# Asthma Update
# AAPA 2020

# Financial Disclosure

**Current Relationships:**
**Speaker/Consultant – Boehringer Ingelheim**
**Speaker – Grifols Pharmaceuticals**
**Speaker/Consultant – Meda Pharmaceuticals**
**Consultant – Aimmune Pharmaceuticals**
**Advisory Board - AstraZeneca**

# Objectives

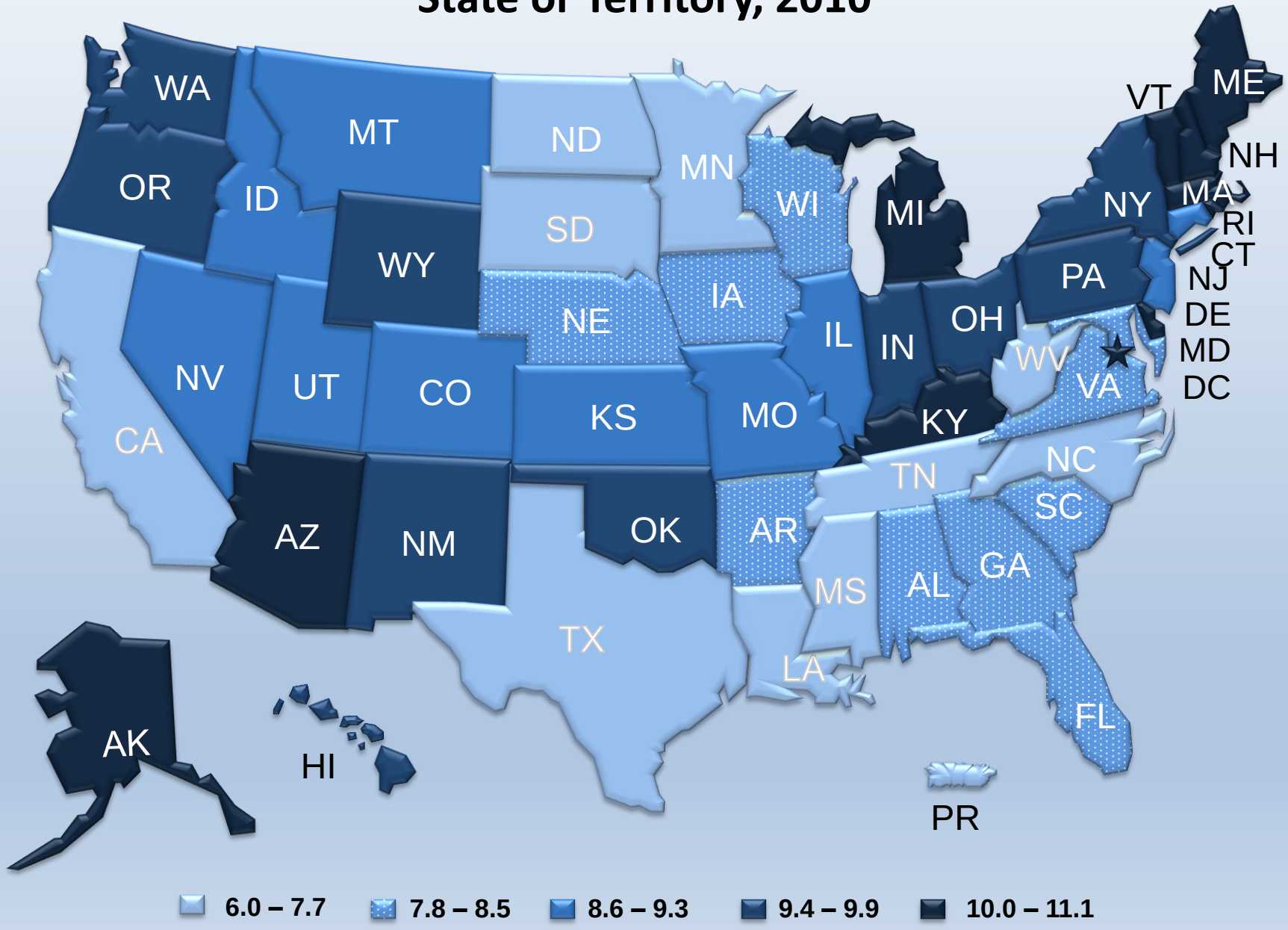
1. Review the prevalence and demographics of asthma
2. Explore the GINA Asthma Guidelines and recent changes
3. Formulate a plan for the diagnosis and staging of asthma
4. Discuss treatment strategies and step therapy
5. Conclusions and clinics pearls
6. Short COVID discussion and helpful links

# Burden of asthma

- Asthma is one of the most common chronic diseases worldwide with an estimated 300 million affected individuals
- Prevalence is increasing in many countries, especially in children
- Asthma is a major cause of school and work absence

- **Every day in America:**
- 40,000 people miss school or work due to asthma.
- 30,000 people have an asthma attack.
- 5,000 people visit the emergency room due to asthma.
- 1,000 people are admitted to the hospital due to asthma.
- 11 people die from asthma

# Adult Self-Reported Current Asthma Prevalence (%) by State or Territory, 2010



# Definition of asthma

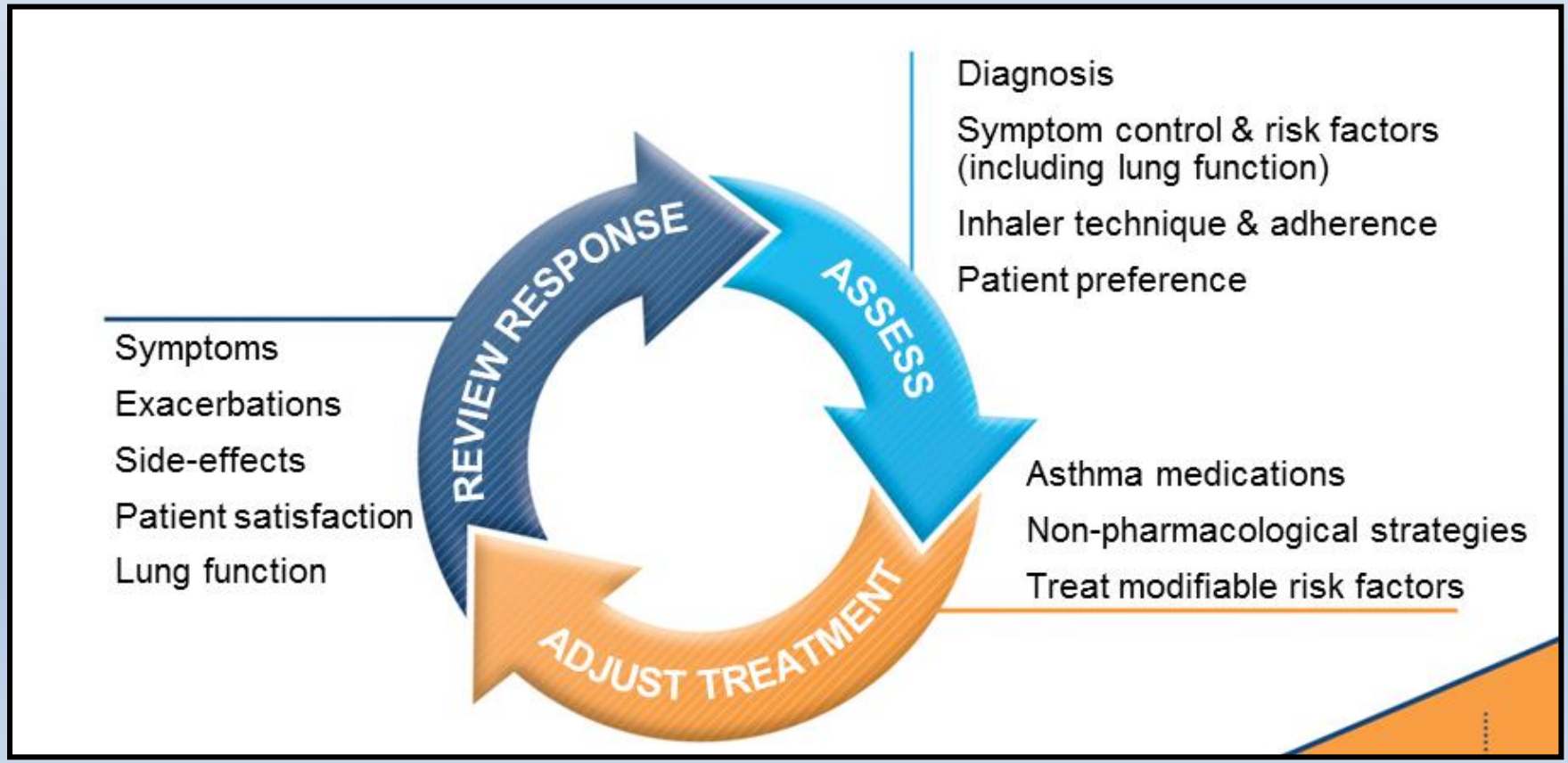
Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation (no longer primarily bronchoconstriction).

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.

