
A New Era
for Treating and Preventing
Asthma Exacerbations

# A New Era for Treating and Preventing Asthma Exacerbations

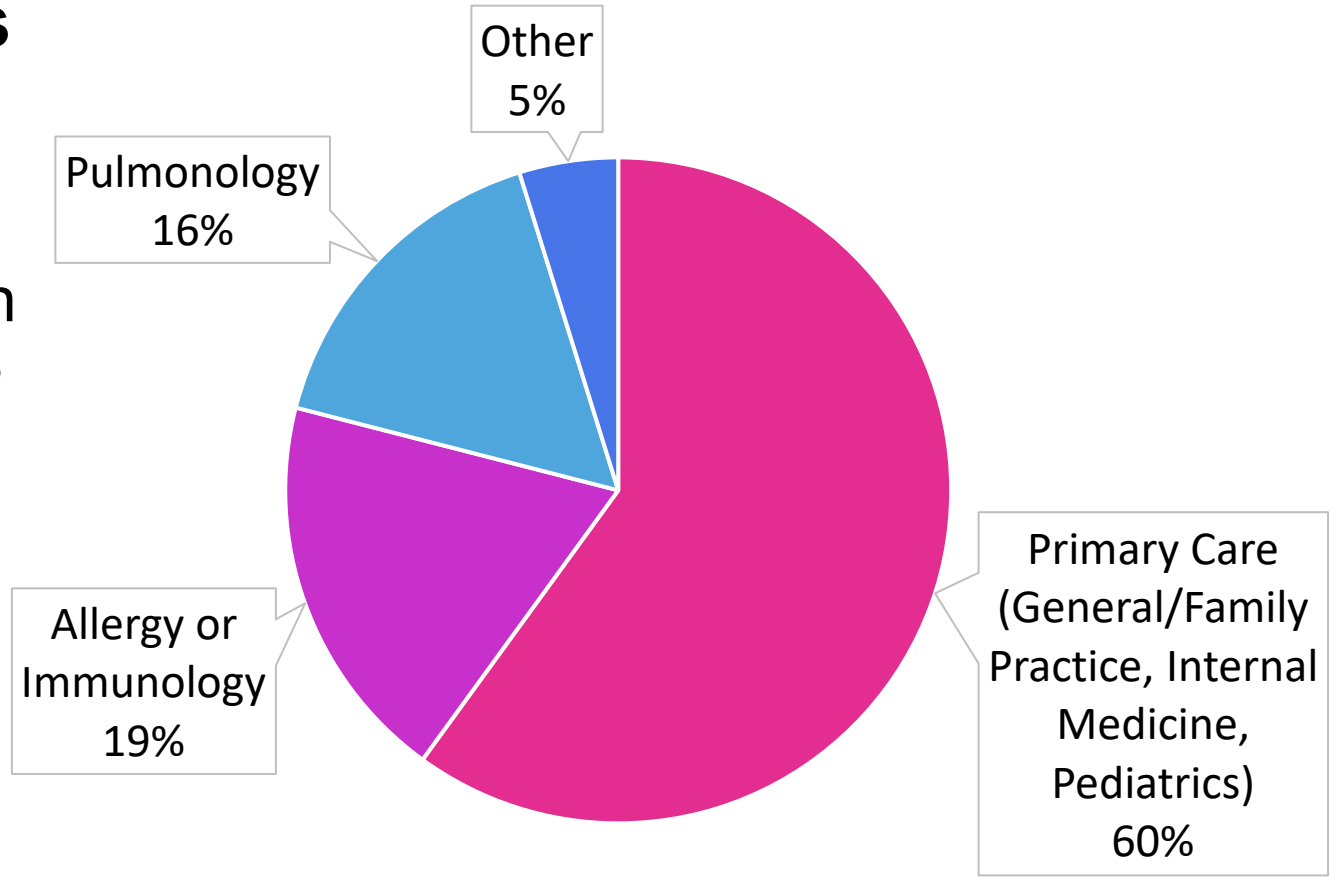
## PART ONE:

## Asthma Management for PCCs

# Asthma – The Role of PCCs

**60% of all asthma visits conducted by PCCs**

- The majority of patients with asthma can successfully be managed by PCCs




PCCs, primary care clinicians

Akinbami LJ, et al. *Natl Health Stat Report*. 2019;128:1-20. Wu TD, et al. *Med Clin North Am*. 2019;103(3):435-452.

# Managing Asthma in Primary Care

International guidance: 2023 GINA Report

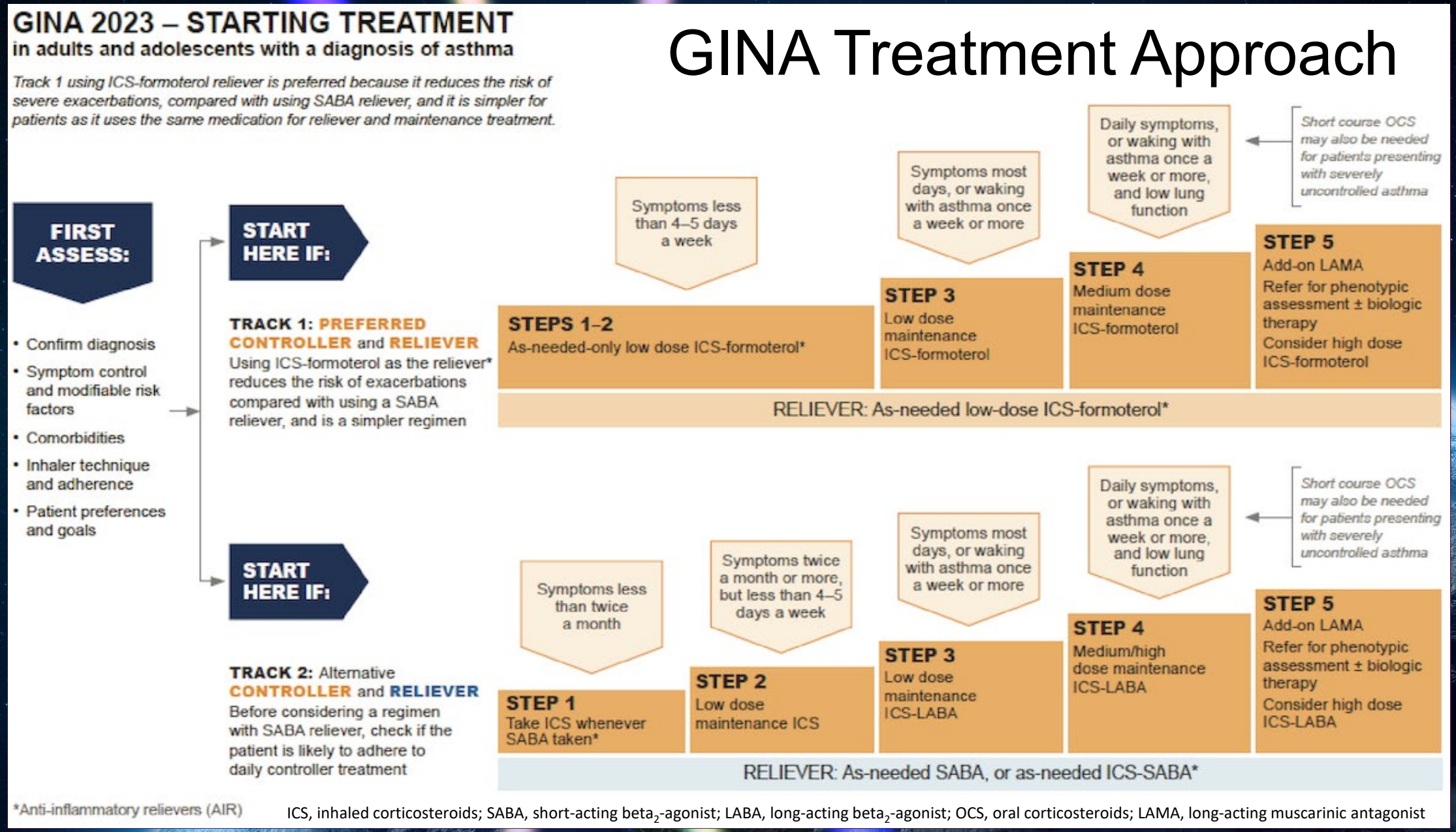
US Guidelines: NAEPP 2020

- Major components of asthma management:
  - Selection of initial therapy
    - Based on assessment of current asthma severity
  - Assessment of asthma control and risk of exacerbations
  - Adjusting therapy based on a stepwise approach

