asthma practice with evidence. A discussion of potential adverse effects and out-of-pocket costs should also be considered to establish expectations, promote adherence, and encourage shared decision-making.[35]

FIGURE 2. GINA tracks 1 and 2: personalized asthma management for adults and adolescents to control symptoms and minimize future risk.[1]



Source: GINA ©2025 Global Initiative for Asthma, reprinted with permission. Available from www.ginasthma.org

Reducing exacerbations in mild asthma

Although exacerbations in patients with occasional symptoms or less severe disease can be difficult to predict, there could be up to a 10-day window of opportunity before an exacerbation peaks, where symptoms and SABA use increase. This window offers a chance for ICS intervention to prevent or reduce the severity of the exacerbation.[36] This can be achieved by patients increasing their maintenance ICS as part of an asthma action plan, or more simply by using a combined ICS-albuterol rescue inhaler.[37]

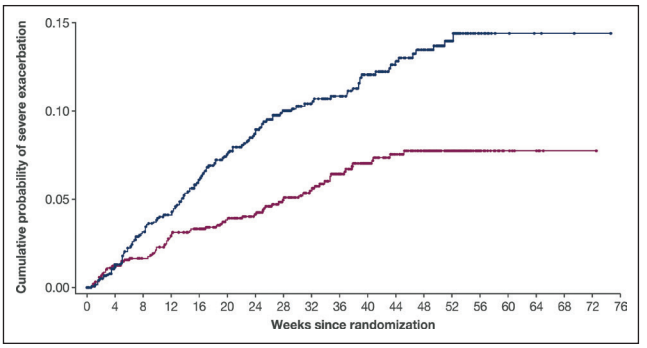
As patients get closer to exacerbation, there is increasing SABA use for both mild and moderate-to-severe disease.[36] Both groups have low use of maintenance therapy prior to an exacerbation but a marked increase in maintenance post-exacerbation, and both groups still have a proportion of patients with subsequent exacerbations (13% in mild and 27% in moderate-to-severe disease).[36] Additionally, a retrospective US study showed that patients treated for intermittent/mild-persistent asthma who receive SABA-only therapy have a greater occurrence of ≥1 severe exacerbation within a year vs those receiving low-dose ICS or a leukotriene modifier (61.2% vs 40.4% and 50.4%; P <.001 for both comparisons).[33] In those receiving SABA-only therapy, the proportions with ≥1 severe exacerbation were the highest, ranging from 52.5% to 70.4%.[33] In those receiving low-dose ICS, proportions with ≥1 severe exacerbation ranged from 36.0% to 44.9%. In those receiving a leukotriene modifier, proportions ranged from 47.3% to 54.7%. These ranges are based on the number of annual SABA fills.[33]

A recent study (BATURA) showed a significant reduction in exacerbations with albuterol-budesonide vs albuterol alone as rescue therapy in patients with mild asthma, highlighting the benefits of ICS-containing rescue therapy for exacerbation prevention.[12,13] BATURA examined the efficacy and safety of albuterol-budesonide 180/160 µg vs albuterol 180 µg in patients ≥12 years of age with mild asthma.[13] Patients were randomized 1:1 to albuterol-budesonide or albuterol alone as needed for symptoms for 12 to 52 weeks.[13] In the per protocol analysis, the albuterol-budesonide group experienced a statistically significant 47% reduction in the risk of a severe exacerbation vs those in the albuterol-only group (primary endpoint; hazard ratio, 0.53; 95% confidence interval: 0.39, 0.73; P <.001; **FIGURE 3**).[13] Secondary endpoints of BATURA showed a 53% reduction in annualized severe exacerbation rate and a 63% reduction in total SCS annualized dose in the albuterol-budesonide group vs the albuterol-only group (P <.001 for both comparisons).[13] Both treatment groups had generally comparable safety profiles.

CASE STUDY (CONTINUED)

The patient in the aforementioned case study is educated by her PCP about her considerable risk of severe exacerbations based on her clinical history and risk factors. Additionally, based on data from the recent BATURA study, continuing a SABA-only rescue therapy is likely to increase the risk of severe exacerbations and SCS use, compared to an ICS-containing rescue therapy.[13] With this understanding, she agrees to accept an ICS-containing rescue therapy in place of the SABA-only rescue therapy to reduce her risk of exacerbations. In this patient's case, ICS-containing

FIGURE 3. Primary endpoint of the BATURA study: time to first severe asthma exacerbation, per protocol analysis.[13]



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rescue therapy is preferred over ICS-containing maintenance therapy because the patient is likely to continue using the rescue inhaler at the expense of maintenance ICS.

SUMMARY

Mild asthma is often misperceived by clinicians and patients as conferring a low risk of asthma symptoms and severe exacerbations. However, recent evidence indicates that a significant proportion of patients with less severe asthma remain at high risk for exacerbations. Regardless of how severity is defined, there is rarely adequate rationale for SABA-alone rescue therapy in the absence of ICS for patients with asthma. ICS-containing rescue therapies reduce exacerbation risk compared to SABA-alone rescue regardless of the background daily maintenance regimen, including when added to daily maintenance ICS. Recognizing these risks and educating patients on the need for effective asthma regimens (ICS-containing maintenance and/or rescue regimens) can substantially reduce risk in patients with so-called mild asthma. ●

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