# Setting up the appointment

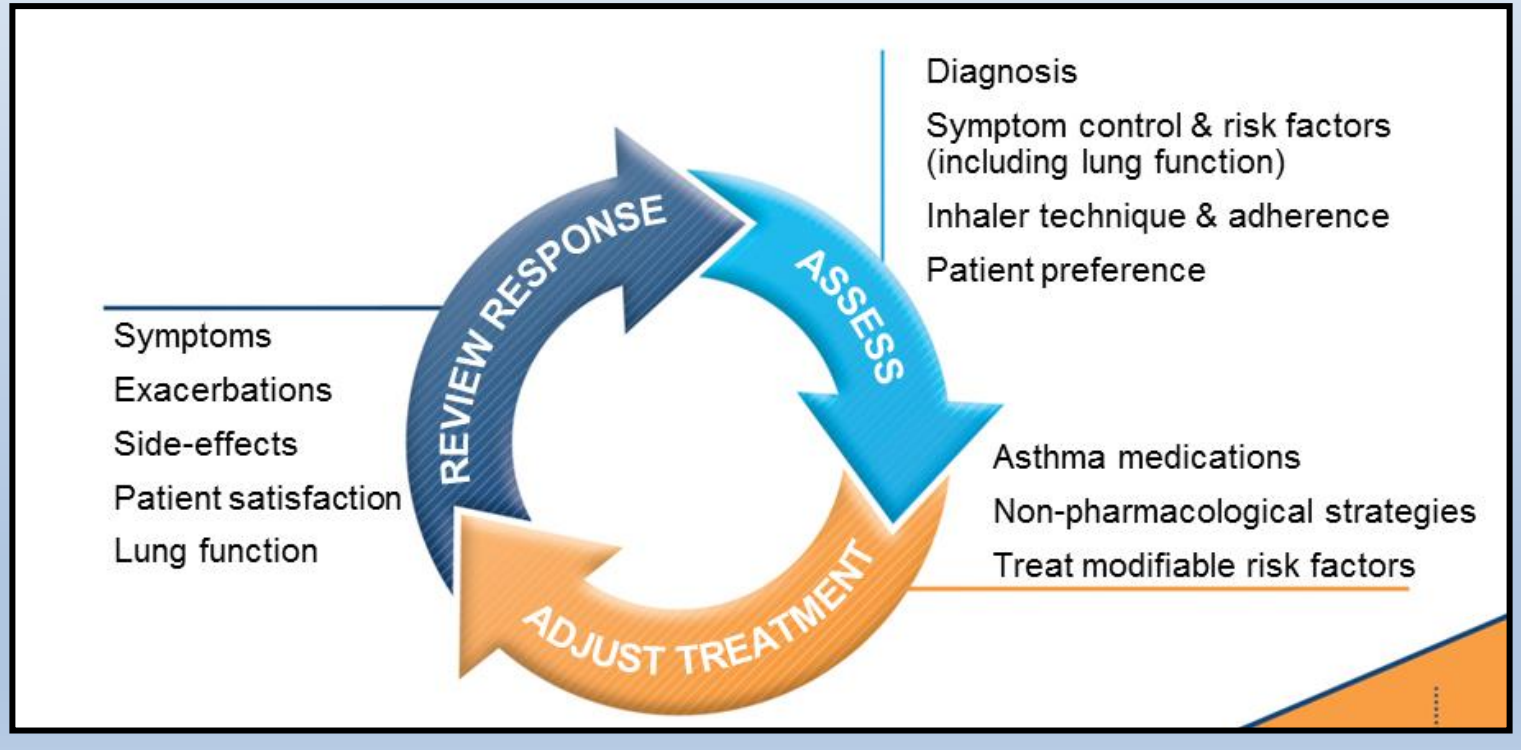
- First few minutes are critical – especially with asthma.  Visualize your last asthma patient as we go through this.

- This is the cycle of asthma. . . .



# Setting up the appointment

- “I just need my inhaler refilled”
- “I only cough at night”



# Lets Review what is new in the last couple years:

- Using GINA Guidelines – they are the best
- Updated twice a year if needed
- International
- Non-asthma specialist focus but good for specialty as well
- https://ginasthma.org/

# A reminder – the key change in GINA 2019

EDITORIAL
GINA 2019

## GINA 2019: a fundamental change in asthma management

Treatment of asthma with short-acting bronchodilators alone is no longer recommended for adults and adolescents

Helen K. Reddel[1], J. Mark FitzGerald[2], Eric D. Bateman[3], Leonard B. Bacharier[4], Allan Becker[5], Guy Brusselle[6], Roland Buhl[7], Alvaro A. Cruz[8], Louise Fleming[9], Hiromasa Inoue[10], Fanny Wai-san Ko[11], Jerry A. Krishnan[12], Mark L. Levy[13], Jiangtao Lin[14], Søren E. Pedersen[15], Aziz Sheikh[16], Arzu Yorgancioglu[17] and Louis-Philippe Boulet[18]

@ERSpublications
**GINA no longer recommends treating adults/adolescents with asthma with short-acting bronchodilators alone. Instead, they should receive symptom-driven (in mild asthma) or a daily corticosteroid-containing inhaler, to reduce risk of severe exacerbations.** http://bit.ly/310LLzE

**Cite this article as:** Reddel HK, FitzGerald JM, Bateman ED, *et al.* GINA 2019: a fundamental change in asthma management. *Eur Respir J* 2019; 53: 1901046 [https://doi.org/10.1183/13993003.01046-2019].

# Key changes – *Points of emphasis*

- Lung function trajectories and Height
  - Children with persistent asthma may have reduced growth (height) and lung function and some are at risk of accelerated decline in lung function in early adult life *[McGeachie, NEJMed 2016].*
  - Growth velocity may be lower in the first 1-2 years of ICS treatment, but this is not progressive or cumulative. ▪ Long-term outcomes showed a difference of only 0.7% in adult height (LESS height loss than untreated asthma)
- Patients with *apparently mild asthma* are at risk of serious adverse events (this is the percent that had symptoms “once a week or less” in the 6 months before the event)
  - 30–37% of adults with acute asthma
  - 16% of patients with near-fatal asthma
  - 15–20% of adults dying of asthma

# Key changes – *Albuterol use*

Inhaled SABA has been first-line treatment for asthma for 50 years

This dates from an era when asthma was thought to be a disease of bronchoconstriction

Patient satisfaction with, and reliance on, SABA treatment is reinforced by its rapid relief of symptoms, its prominence in ED and hospital management of exacerbations, and low cost

Patients commonly believe that *"My reliever gives me control over my asthma"*, so they often don't see the need for additional treatment

# Key changes – *Albuterol use*

- Regular or frequent use of SABA is associated with adverse effects
  - β-receptor downregulation, decreased bronchoprotection, rebound hyperresponsiveness, decreased bronchodilator response *(Hancox, Respir Med 2000)*
  - Increased allergic response, and increased eosinophilic airway inflammation *(Aldridge, AJRCCM 2000)*
- Higher use of SABA is associated with adverse clinical outcomes
  - Dispensing of ≥3 canisters per year (average 1.7 puffs/day) is associated with higher risk of emergency department presentations *(Stanford, AAAI 2012)*
  - Dispensing of ≥12 canisters per year is associated with higher risk of death, *YEP 1 A MONTH. . . .*

# Key changes – *Asthma Treatment (Here it is. . )*

- For safety, GINA no longer recommends SABA-only treatment for Step 1
  - This decision was based on evidence that SABA-only treatment increases the risk of severe exacerbations, and that adding any ICS significantly reduces the risk

- GINA now recommends that all adults and adolescents with asthma should receive symptom-driven or regular low dose ICS-containing controller treatment, to reduce the risk of serious exacerbations
  - This is a population-level risk reduction strategy, e.g. statins, anti-hypertensives

# OK, Big Picture Review

- We have been talking about asthma patients with MILD asthma, that right now only have a RESCUE INHALER.
- A large portion of your patient's that come in for their rescue inhaler need an ICS.

Next – the next group – those that need DAILY controller therapy: there are two good options – this is option #1

## Regular low dose ICS with as-needed SABA

- A large body of evidence from RCTs and observational studies that low dose ICS substantially reduces risks of severe exacerbations, hospitalizations and death
- Serious exacerbations halved even in patients with symptoms 0-1 days per week
- Improved symptom control and reduced exercise-induced bronchoconstriction

- Why?
  - This prevents asthma deaths and severe exacerbations

## Option #2 (again for those that need daily therapy)

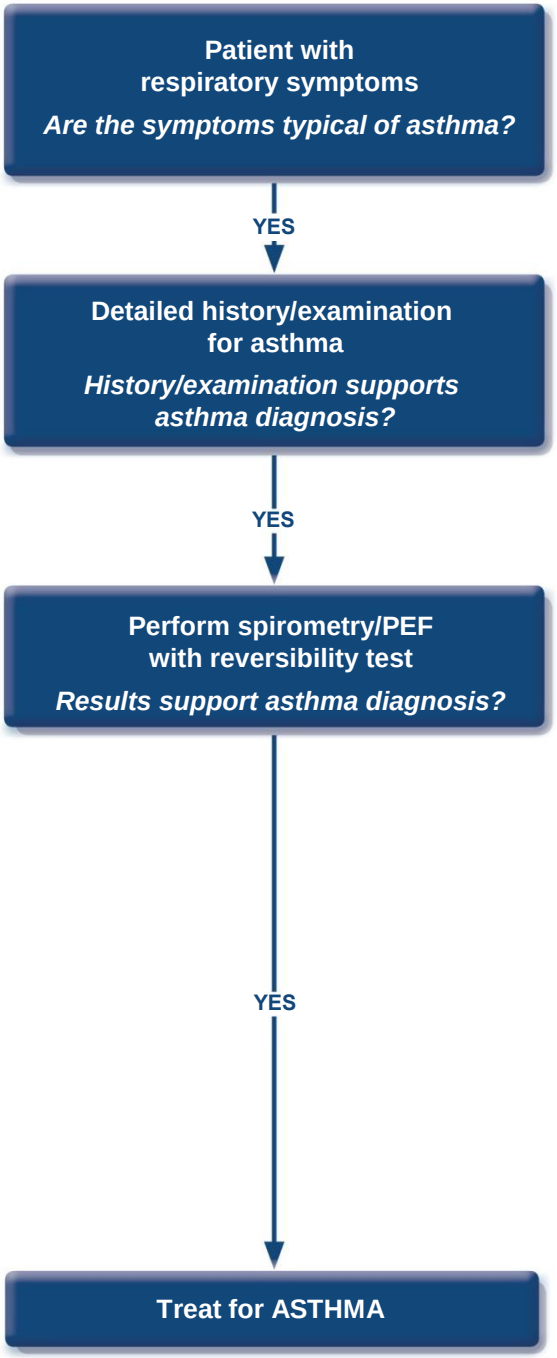
As-needed low dose ICS-formoterol (off-label; all evidence with budesonide-formoterol)