GINA, Global Initiative for Asthma; NAEPP, National Asthma Education and Prevention Program

Cloutier MM, et al. *J Allergy Clin Immunol*. 2020;146(6):1217-1270. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org

# GINA Treatment Approach




ICS, inhaled corticosteroids; SABA, short-acting beta$_2$-agonist; LABA, long-acting beta$_2$-agonist; OCS, oral corticosteroids; LAMA, long-acting muscarinic antagonist

# GINA Treatment Approach – Initial Assessment

**FIRST ASSESS:**

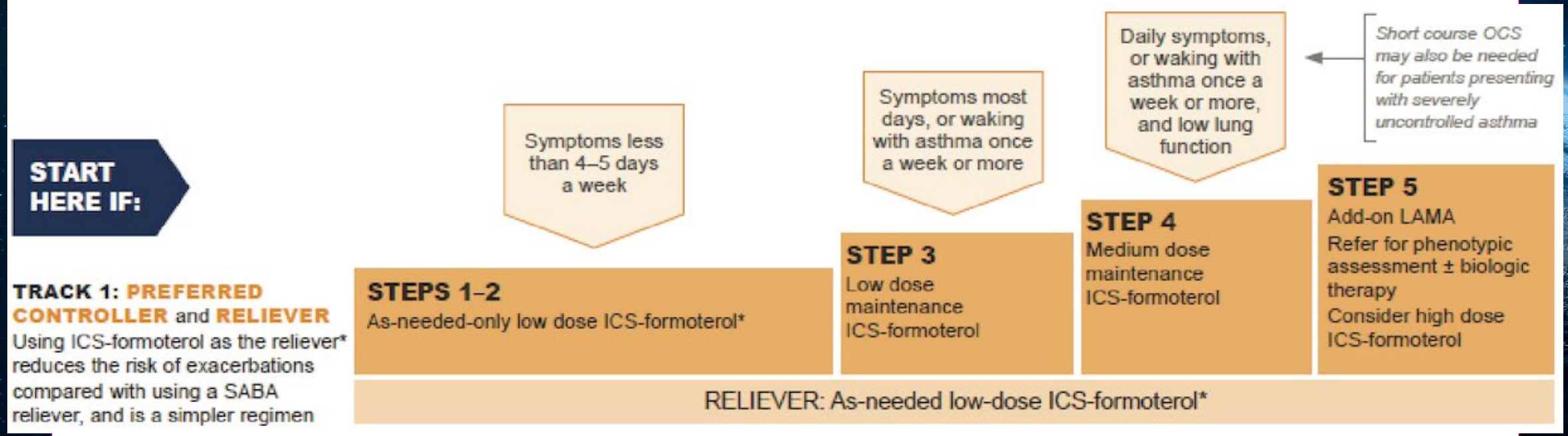
- Confirm diagnosis
- Symptom control and modifiable risk factors
- Comorbidities
- Inhaler technique and adherence
- Patient preferences and goals

## GINA 2023 – STARTING TREATMENT

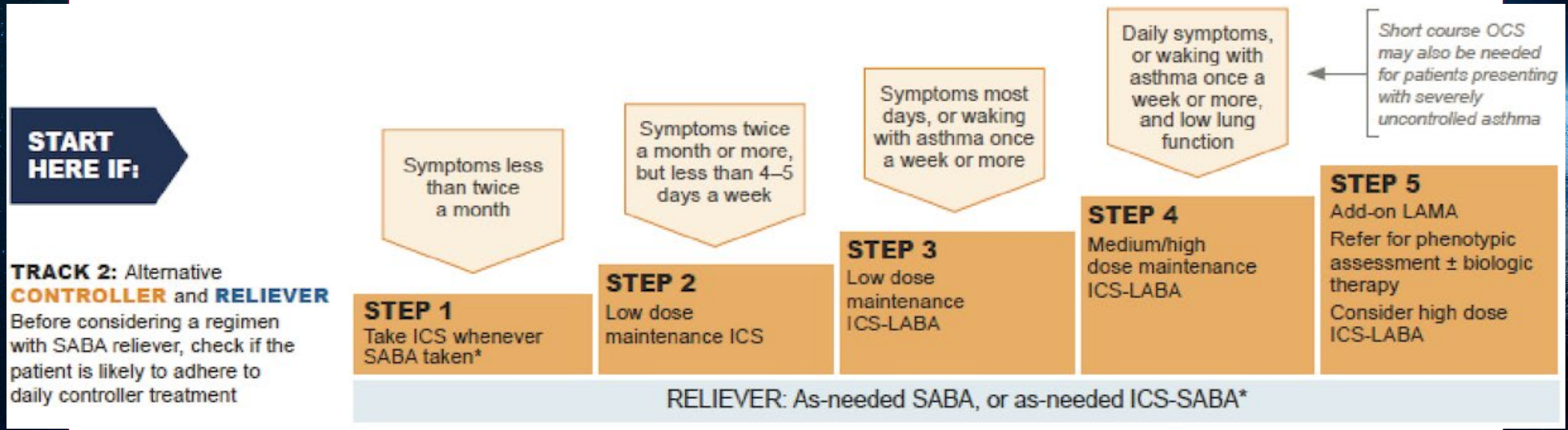
**in adults and adolescents with a diagnosis of asthma**

*Track 1 using ICS-formoterol reliever is preferred because it reduces the risk of severe exacerbations, compared with using SABA reliever, and it is simpler for patients as it uses the same medication for reliever and maintenance treatment.*

# GINA Treatment Approach – Track 1



# GINA Treatment Approach – Track 2



# Asthma – When to Refer

- While many patients with asthma can be successfully managed in primary care it requires adequate training and equipment
- Specialist referral is warranted in some cases
  - Involving specialists (pulmonologists, allergists) can lead to improved outcomes for certain patients

| Common Reasons for Specialist Referral |
| --- |
| Suspected alternative pulmonary diagnosis |
| Unable to confirm asthma diagnosis by usual means |
| Suspicion of occupational asthma |
| Persistently uncontrolled disease |
| Severe disease requiring specialized therapy |

Wu TD, et al. *Med Clin North Am*. 2019;103(3):435-452.

# Assessing Asthma Control

- Determining asthma control is essential for optimizing therapy and achieving treatment goals
- Validated asthma assessment tools acknowledged in GINA and NAEPP
  - GINA and NAEPP each also have a separate set of questions to assess control

- GINA: symptom control should be assessed “at every opportunity”
- NAEPP: periodic assessments at 1–6-month intervals and “ongoing

Cloutier MM, et al. *J Allergy Clin Immunol*. 2020;146(6):1217-1270. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org

# Validated Asthma Assessment Tools

| Assessment Tool | Description |
| --- | --- |
| Asthma Control Test (ACT) | • Scores range from 5-25 with higher scores indicating better control<br>• Score of 20-25 indicates well-controlled asthma, and the maximum clinically important difference is 3 points |

Nathan RA, et al. *J Allergy Clin Immunol*. 2004;113(1):59-65. Schatz M, et al. *J Allergy Clin Immunol*. 2009;124(4):719-723.