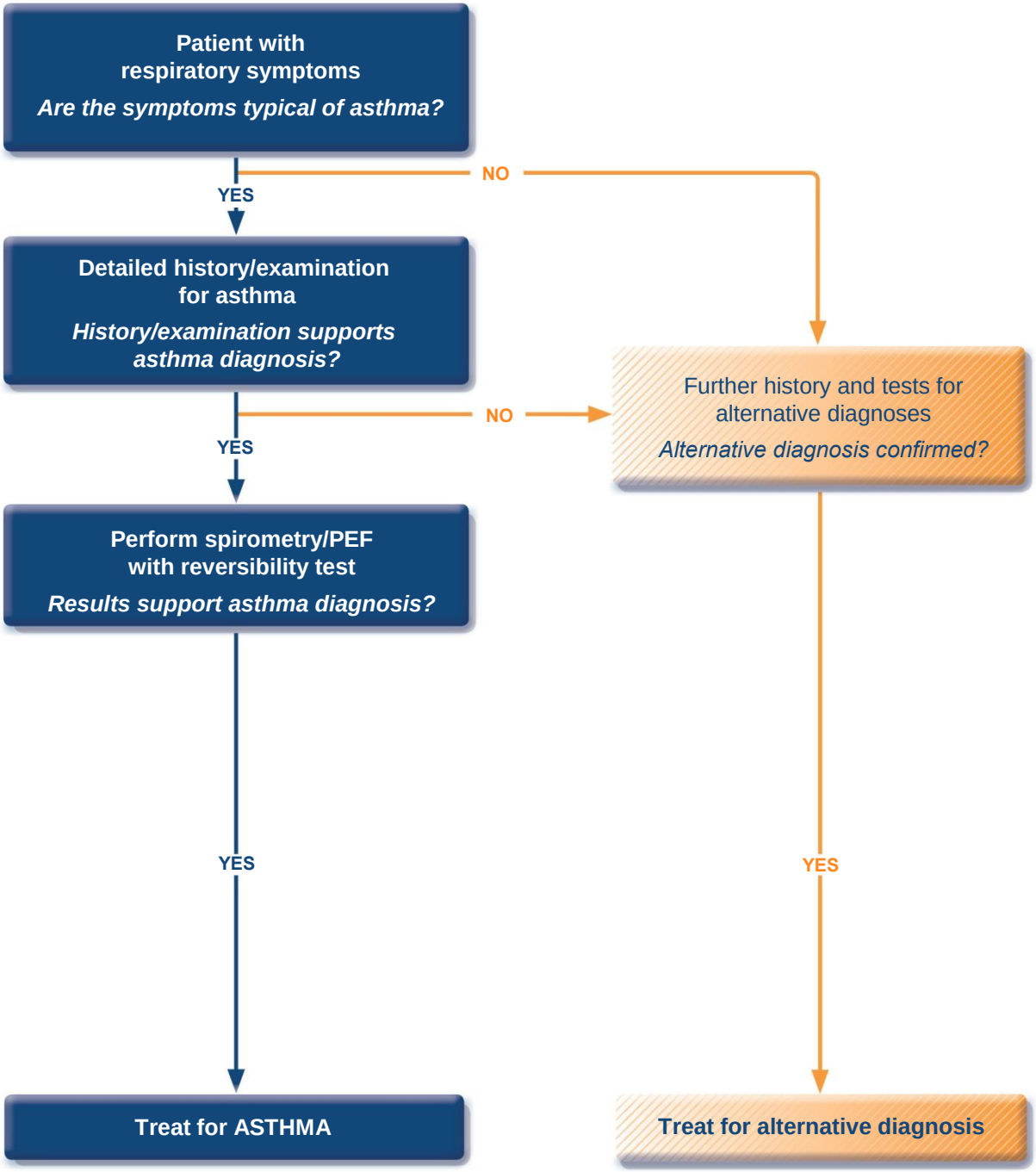
- Evidence
  - Direct evidence from two large studies of non-inferiority for severe exacerbations vs daily low dose ICS + as-needed SABA *(O'Byrne, NEJMed 2018, Bateman, NEJMed 2018)*
  - Direct evidence from one large study of 64% reduction in severe exacerbations vs SABA-only treatment *(O'Byrne, NEJMed 2018)*
  - Symptoms reduced; one study showed reduced exercise-induced bronchoconstriction
- Why?
  - High importance was given to preventing severe exacerbations, **avoiding need for daily ICS in patients with mild or infrequent symptoms,** and safety of as-needed ICS-formoterol in maintenance and reliever therapy, with no new safety signals found (no new risks)
  - Makes use of normal patient behavior (seeking symptom relief) to deliver controller

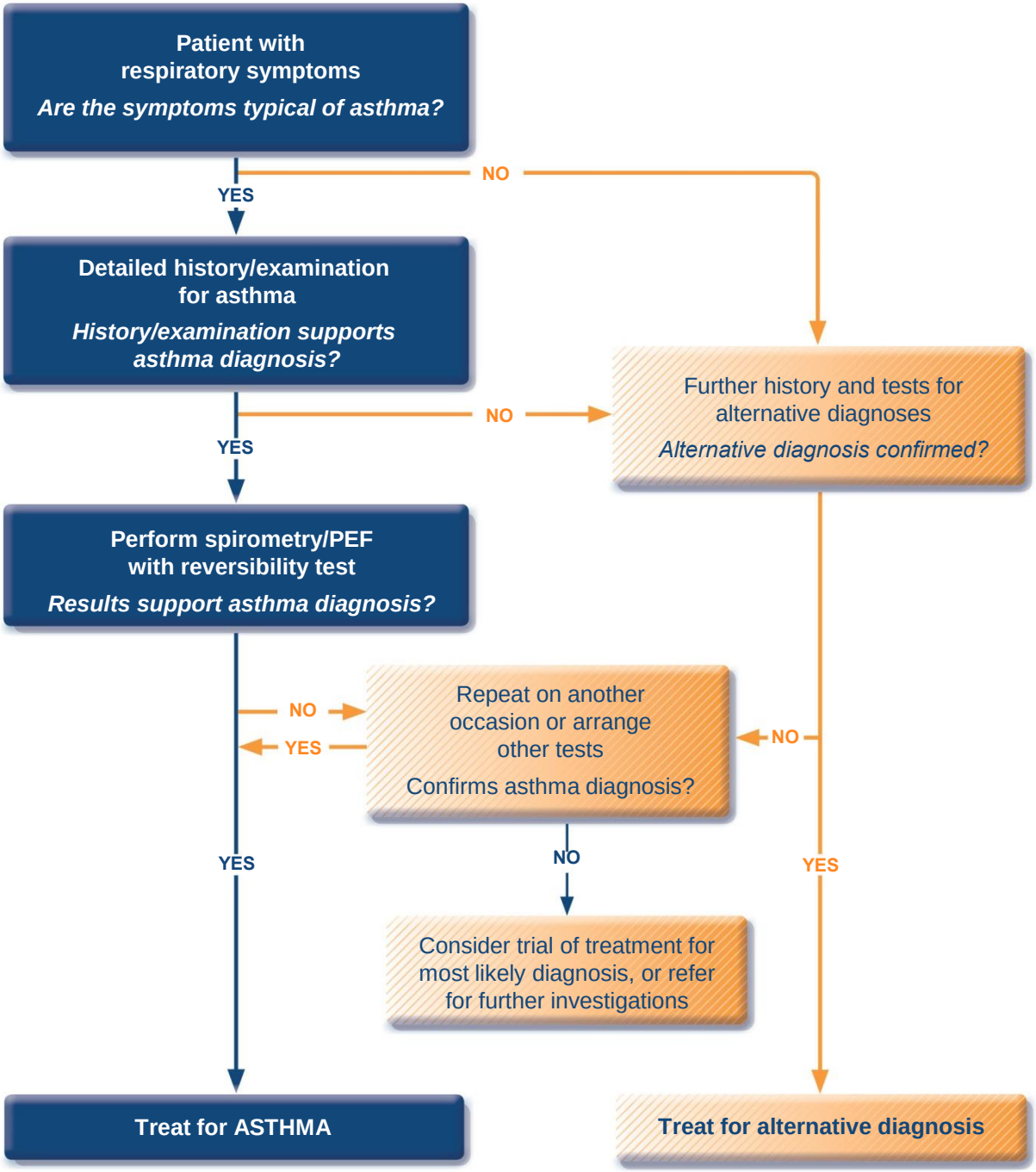
# Key changes – other treatment

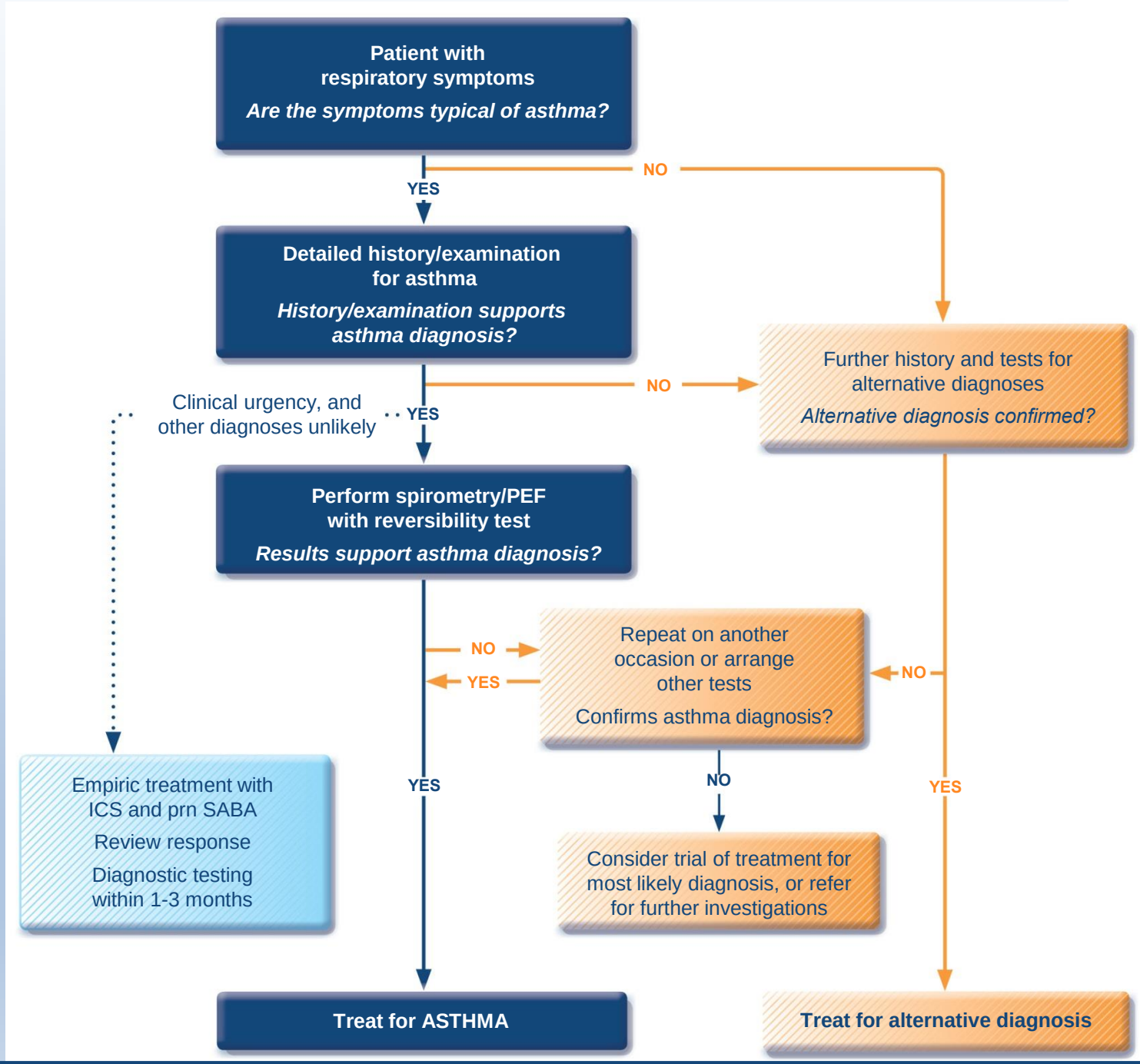
- Step 5 treatment for severe asthma
  - Biologics for asthma are very effective
- Step-down from low-dose ICS
  - Add-on LTRA may help (for ATOPIC patients montelukast is mandatory)
- Side-effects of oral corticosteroids
  - When prescribing short-term OCS, remember to advise patients about common side-effects (sleep disturbance, increased appetite, reflux, mood changes); references added
- Vitamin D
  - To date, there is minimal evidence that Vitamin D supplementation leads to improved asthma control or fewer exacerbations. Checking vitamin D levels is reasonable in those with uncontrolled asthma and some data supporting treating those with very low levels.
- Chronic sinonasal disease
  - Treatment with nasal corticosteroids improves sinonasal symptoms but not asthma outcomes

# Diagnosis of asthma (be brave!)





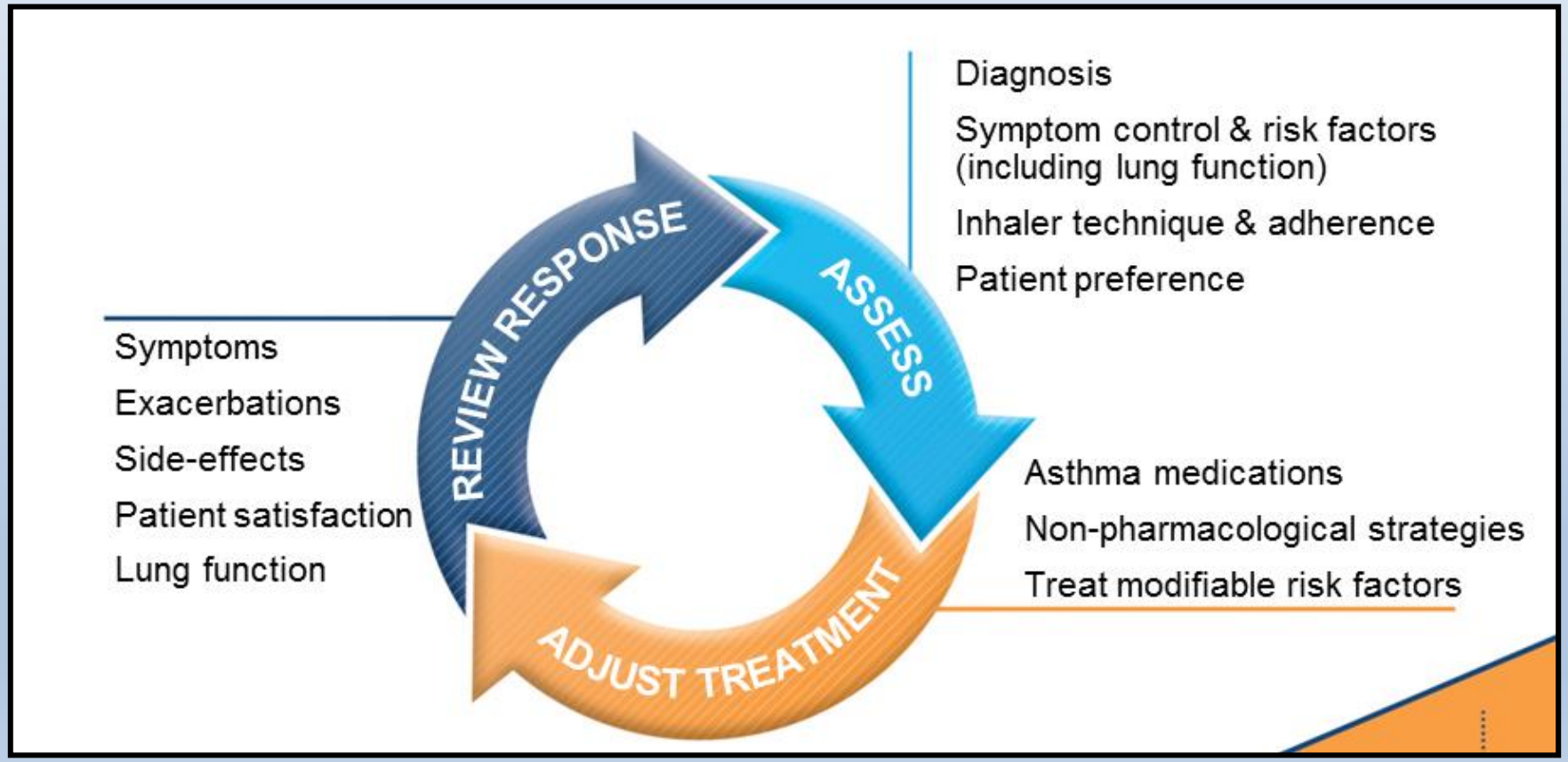




# Diagnosis of asthma – variable airflow limitation

- Confirm presence of airflow limitation
  - Document that $FEV_1$/FVC is reduced (at least once, when $FEV_1$ is low)
  - $FEV_1$/ FVC ratio is normally >0.75 – 0.80 in healthy adults, and >0.90 in children
- Confirm variation in lung function is greater than in healthy individuals
  - The greater the variation, or the more times variation is seen, the greater probability that the diagnosis is asthma
  - **Excessive bronchodilator reversibility (adults: increase in $FEV_1$ >12% and >200mL; children: increase >12% predicted)**
  - Excessive diurnal variability from 1-2 weeks' twice-daily PEF monitoring (daily amplitude x 100/daily mean, averaged)
  - **Significant increase in $FEV_1$ or PEF after 4 weeks of controller treatment**
  - If initial testing is negative:
    - Repeat when patient is symptomatic, or after withholding bronchodilators
    - Refer for additional tests (especially children ≤5 years, or the elderly)

# Assessment of asthma



**Keep it simple!**

**Determine if they are in control or not. . . .**

# Asthma Control:

- When asthma is well-controlled, patients can
  - ✓ Avoid troublesome symptoms during the day and night
  - ✓ Need little or no reliever medication
  - ✓ Have productive, physically active lives
  - ✓ Have normal or near-normal lung function
  - ✓ Avoid serious asthma flare-ups (also called exacerbations, or severe attacks)
  - ✓ REMEMBER THE RULE OF 2s

# Assessment of asthma

1. Asthma control
   - Assess symptom control over the last 4 weeks
   - Assess risk factors for poor outcomes, including low lung function
2. Treatment issues
   - Check inhaler technique and adherence
   - Ask about side-effects
   - Does the patient have a written asthma action plan?
   - What are the patient's attitudes and goals for their asthma?
3. Comorbidities
   - Think of rhinosinusitis, GERD, obesity, obstructive sleep apnea, depression, anxiety
   - These may contribute to symptoms and poor quality of life