# Validated Asthma Assessment Tools (cont.)

| Assessment Tool | Description |
|---|---|
| Asthma Therapy Assessment Questionnaire (ATAQ) | • 4-question assessment with scores ranging from 0-4<br>• Higher score indicates worse asthma control |

Vollmer WM, et al. *Am J Respir Crit Care Med*. 1999;160(5):1647-1652.

# Validated Asthma Assessment Tools (cont.)

| Assessment Tool | Description |
|---|---|
| Asthma Control Questionnaire (ACQ) | • Includes 5 symptom questions<br>• SABA rescue use included in ACQ-6 and pre-bronchodilator forced expiratory volume in 1 second (FEV1) included in ACQ-7<br>• Scores range from 0-6, with higher scores indicating worse asthma control<br>• Total score is an average of individual items |

Juniper EF, et al. *Eur Respir J.* 1999;14(4):902-907.

# Validated Asthma Assessment Tools (cont.)

| Assessment Tool | Description |
|---|---|
| Asthma Impairment and Risk Questionnaire (AIRQ) | • Incorporates both impairment and risk assessment<br>• Scores range from 0-10, with a score of 0-1 indicating well-controlled asthma and higher scores representing worsening asthma control<br>• Follow-up version of AIRQ available intended to assess control with a 3-month recall period, in between annual visits |

Murphy KR, et al. *J Allergy Clin Immunol Pract*. 2020;8(7):2263-2274. Chipps BE, et al. *Ann Allergy Asthma Immunol*. 2022;128(5):544-552.

# Preventing Asthma Exacerbations

**Preventing exacerbations is a key outcome for treating asthma**

- Fewer exacerbations leads to:
  - Fewer visits to the emergency department
  - Lower rates of hospitalization
  - Lower mortality rates
  - Improvement in quality of life
- Regular ICS use leads to reductions in exacerbations across asthma severity levels
- Adding a fast-acting bronchodilator to ICS as rescue or maintenance and rescue therapy has demonstrated additional benefit

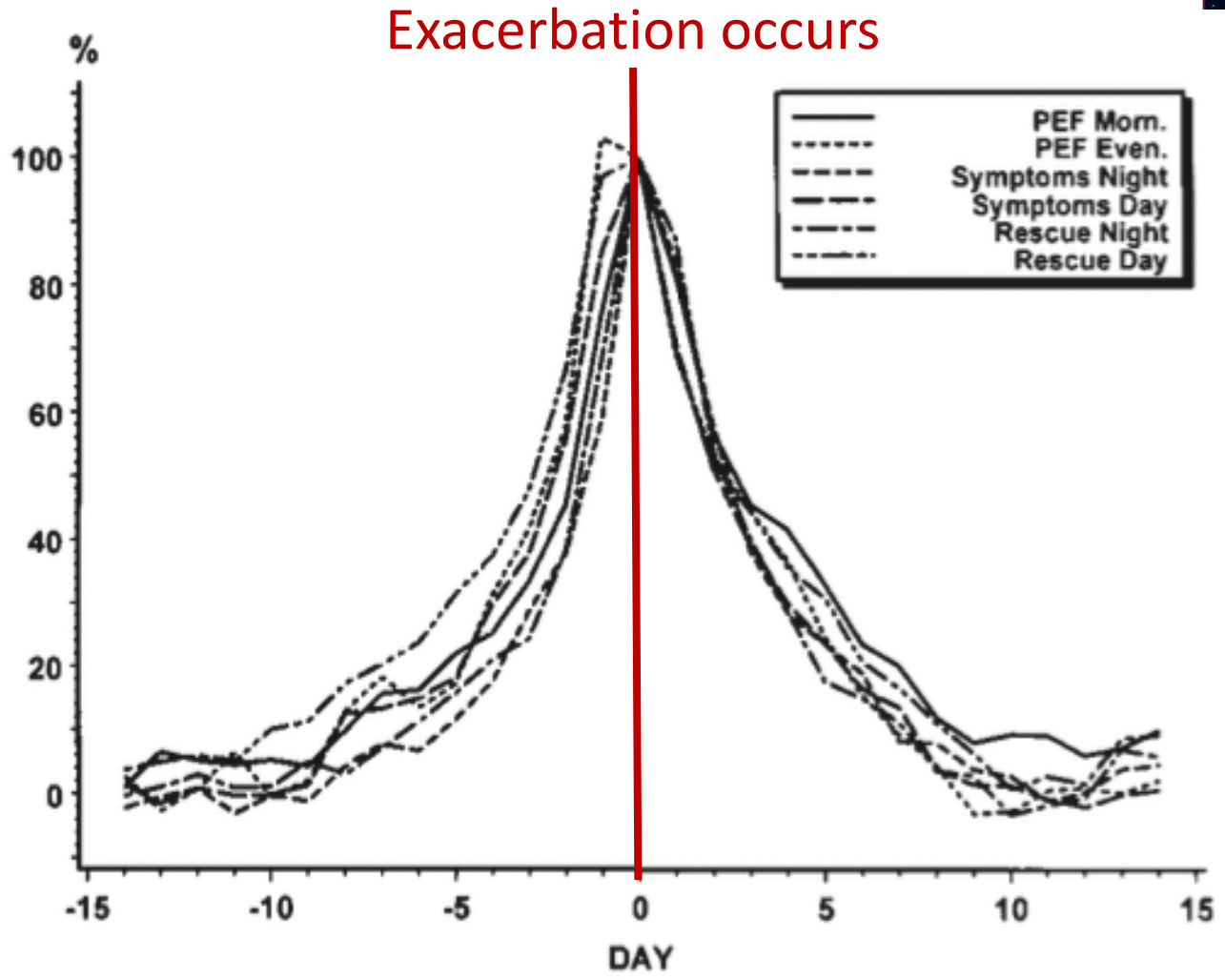
Suissa S, et al. *N Engl J Med*. 2000;343(5):332-336. Adams NP, et al. *Cochrane Database Syst Rev*. 2005;(1):CD002738. Bateman ED, et al. *N Engl J Med*. 2018;378(20):1877-1887. Israel E, et al. *N Engl J Med*. 2022;386:1505-1518. Chipps BE, et al. *BMJ Open Respir Res*. 2021;8(1):e001077.

# Preventing Asthma Exacerbations: The Window of Opportunity

**10-14 days before an exacerbation:**

- Peak expiratory flow worsens
  - (inverse relationship shown in figure)
- Symptoms increase
- SABA use increases

**The time leading up to an exacerbation may offer a window of opportunity to mitigate exacerbation occurrence or severity with anti-inflammatory therapy (ICS)**



# Summary and Key Takeaways

- Most asthma visits (60%) are conducted in primary care – PCCs play a significant role in asthma management
- The GINA 2023 Report provides the most updated guidance for asthma care based on current evidence
- GINA step therapy approaches emphasize the use of ICS with SABA for rescue/reliever therapy
- Several tools are available to assess asthma control
- Early intervention with ICS can prevent asthma exacerbations