# Assessment of symptom control

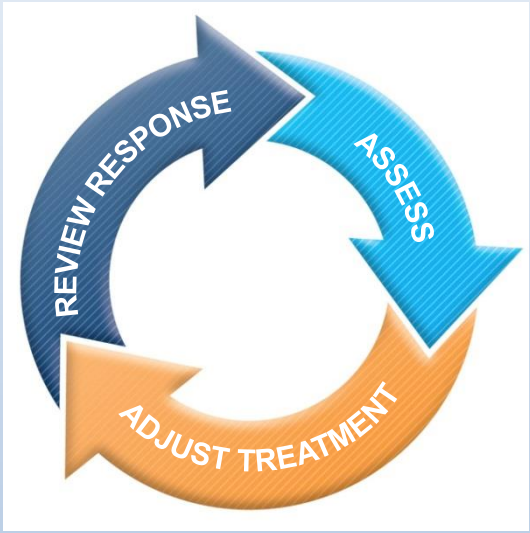
| A. Symptom control | | Level of asthma symptom control | | |
|---|---|---|---|---|
| **In the past 4 weeks, has the patient had:** | | **Well-controlled** | **Partly controlled** | **Uncontrolled** |
| • Daytime asthma symptoms more than twice a week? | Yes❑ No❑ | None of these | 1-2 of these | 3-4 of these |
| • Any night waking due to asthma? | Yes❑ No❑ | | | |
| • Reliever needed for symptoms* more than twice a week? | Yes❑ No❑ | | | |
| • Any activity limitation due to asthma? | Yes❑ No❑ | | | |

Two quick tips:

1. Excludes reliever taken before exercise, because many people take this routinely
2. WHY they reached for their inhaler is just as important as the fact that they used it

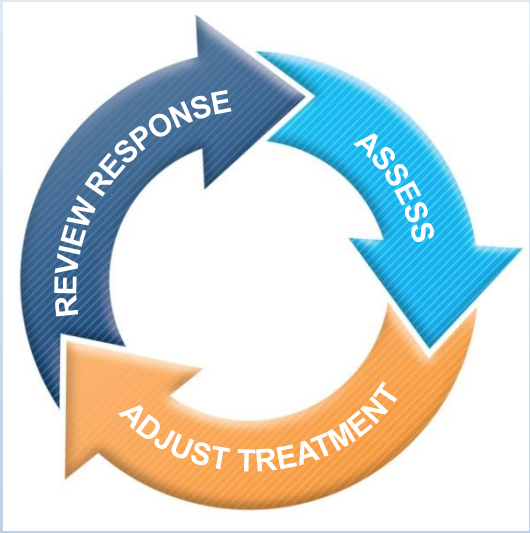
# Treating to control symptoms and minimize risk

- Establish a patient-PA partnership
- Manage asthma in a continuous cycle:
  - **Assess**
  - **Adjust** treatment (pharmacological and non-pharmacological)
  - **Review** the response
- Teach and reinforce essential skills
  - Inhaler skills
  - Adherence
  - Guided self-management education
    - Written asthma action plan
    - Self-monitoring
    - Regular medical review



# Treating to control symptoms and minimize risk

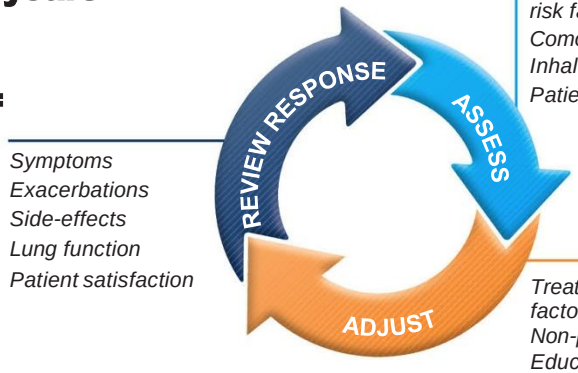
- BUT! Treatment with a controller is more than just reducing symptoms – remember its about reducing exacerbations and reducing risk



Box 3-5A

## Adults & adolescents 12+ years

**Personalized asthma management:**
Assess, Adjust, Review response




*Confirmation of diagnosis if necessary*
*Symptom control & modifiable risk factors (including lung function)*
*Comorbidities*
*Inhaler technique & adherence*
*Patient goals*

*Symptoms*
*Exacerbations*
*Side-effects*
*Lung function*
*Patient satisfaction*

*Treatment of modifiable risk factors & comorbidities*
*Non-pharmacological strategies*
*Education & skills training*
*Asthma medications*

**Asthma medication options:**
Adjust treatment up and down for individual patient needs

| | STEP 1 | STEP 2 | STEP 3 | STEP 4 | STEP 5 |
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| **PREFERRED CONTROLLER** to prevent exacerbations and control symptoms | As-needed low dose ICS-formoterol * | Daily low dose inhaled corticosteroid (ICS), or as-needed low dose ICS-formoterol * | Low dose ICS-LABA | Medium dose ICS-LABA | High dose ICS-LABA<br>Refer for phenotypic assessment ± add-on therapy, e.g.tiotropium, anti-IgE, anti-IL5/5R, anti-IL4R |
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| **PREFERRED RELIEVER** | As-needed low dose ICS-formoterol * | | As-needed low dose ICS-formoterol ‡ | | |
| *Other reliever option* | *As-needed short-acting $\beta_2$ -agonist (SABA)* | | | | |

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# Consider adding HDM SLIT for sensitized patients with allergic rhinitis and FEV >70% predicted

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'Controller' treatment means the treatment taken to prevent exacerbations

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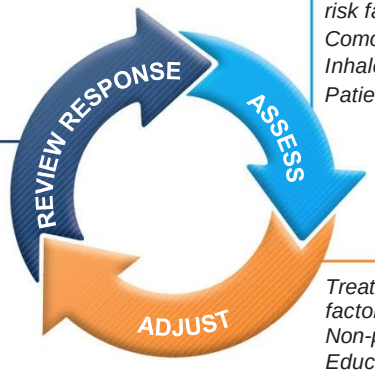


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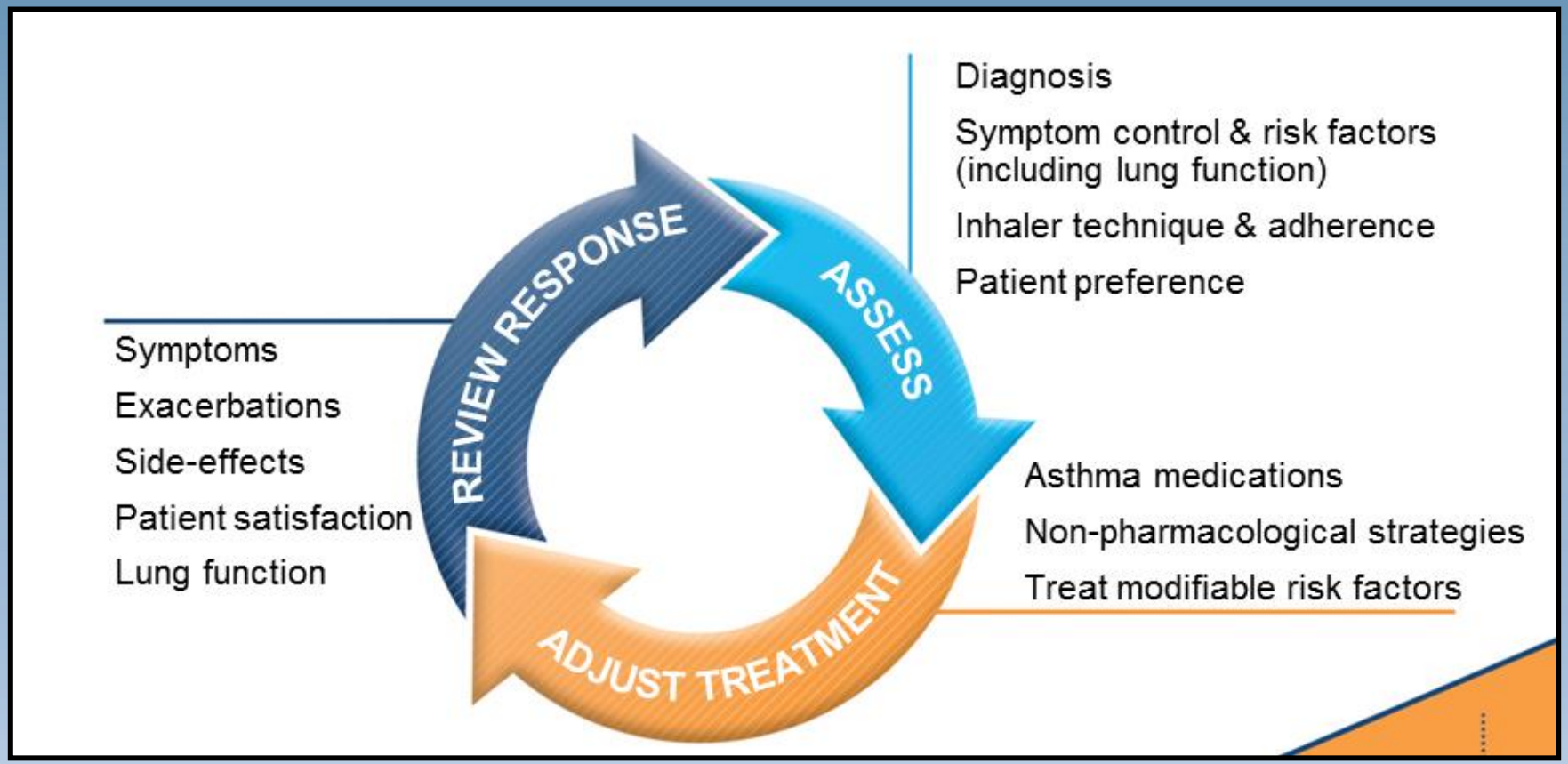
# Step 1 to Step 2



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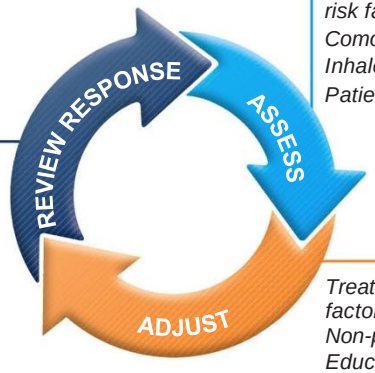


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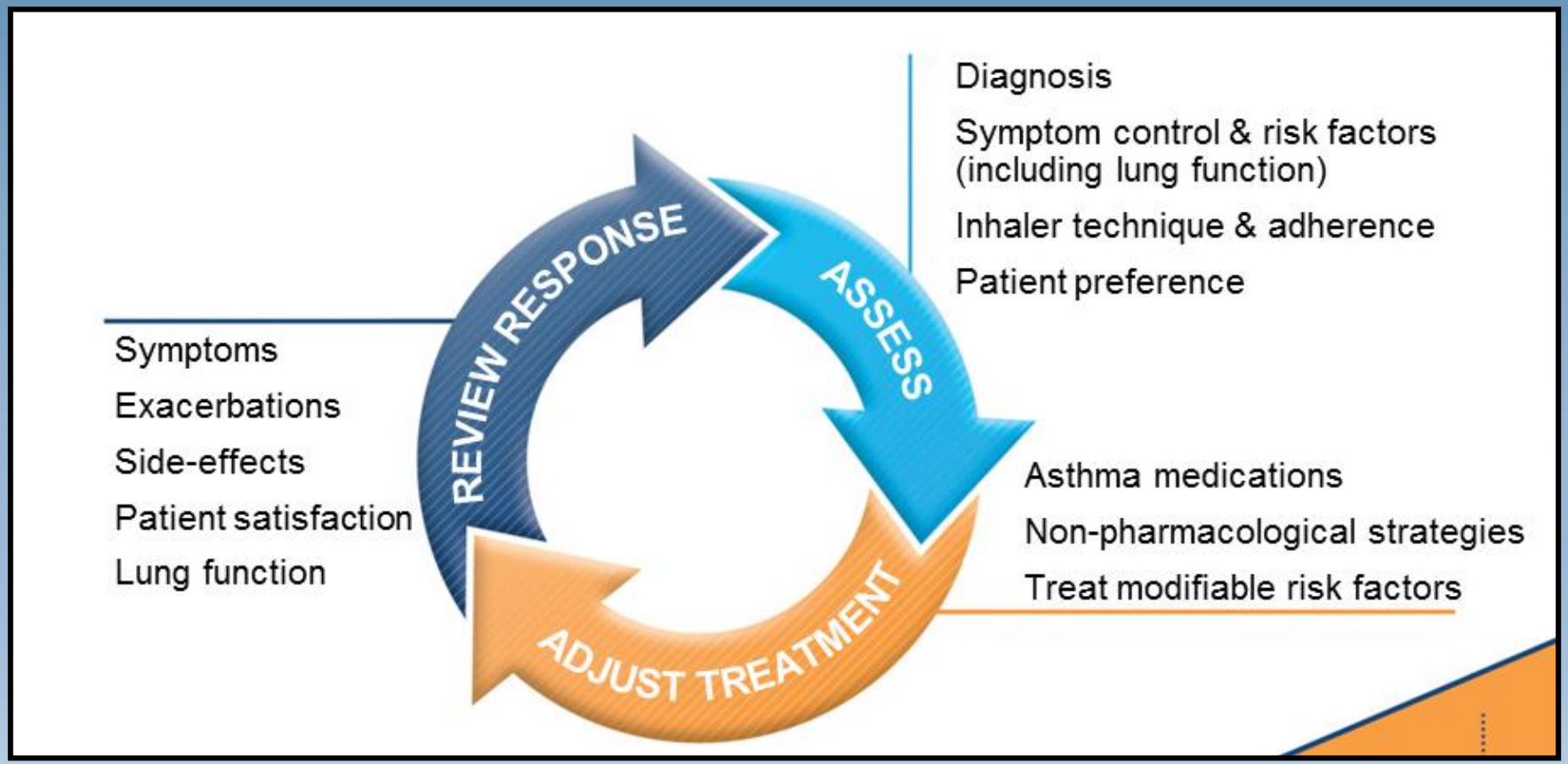
Start to look for ALLERGY symptoms, SINUSITIS symptoms, GERD symptoms

# Step 2 to Step 3



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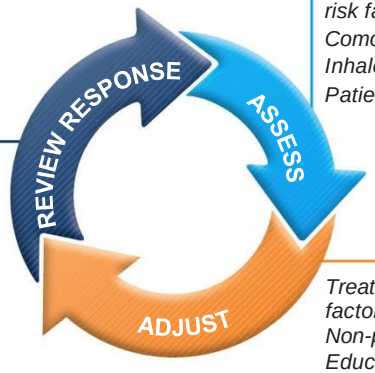


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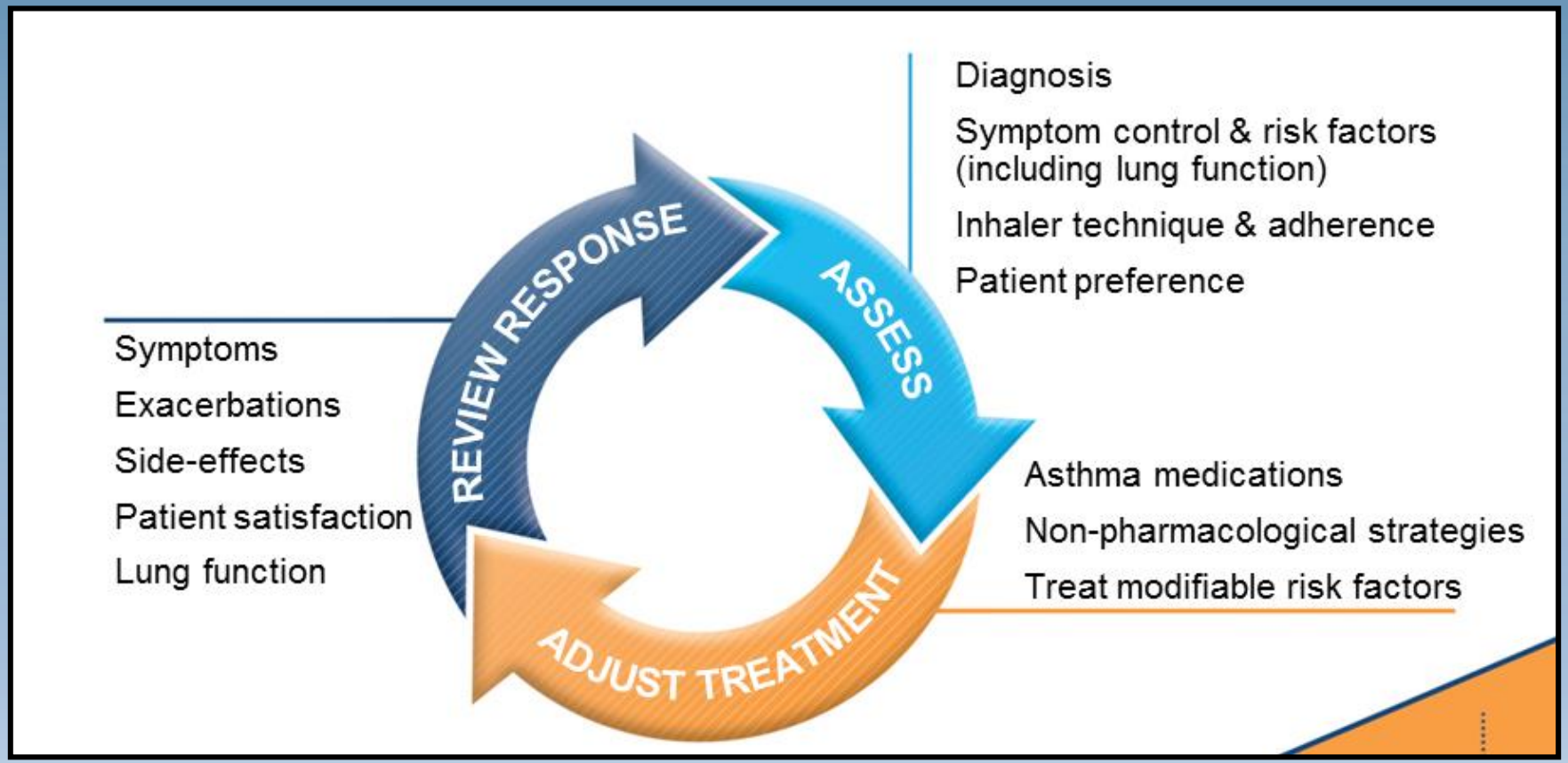
Again: co-morbid conditions, check inhaler technique, add in a spacer. If older. . can they inhale?