# A New Era for Treating and Preventing Asthma Exacerbations

## PART TWO:

## Navigating Patient Access and Costs of Asthma Care

# Asthma Overview

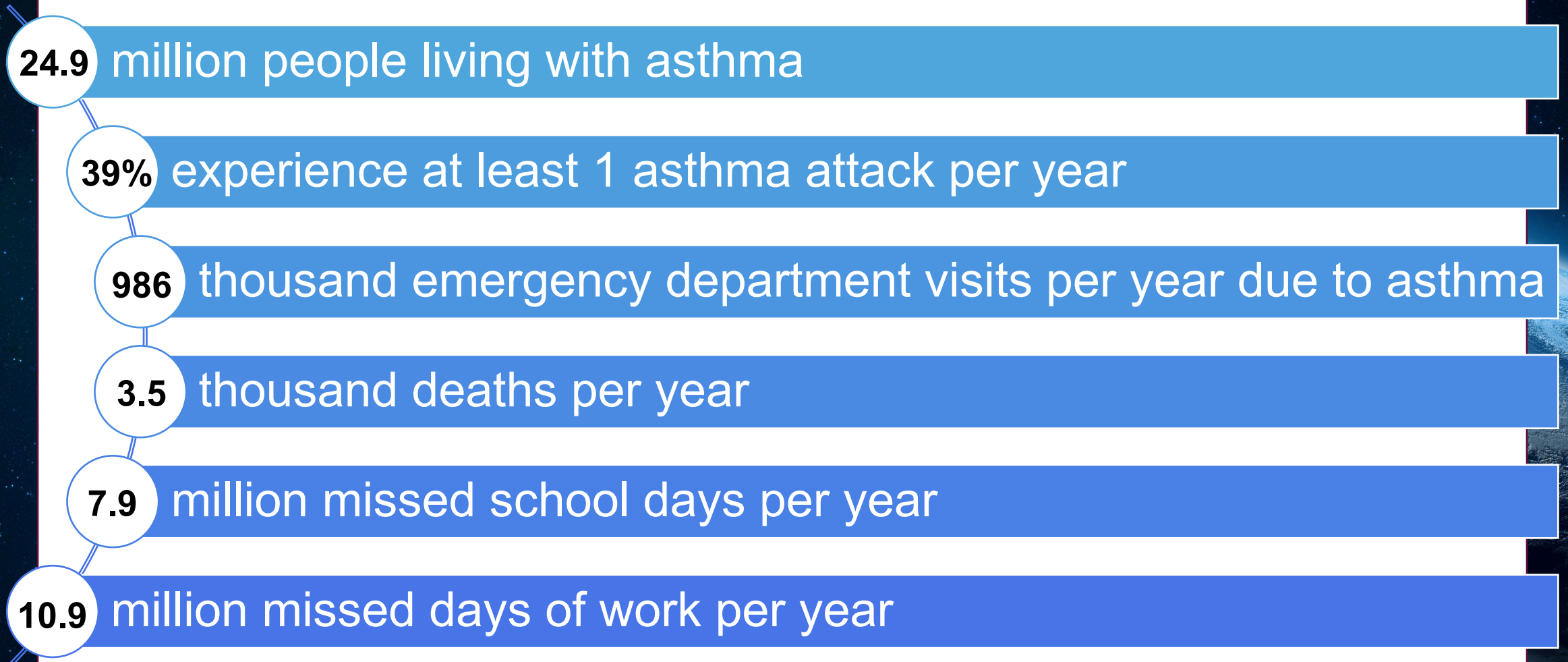
**Definition of asthma:**

> "Asthma is a heterogenous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness and cough, that vary over time and in intensity, together with variable expiratory airflow limitation. Airflow limitation may later become persistent."[1]
>
> - 2023 GINA Report

- Asthma affects approximately 339 million people worldwide[1,2]
- Despite significant advances in guidance and treatments, asthma continues to cause substantial health burden[1,2]

Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org. Fletcher MJ, et al. *NPJ Prim Care Respir Med*. 2020;30:29.

# Asthma in the US – By the Numbers




Centers for Disease Control and Prevention. Most Recent National Asthma Data. Updated May 10, 2023. Accessed September 12, 2023. https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm; American Lung Association. Asthma Trends and Burden. Accessed September 12, 2023. https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/trends-and-burden

# Asthma Costs in the US

- Lack of asthma control is associated with substantial cost burdens at both the individual and population level
- Projections for 2019-2038 estimate:
  - **52%** of asthma patient-years will be uncontrolled
  - Total direct and indirect costs for asthma care will **approach $1 trillion**
  - Associated **loss in patients' quality of life**

Much of the burden of uncontrolled asthma is preventable

Adherence to evidence-based management strategies by patients and clinicians can significantly reduce costs and improve quality of life

Yaghoubi M, et al. *Am J Respir Crit Care Med*. 2019;200(9):1102-1112.

# Disparities in Asthma Care

The burden of asthma uniquely affects patients across different age, socioeconomic, and minority groups

- Black and/or Hispanic/Latinx individuals of Puerto Rican origin have the highest rates of asthma and the highest asthma death rates in the US
- Black individuals are nearly 3 times more likely to die from asthma than White individuals
- Refugees and other immigrants face unique barriers in accessing the health care system
  - Language barriers
  - Lack of familiarity with the health care system
  - Cultural barriers, such as misinformed fears of ICS being addictive

Nanda A, et al. *J Allergy Clin Immunol*. 2023;151(4):869-880.

# Addressing Disparities – Challenges and Solutions

## Clinicians

**Challenges**

- Availability of asthma specialist care
- Linguistic and cultural competency
- Limitations from payors

**Solutions**

- Assess access of specialist asthma care
- Telemedicine and technology use
- Improve medication coverage

Nanda A, et al. *J Allergy Clin Immunol*. 2023;151(4):869-880.

# Addressing Disparities – Challenges and Solutions

## Patients

### Challenges

- Treatment preferences
- Adherence issues
- Limited health literacy
- Social environment
- Economic instability
- Health behavior
- Risk behavior

### Solutions

- Telemedicine
- Care coordination
- Referral to local services
- Improve opportunities for higher education and employment
- Improve access to social work services

Nanda A, et al. *J Allergy Clin Immunol*. 2023;151(4):869-880.

# Addressing Disparities – Challenges and Solutions

## Health Care System

**Challenges**

- Medication coverage
- Asthma health literacy
- Limited access to quality asthma services
- Inequitable receipt of care

**Solutions**

- Care coordination
- collaborate with pharmaceutical agencies
- Combat implicit and explicit bias
- Address health equity
- Enhance community-based programming
- Telemedicine

Nanda A, et al. *J Allergy Clin Immunol*. 2023;151(4):869-880.

# Access to Asthma Care and Treatments

- Free clinics often available to patients who are uninsured or underinsured
- Many pharmaceutical companies offer financial assistance programs for asthma medications that have high out-of-pocket cost
- Increased focus on adherence to therapy
  - May be improved by digital health interventions and telemedicine
  - More frequent touchpoints
- Community-based asthma education programs can improve health literacy and cultural competency

Nanda A, et al. *J Allergy Clin Immunol*. 2023;151(4):869-880.

# Case #1 – Patient with commercial insurance

**48-year-old female with moderate asthma (GINA Step 4)**

- Insured commercially through her employer-sponsored insurance
  - Prescription insurance coverage
  - $50 copay for preferred brand medications
- Currently prescribed medium-dose maintenance ICS-LABA
- Presents with complaints of worsening shortness of breath
- Asks for a refill of her albuterol inhaler

What might contribute to problems with medication access for this patient?

How could her asthma regimen be optimized to better align with current evidence?

# Case #1 – Patient with commercial insurance

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- Insured commercially through her employer-sponsored insurance
  - Prescription insurance coverage
  - $50 copay for preferred brand medications
- Currently prescribed medium-dose maintenance ICS-LABA
- Presents with complaints of worsening shortness of breath
- Asks for a refill of her albuterol inhaler
- Further investigation finds that she only uses her ICS-LABA 2-3 times a week because she doesn't like paying $50 every time she picks up the ICS-LABA inhaler, and albuterol is less expensive

What could you do to improve this patient's medication access for the ICS-LABA inhaler?

# Case #2 – Patient with government insurance

**70-year-old Black female with mild asthma (GINA Step 2)**

- Has Medicare Part D prescription insurance
  - $50 copay for preferred brand medications
- Currently prescribed low-dose ICS and as-needed SABA
  - Instructed to take her ICS when she uses her SABA
  - Says she follows her regimen as prescribed
- She states that she's having trouble affording her ICS inhaler because she's on a fixed income

What asthma care disparities does this patient have (or is at risk for)?

How could you improve her access to her asthma treatments?

# Case #3 – Patient without insurance

**35-year-old Hispanic male with moderate asthma (GINA Step 3)**

- Presents to your federally-qualified health center (FQHC) to establish care; he has been in the US for about 3 years
- His asthma has not been well-managed previously
  - Several emergency department visits in the last 3 months
- He's currently not taking any asthma medication because his inhalers have all run out, including those he received at the hospital

What asthma care disparities does this patient have (or is at risk for)?

What regimen might you consider for this patient's asthma, and how could you help ensure access to treatments?

# Summary and Key Takeaways

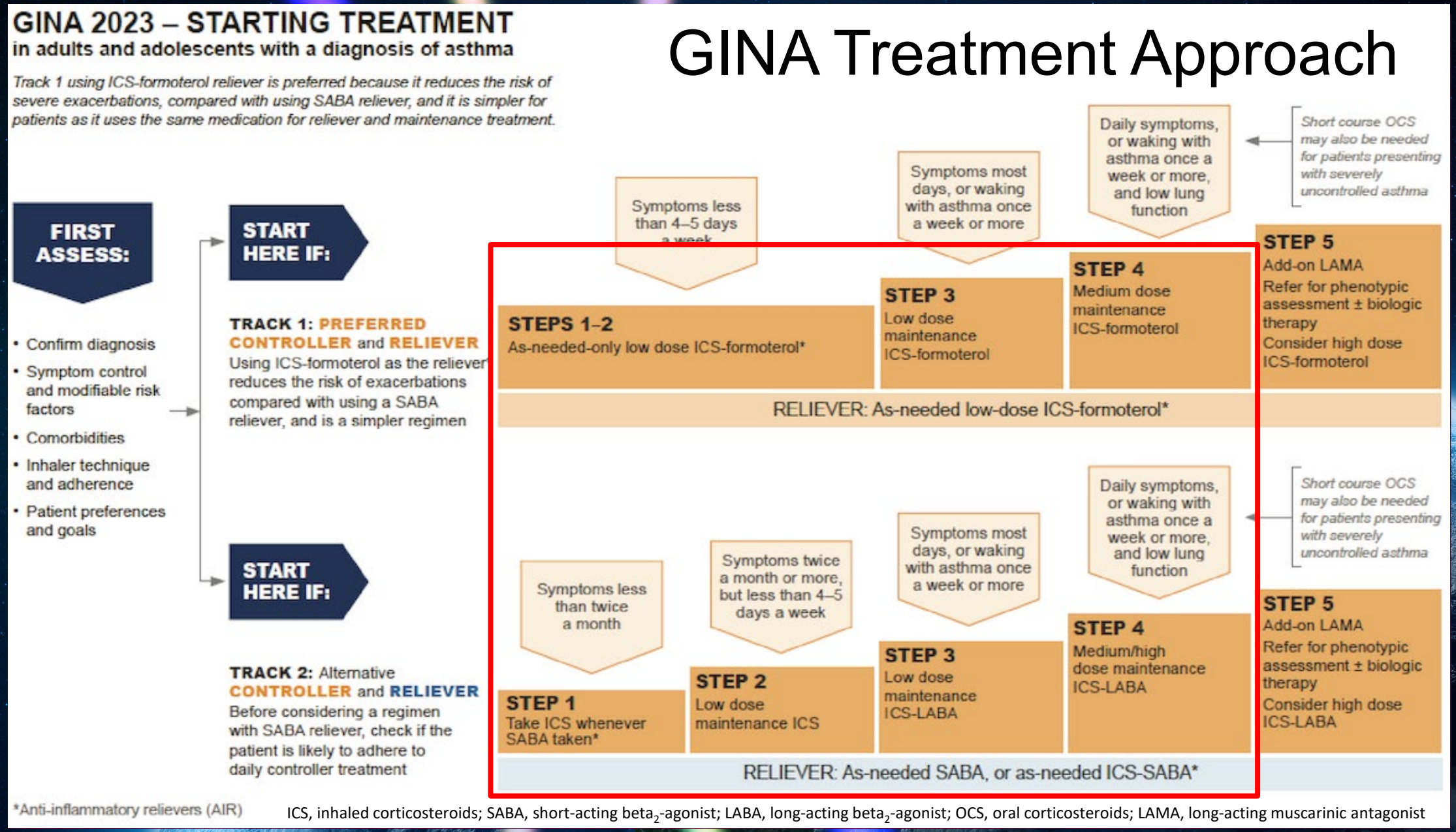
- Asthma poses a substantial health and cost burden globally and in the US
- Disparities in asthma care contribute to different risks based on age, socioeconomic status, and among minority groups
- Solutions for addressing disparities from the perspective of clinicians, patients, and the healthcare system can improve asthma care equity
- Options for improved access to asthma care and treatments include government-subsidized care settings, copay cards,and patient assistance programs