# Step 3 to Step 4&5



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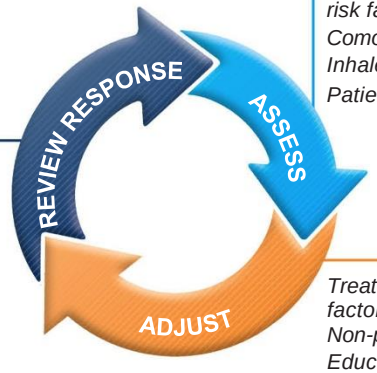


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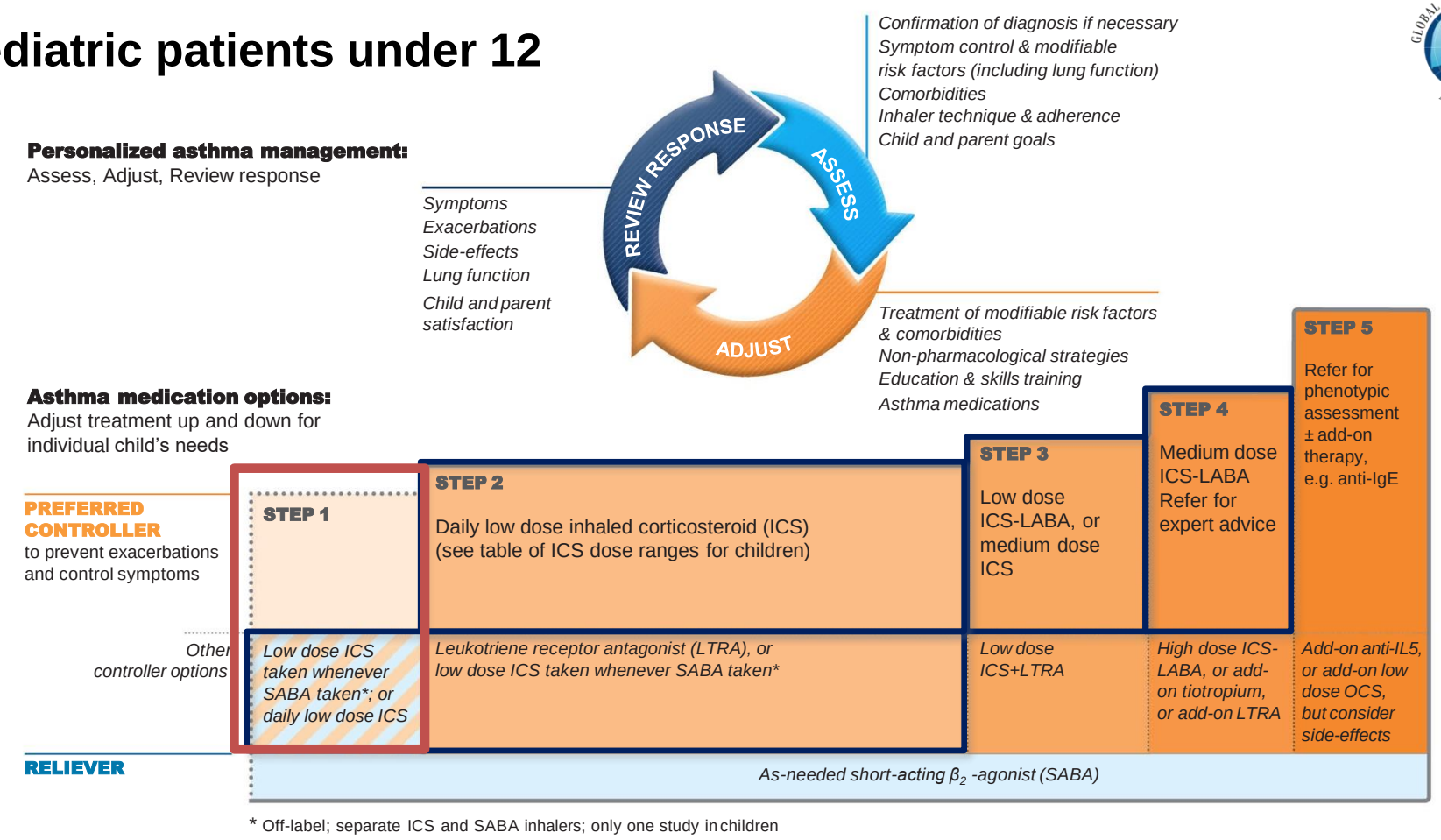
| | STEP 1 | STEP 2 | STEP 3 | STEP 4 | STEP 5 |
|---|---|---|---|---|---|
| **PREFERRED CONTROLLER** to prevent exacerbations and control symptoms | As-needed low dose ICS-formoterol * | Daily low dose inhaled corticosteroid (ICS), or as-needed low dose ICS-formoterol * | Low dose ICS-LABA | Medium dose ICS-LABA | High dose ICS-LABA<br>Refer for phenotypic assessment ± add-on therapy, e.g.tiotropium, anti-IgE, anti-IL5/5R, anti-IL4R |
| *Other controller options* | *Low dose ICS taken whenever SABA is taken †* | *Leukotriene receptor antagonist (LTRA), or low dose ICS taken whenever SABA taken †* | *Medium dose ICS, or low dose ICS+LTRA #* | *High dose ICS, add-on tiotropium, or add-on LTRA #* | *Add low dose OCS, but consider side-effects* |
| **PREFERRED RELIEVER** | As-needed low dose ICS-formoterol * | | As-needed low dose ICS-formoterol ‡ | | |
| *Other reliever option* | *As-needed short-acting $\beta_2$ -agonist (SABA)* | | | | |

* Off-label; data only with budesonide-formoterol (bud-form)
† Off-label; separate or combination ICS and SABA inhalers
‡ Low-dose ICS-form is the reliever for patients prescribed bud-form or BDP-form maintenance and reliever therapy
# Consider adding HDM SLIT for sensitized patients with allergic rhinitis and FEV >70% predicted



High dose, add in tiotropium, check inhaler technique but please refer these patients, biologics are life changing

# Pediatric patients under 12




* Off-label; separate ICS and SABA inhalers; only one study in children

# Low, medium and high dose inhaled corticosteroids Adults and adolescents (≥12 years)

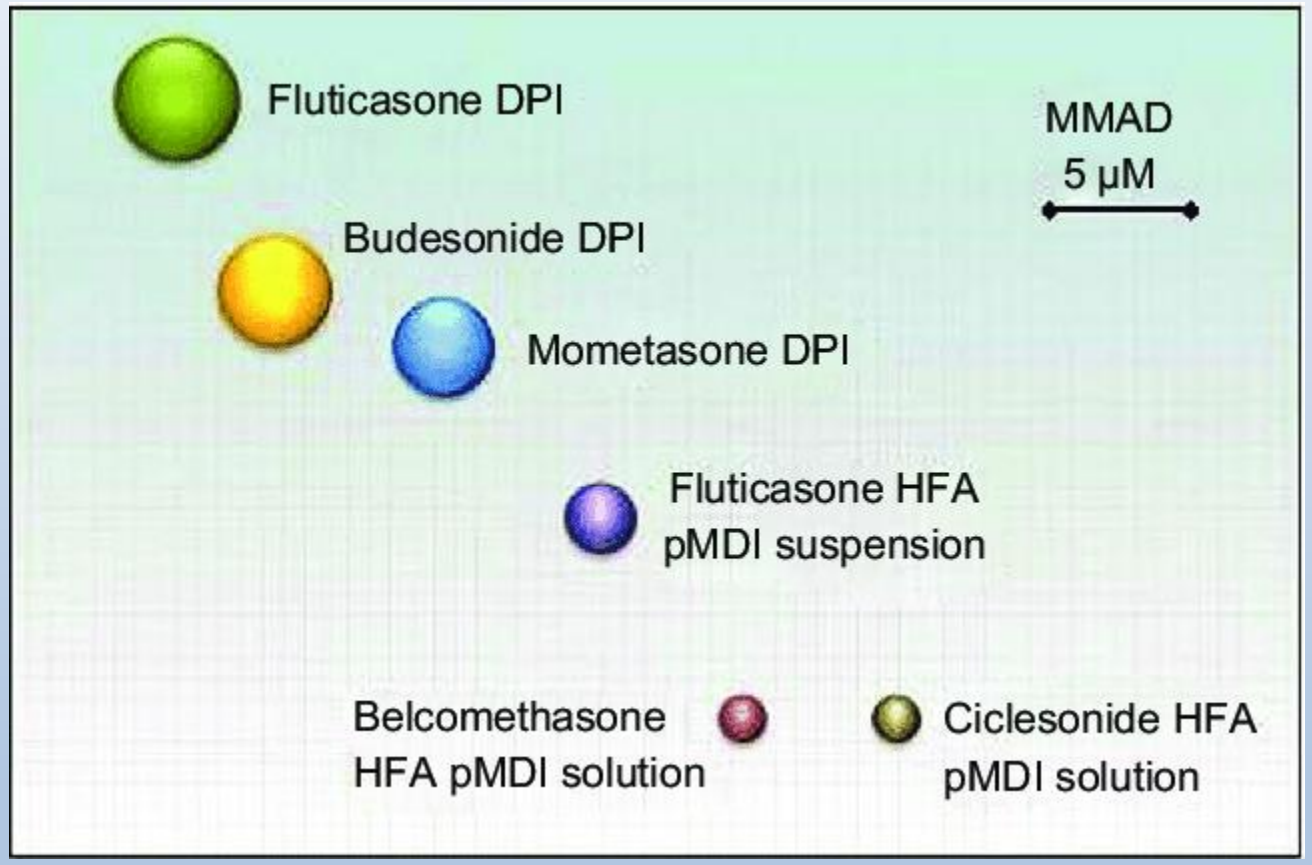
| Inhaled corticosteroid | Total daily dose (mcg) | | |
|---|---|---|---|
| | Low | Medium | High |
| Beclometasone dipropionate (CFC) | 200–500 | >500–1000 | >1000 |
| Beclometasone dipropionate (HFA) | 100–200 | >200–400 | >400 |
| Budesonide (DPI) | 200–400 | >400–800 | >800 |
| Ciclesonide (HFA) | 80–160 | >160–320 | >320 |
| Fluticasone furoate (DPI) | 100 | n.a. | 200 |
| Fluticasone propionate (DPI or HFA) | 100–250 | >250–500 | >500 |
| Mometasone furoate | 110–220 | >220–440 | >440 |
| Triamcinolone acetonide | 400–1000 | >1000–2000 | >2000 |

- This is not a table of equivalence, but of estimated clinical comparability
- Most of the clinical benefit from ICS is seen at low doses
- High doses are arbitrary, but for most ICS are those that, with prolonged use, are associated with increased risk of systemic side-effects