# A New Era for Treating and Preventing Asthma Exacerbations

## PART THREE:

## New FDA-Approved Options for Mild to Moderate Asthma Care

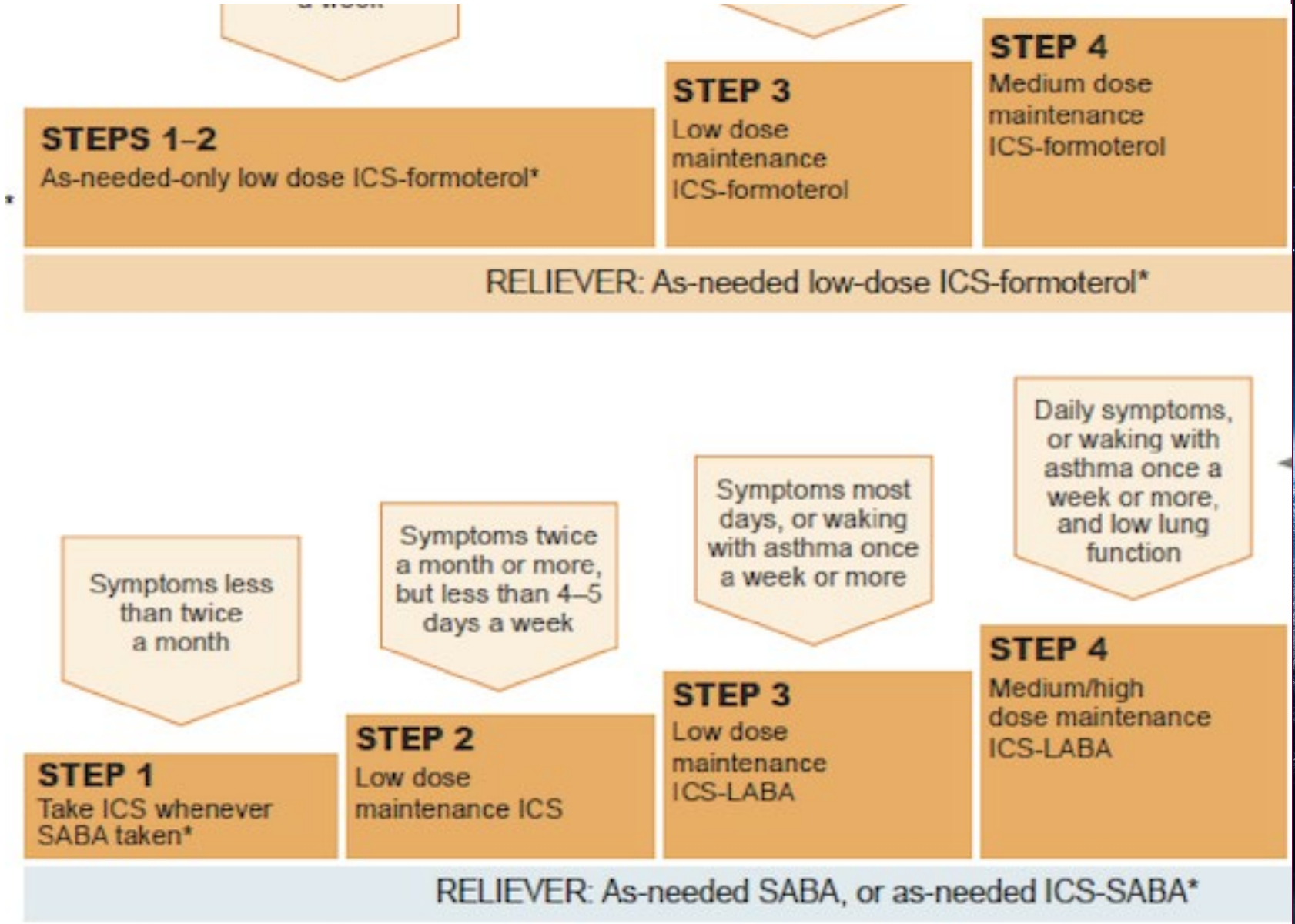
# GINA Treatment Approach




ICS, inhaled corticosteroids; SABA, short-acting beta$_2$-agonist; LABA, long-acting beta$_2$-agonist; OCS, oral corticosteroids; LAMA, long-acting muscarinic antagonist

# GINA Treatment Approach

## Mild to Moderate Asthma Step Therapy



# The Importance of ICS in Rescue/Reliever Therapy

**ICS have both nongenomic and genomic anti-inflammatory effects**

- Both contribute to role for lowering airway inflammation related to an exacerbation

| Nongenomic Effects (Rapid onset – seconds to minutes) | Genomic Effects (Delayed onset – 4–24 hours) |
|---|---|
| Decreased airway mucosal blood flow | Increased transcription of anti-inflammatory genes |
| Decreased airway edema | Decreased transcription of inflammatory genes |
| Immune cell activity modulation | |
| Potentiation of bronchodilator effects | |

Panettiere RA, et al. *Trends Pharmacol Sci*. 2019;40(1):38-49. Alangari AA. *Ann Thorac Med*. 2010;5(3):133-139.

# The Role of ICS + Fast-acting Bronchodilator

## Budesonide-formoterol studies

- Budesonide-formoterol as a fixed-dose combination inhaler evaluated for use as rescue and rescue and maintenance therapy across asthma severities
- Compared with PRN SABA, budesonide maintenance therapy, or budesonide-formoterol maintenance therapy with PRN SABA:
  - Reduced ICS exposure
  - Better symptom control
  - Improved lung function

Formoterol is considered a LABA; however, onset of action is within 3 minutes

- Collectively, trials demonstrate reductions in asthma exacerbations with PRN budesonide-formoterol compared to PRN SABA alone

**Budesonide-formoterol is not currently FDA-approved for PRN use in the US**

O'Byrne PM, et al. *N Engl J Med*. 2018;378(20):1865-1876. O'Byrne PM, et al. *Lancet Respir Med*. 2021;9(2):149-158. Bateman ED, et al. *N Engl J Med*. 2018;378(20);1877-1887. O'Byrne PM, et al. *Am J Respir Crit Care Med*. 2005;171(2):129-136. Scicchitano R, et al. *Curr Med Res Opin*. 2004;20(9):1403-1418. Rabe KF, et al. *Chest*. 2006;129(2):246-256. Kuna P, et al. *Int J Clin Pract*. 2007;61(5):725-736. Beasley R, et al. *N Engl J Med*. 2019;380(21)2020-2030.

# The Role of ICS + Fast-acting Bronchodilator

## Select budesonide-formoterol studies

### SYGMA Trials (mild asthma)

**SYGMA 1**

- 65% reduction in annualized exacerbation rate compared to PRN terbutaline
- Equally effective as budesonide maintenance therapy for preventing exacerbations
- Post-hoc analysis: a single day of treatment with ≥2 PRN inhalations of budesonide formoterol reduced short-term risk of severe exacerbations

**SYGMA 2**

- Equally effective compared to budesonide maintenance therapy for preventing exacerbations
- 75% reduction of inhaled corticosteroid exposure

**Note: Although most maintenance and rescue therapy studies of ICS + fast-acting bronchodilator were conducted with budesonide-formoterol, mometasone-formoterol is also an ICS + fast-acting bronchodilator combination inhaler. It also lacks approval for PRN use in the US.**

O'Byrne PM, et al. *N Engl J Med*. 2018;378(20):1865-1876. O'Byrne PM, et al. *Lancet Respir Med*. 2021;9(2):149-158. Bateman ED, et al. *N Engl J Med*. 2018;378(20);1877-1887.

# ICS + SABA Studies

## PREPARE Trial

| |
|---|
| Adults with moderate-to-severe asthma |
| Randomly assigned to:<br>• Patient-activated ICS + SABA for rescue therapy along with usual maintenance therapy<br>or<br>• Usual maintenance or SABA for rescue therapy along with usual maintenance therapy |
| Patients who were instructed to take ICS every time they used rescue therapy had a **lower annualized rate of severe exacerbations** than the control group (HR 0.85; 95% CI 0.72–0.999; *P* = .048) |
| Intervention group also had better asthma control and fewer missed days of work, school, and usual activities |

Israel E, et al. *N Engl J Med*. 2022;386(16):1505-1518.

# ICS + SABA Studies

## MANDALA Trial

Note: all data are from the pre-planned efficacy analysis

| |
|---|
| 3132 adolescent and adult patients with moderate-to-severe asthma |
| Key patient groups:<br>• PRN fixed-dose combination of albuterol 180 mcg + budesonide 160 mcg along with routine therapy<br>• PRN albuterol 180 mcg along with routine therapy |
| Patients in the fixed-dose group compared to albuterol-alone group experienced:<br>• 27% reduction in risk of severe exacerbations (HR 0.73; 95% CI 0.61–0.88)<br>• Lower mean annualized total dose of SCS (86.2 ± 262.9 mg prednisone equivalents versus 129.3 ± 657.2 mg)<br>• Improvement in asthma control (ACQ; OR, 1.22; 95% CI, 1.02 to 1.47)<br>• Improved asthma-related quality of life (AQLQ+12; OR, 1.23; 95% CI 1.02–1.48) |

AQLQ+12, Asthma Quality of Life Questionnaire validated for persons ≥12 years of age

Papi A, et al. *N Engl J Med*. 2022;386(22):2071-2083.

# ICS + SABA Studies

## DENALI Trial

| |
|---|
| 989 patients aged ≥ 12 years with mild-to-moderate asthma |
| Patients were randomized 1:1:1:1:1 for 12 weeks to receive four-times-daily:<br>• Fixed-dose combination of albuterol 180 mcg + budesonide 160 mcg<br>• Fixed-dose combination of albuterol 180 mcg + budesonide 80 mcg<br>• Albuterol 180 mcg<br>• Budesonide 160 mcg<br>• Placebo |
| • Change from baseline in $FEV_1$ $AUC_{0\text{-}6h}$ over 12 weeks was greater with albuterol-budesonide 180/160 mcg vs budesonide 160 mcg (*P* = .003)<br>• Change in trough $FEV_1$ at week 12 was greater with albuterol-budesonide 180/160 and 180/80 µg vs albuterol 180 µg (*P* < .001)<br>• Both monocomponents contributed to albuterol-budesonide lung function efficacy |

FEV1, forced expiratory volume in 1 second; AUC, area under the curve

Chipps BE, et al. *Chest*. 2023;164(3):585-595.

# FDA Approval of Albuterol/Budesonide

**January 2023**

- The FDA approved the combination inhaler albuterol/budesonide “for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older.”

- **Strength**: albuterol 90 mcg and budesonide 80 mcg per inhalation
- **Dosing**: 2 inhalations  as needed for asthma symptoms
  - Maximum dose: 12 inhalations in 24 hours
- Current availability and place in therapy to be determined
- Will be an option for ensuring patients have an ICS with their rescu/reliever treatment
- The approval fills a long-time gap in asthma management in the US

Airsupra [Package Insert]. Updated January 2023, accessed September 11, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/214070s000lbl.pdf. US Food & Drug Administration. FDA approves drug combination treatment for adults with asthma.  Updated January 11, 2023, accessed September 11, 2023. https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-drug-combination-treatment-adults-asthma

# Summary and Key Takeaways

- ICS have rapid nongenomic effects on airway inflammation
- There is a large body of evidence supporting the use of a fast-acting bronchodilator + ICS combination to reduce exacerbations
- Use of fast-acting bronchodilator + ICS can also improve symptoms and lung function
- FDA approval of albuterol/budesonide represents the first approval of a fast-acting bronchodilator + ICS combination inhaler indicated for as-needed therapy to reduce the risk of exacerbations

# A New Era for Treating and Preventing Asthma Exacerbations

## PART FOUR:

## Comprehensive Case Studies in Asthma Care

# Case #1

**A 54-year-old female presents to her PCC for an asthma follow-up visit**

- Busy accountant
- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection

What additional information do you need to assess this patient's asthma control?

# Case #1 – Initial Assessment

**A 54-year-old female presents to her PCC for an asthma follow-up visit**

- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection
- She initially states that she is adherent to her medications
- She acknowledges that she often skips 1 of the 2 doses of her maintenance inhaler, and sometimes misses using the inhaler all together
- She says that the albuterol inhaler seems to really help her breathe better, so she carries this with her and uses it most days of the week

How would you assess this patient's asthma control?

# AIRQ Assessment Tool

**In the past 2 weeks, has coughing, wheezing, shortness of breath, or chest tightness:**

| | | |
|---|---|---|
| **1.** Bothered you during the day on **more than 4 days**? | Yes | No |
| **2.** Woke you up from sleep **more than 1 time**? | Yes | No |
| **3.** Limited the activities you want to do **every day**? | Yes | No |
| **4.** Caused you to use your rescue inhaler or nebulizer **every day**? | Yes | No |

Primatene® MIST (Amphastar Pharmaceuticals) or Epinephrine

ProAir RespiClick® (Teva Respiratory, LLC) or Albuterol sulfate

Proventil® HFA (Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.) or Albuterol sulfate

Ventolin® HFA (GlaxoSmithKline) or Albuterol sulfate

Xopenex HFA® (Sunovion Pharmaceuticals Inc.) or Levalbuterol tartrate

Albuterol sulfate or Xopenex® (Sunovion Pharmaceuticals Inc.) or Levalbuterol HCl

**Please see all prescribing information for all products.**

**In the past 2 weeks:**

| | | |
|---|---|---|
| **5.** Did you have to limit your social activities (such as visiting with friends/relatives or playing with pets/children) because of your asthma? | Yes | No |
| **6.** Did coughing, wheezing, shortness of breath, or chest tightness limit your ability to exercise? | Yes | No |
| **7.** Did you feel that it was difficult to control your asthma? | Yes | No |

**In the past 12 months, has coughing, wheezing, shortness of breath, or chest tightness:**

| | | |
|---|---|---|
| **8.** Caused you to take steroid pills or shots, such as prednisone or Medrol®*? | Yes | No |
| **9.** Caused you to go to the emergency room or have unplanned visits to a health care provider? | Yes | No |
| **10.** Caused you to stay in the hospital overnight? | Yes | No |

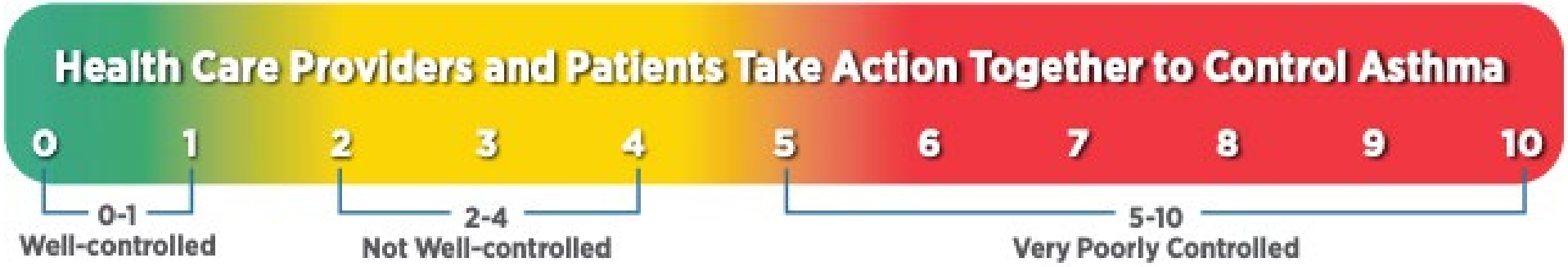
**Total YES Answers** ☐

AIRQ, Asthma Impairment and Risk Questionnaire

# Case #1 – AIRQ Results

**A 54-year-old female presents to her PCC for an asthma follow-up visit**

- The patient's AIRQ score is 4, indicating not well-controlled



# Case #1 – Treatment Approach

**A 54-year-old female presents to her PCC for an asthma follow-up visit**

- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection
- She initially states that she is adherent to her medications
- She acknowledges that she often skips 1 of the 2 doses of her maintenance inhaler, and sometimes misses using the inhaler all together
- She says that the albuterol inhaler seems to really help her breathe better, so she carries this with her and uses it most days of the week

How would you approach discussing the patient's treatment regimen?

# Case #1 – Evaluating Treatment Response

**A 54-year-old female presents to her PCC for an asthma follow-up visit**

- You decide to continue the medium-dose ICS maintenance inhaler and prescribe ICS-SABA instead of her albuterol inhaler for improved symptom control and to reduce the risk of severe exacerbations

- She comes back for a follow-up visit 3 months later

How would you assess the patient's response to therapy?

# Follow-up AIRQ

**In the past 2 weeks, has coughing, wheezing, shortness of breath, or chest tightness:**

1. Bothered you during the day on **more than 4 days**? Yes No
2. Woke you up from sleep **more than 1 time**? Yes No
3. Limited the activities you want to do **every day**? Yes No
4. Caused you to use your rescue inhaler or nebulizer **every day**? Yes No

Primatene® MIST (Amphastar Pharmaceuticals) or Epinephrine

ProAir RespiClick® (Teva Respiratory, LLC) or Albuterol sulfate

Proventil® HFA (Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.) or Albuterol sulfate

Ventolin® HFA (GlaxoSmithKline) or Albuterol sulfate

Xopenex HFA® (Sunovion Pharmaceuticals Inc.) or Levalbuterol tartrate

Albuterol sulfate or Xopenex® (Sunovion Pharmaceuticals Inc.) or Levalbuterol HCl

**Please see all prescribing information for all products.**

**In the past 2 weeks:**

5. Did you have to limit your social activities (such as visiting with friends/relatives or playing with pets/children) because of your asthma? Yes No
6. Did coughing, wheezing, shortness of breath, or chest tightness limit your ability to exercise? Yes No
7. Did you feel that it was difficult to control your asthma? Yes No

**In the past 3 months, has coughing, wheezing, shortness of breath, or chest tightness:**

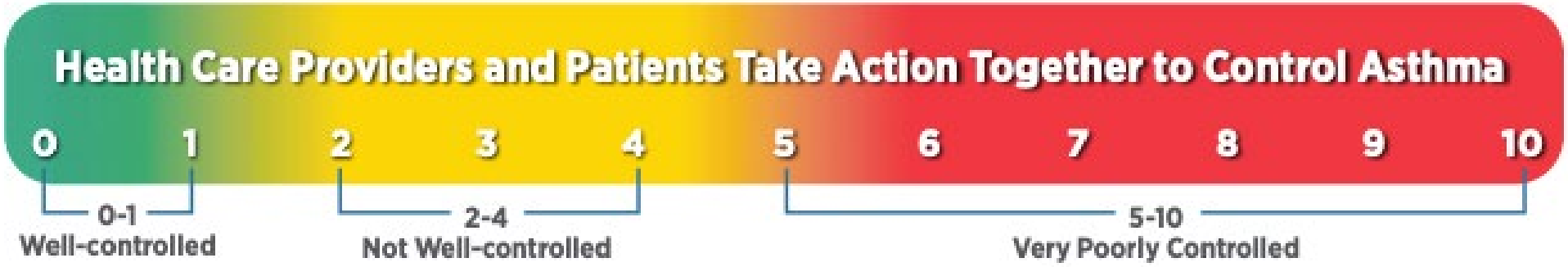
8. Caused you to take steroid pills or shots, such as prednisone or Medrol**? Yes No
9. Caused you to go to the emergency room or have unplanned visits to a health care provider? Yes No
10. Caused you to stay in the hospital overnight? Yes No

**Total YES Answers** ☐

# Case #1 – Follow-up AIRQ Results

**A 54-year-old female presents to her PCC for an asthma follow-up visit**

- The patient's AIRQ score is 1, indicating well-controlled



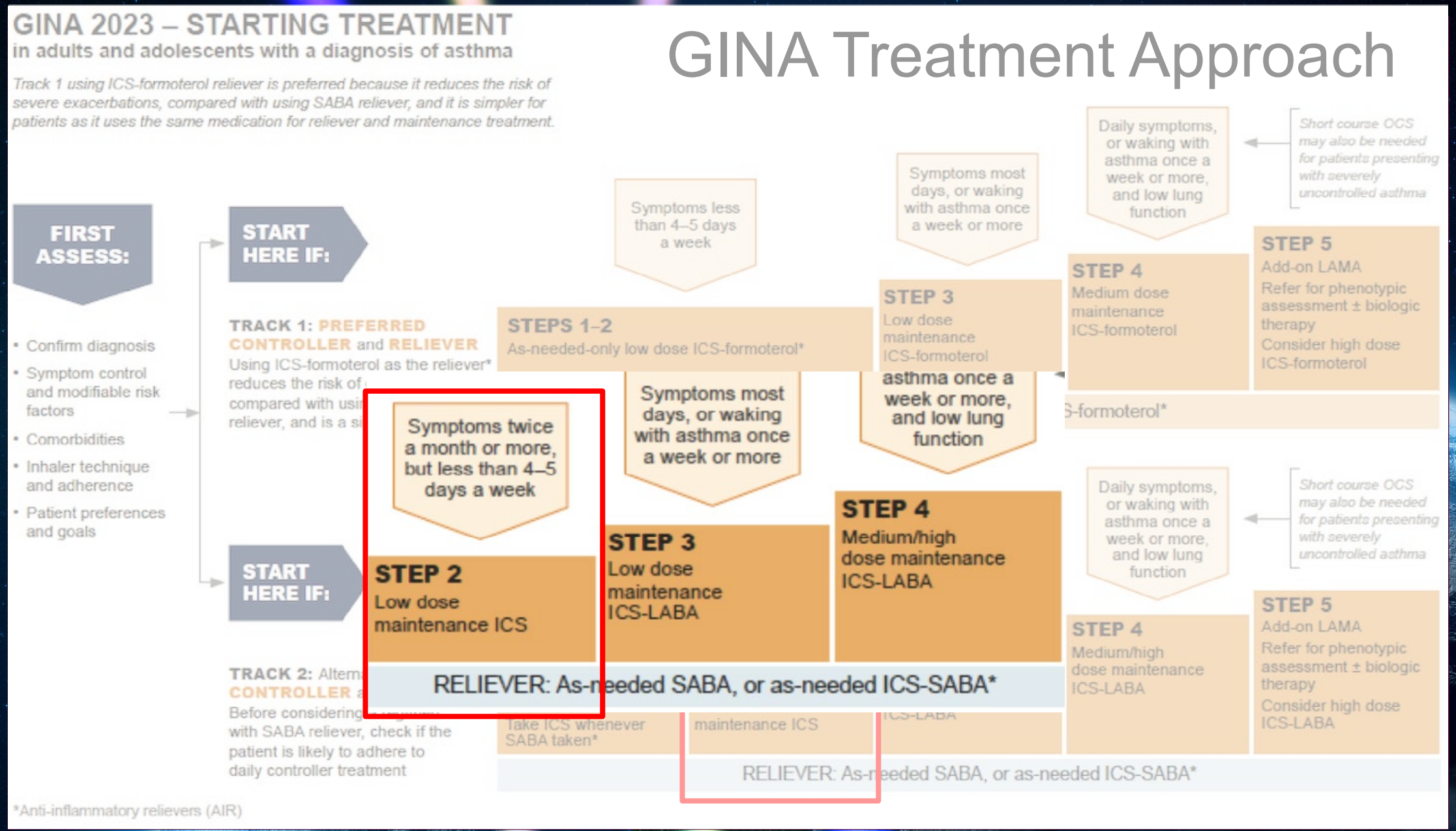
# Case #2 – Initial Assessment

**A 36-year-old male with asthma presents to his PCC in October for a routine visit.**

- He is adherent to his inhaler regimen (low-dose ICS daily) with good inhaler technique.
- He notes that he's feeling great and has had no trouble with his breathing recently.
- His AIRQ score today is 2 (steroids in the past 12 months and emergency room visit for breathing symptoms), indicating "not well-controlled" asthma.
- Upon further discussion, he adds that he gets "asthma attacks" when he exercises during allergy seasons (fall and spring) and so he always uses his albuterol inhaler before jogging (5 times/week) during these times of the year.

How would you classify the patient's asthma?

# GINA Treatment Approach



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Is the patient at risk for asthma adverse outcomes or exacerbations?

# Case #2 – Treatment Approach

**A 36-year-old male with asthma presents to his PCC in October for a routine visit.**

- You decide to recommend taking his ICS inhaler every time he uses his SABA
- The patient agrees

- He returns 3 months later (January) for follow up

# Case #2 – Treatment Access

**A 36-year-old male with asthma presents to his PCC in January for a follow-up visit.**

- He reports that he recently lost his job and has trouble affording his inhalers now
- He has run out of both inhalers
- He currently doesn’t have prescription drug insurance
- His AIRQ score has worsened to 4, indicating “not well-controlled” likely due to nonadherence

What would you recommend to improve this patient’s access to medication?

# Summary and Key Takeaways

- Asthma severity according to GINA is assessed retroactively based on the patient's minimum effective medication dose at which their asthma remains well-controlled
- Assessment of asthma control involves evaluating symptoms and impairment of quality of life over a period of time
- Treatment regimens for asthma should be individualized based on patients' characteristics, needs, and preferences
- Always consider access to treatment – if patients have difficulty obtaining asthma medications, asthma control is often worse
- Assess treatment response approximately every 3 months after therapy changes using a validated tool to determine whether additional changes are needed

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