# Low, medium and high dose inhaled corticosteroids Children 6–11 years

| Inhaled corticosteroid | Total daily dose (mcg) | | |
|---|---|---|---|
| | Low | Medium | High |
| Beclometasone dipropionate (CFC) | 100–200 | >200–400 | >400 |
| Beclometasone dipropionate (HFA) | 50–100 | >100–200 | >200 |
| Budesonide (DPI) | 100–200 | >200–400 | >400 |
| Budesonide (nebules) | 250–500 | >500–1000 | >1000 |
| Ciclesonide (HFA) | 80 | >80–160 | >160 |
| Fluticasone furoate (DPI) | n.a. | n.a. | n.a. |
| Fluticasone propionate (DPI) | 100–200 | >200–400 | >400 |
| Fluticasone propionate (HFA) | 100–200 | >200–500 | >500 |
| Mometasone furoate | 110 | ≥220–<440 | ≥440 |
| Triamcinolone acetonide | 400–800 | >800–1200 | >1200 |

- This is not a table of equivalence, but of estimated clinical comparability
- Most of the clinical benefit from ICS is seen at low doses
- High doses are arbitrary, but for most ICS are those that, with prolonged use, are associated with increased risk of systemic side-effects


Fluticasone DPI
MMAD
5 µM
Budesonide DPI
Mometasone DPI
Fluticasone HFA
pMDI suspension
Belcomethasone
HFA pMDI solution
Ciclesonide HFA
pMDI solution

# Reviewing response and adjusting treatment


- How often should asthma be reviewed?
  - 1-3 months after treatment started, then every 3-12 months
  - During pregnancy, every 4-6 weeks
  - After an exacerbation, within 1 week
- Stepping up asthma treatment
  - *Sustained step-up*, for at least 2-3 months if asthma poorly controlled
    - Important: first check for common causes (symptoms not due to asthma, incorrect inhaler technique, poor adherence)
  - *Short-term step-up*, for 1-2 weeks, e.g. with viral infection or allergen
    - May be initiated by patient with written asthma action plan
  - *Day-to-day adjustment*
    - For patients prescribed low-dose ICS/formoterol maintenance and reliever regimen*
- Stepping down asthma treatment
  - Consider step-down after good control maintained for 3 months
  - Find each patient's minimum effective dose, that controls both symptoms and exacerbations

# Treating modifiable risk factors

- Provide skills and support for guided asthma self-management
  - This comprises self-monitoring of symptoms and/or PEF,  a written asthma action plan and regular medical review
- Encourage avoidance of tobacco smoke
  - Provide smoking cessation advice and resources at every visit
- GERD
  - Treat or refer for this.  It good deal of people have asthma improve once this is controlled
- Nasal congestion and post-nasal drip
  - Treat this aggressively.  REMEMBER that older individual especially have cholinergic, not allergic rhinitis.  Ipratropium Nasal is wonderful for this.

# Check adherence with asthma medications

- Poor adherence:
  - Is very common: it is estimated that 50% of adults and children do not take controller medications as prescribed
  - Contributes to uncontrolled asthma symptoms and risk of exacerbations and asthma-related death
- Contributory factors
  - Unintentional (e.g. forgetfulness, cost, confusion) and/or
  - Intentional (e.g. no perceived need, fear of side-effects, cultural issues, cost)
- How to identify patients with low adherence:
  - Ask an empathic question, e.g. "*Do you find it easier to remember your medication in the morning or the evening?*", or "*Would you say you are taking it 3 days a week, or less, or more?*"
  - Check prescription date, label date and dose counter
  - Ask patient about their beliefs and concerns about the medication

# The Exacerbation -

- Prednisone – treat aggressively.  No need to taper for most.
  - Kids – ok to treat QD!  0.5 mg/kg or more.
  - Adults – 40 mg minimum, many need more.  Dose in AM with food. Sugar changes are transient.
  - Bump up therapy  - short term combination therapy etc.
- The opportunity
  - Exacerbations often represent failures in chronic asthma care, and they provide opportunities to review the patient's asthma management
- At follow-up visit(s), check:
  - The patient's understanding of the cause of the flare-up
  - Modifiable risk factors, e.g. smoking
  - Adherence with medications, and understanding of their purpose
  - Inhaler technique skills
  - Written asthma action plan

# A Note on FeNO

- FeNO is a great test to measure the amount of Nitric Oxide in exhaled breath
- Exhaled Nitric Oxide is a very good way to TRACK allergic asthma (so great for kids)
- Exhaled Nitric Oxide is not great to diagnose asthma by itself.
- There is no better way to track asthma flares and to confirm use of controller inhalers - not peak flow and not spirometry
- Cheap and cost effective.

# A Note on Nebulizers

- Nebulizers are a known quantity – this can be helpful
- Avoid reliance on them for those school age and older but don't be afraid to keep them around
- If using budesonide its ok to add albuterol/ipratropium in the same treatment
- Over 2 years should be both albuterol/ipratropium, under 2 it's anyone's guess.
- OK to give ½ treatment before bed etc
- Move your senior patients with asthma or COPD to nebulized budesonide with Brovana or Perforomist if they are struggling or have poor inspiratory capacity

# How to treat Hard-to-treat asthma?

# Terminology

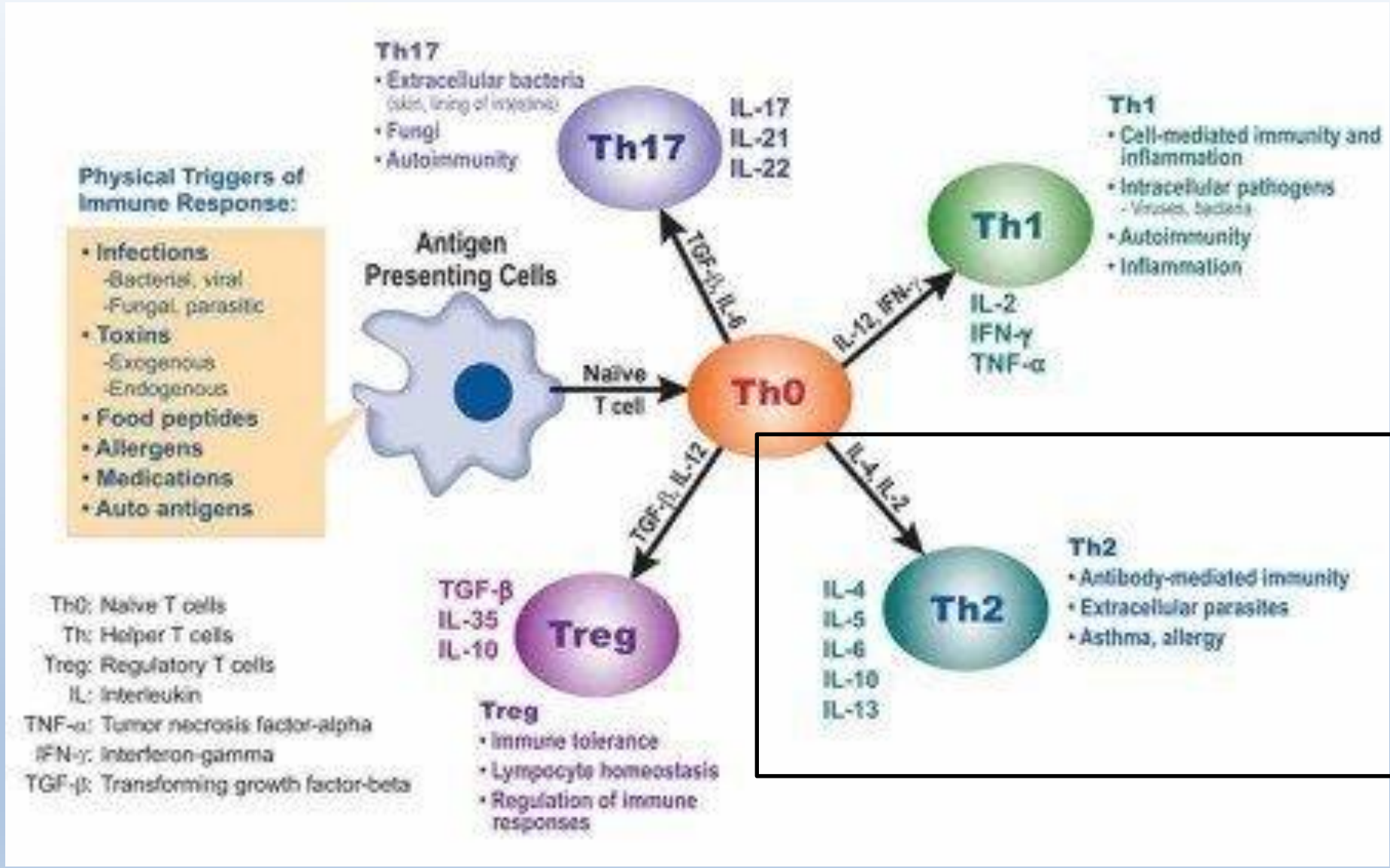
- Uncontrolled asthma
  - Frequent symptoms and/or flare-ups (exacerbations)
  - Many of these patients may potentially have mild asthma, i.e. their asthma could be well-controlled with low dose ICS, if taken regularly
- Difficult-to-treat asthma
  - (not difficult patients!)
  - Asthma uncontrolled despite prescribing high dose preventer treatment
  - Contributory factors may include incorrect diagnosis, incorrect inhaler technique, poor adherence, comorbidities
- Severe asthma
  - "Severe asthma" has had many different meanings *(Taylor, ERJ 2008; Reddel AJRCCM 2009)*
  - Now defined as asthma that is uncontrolled despite maximal optimised therapy and treatment of contributory factors, or that worsens when high dose treatment is decreased *(Chung, ERJ 2014)*

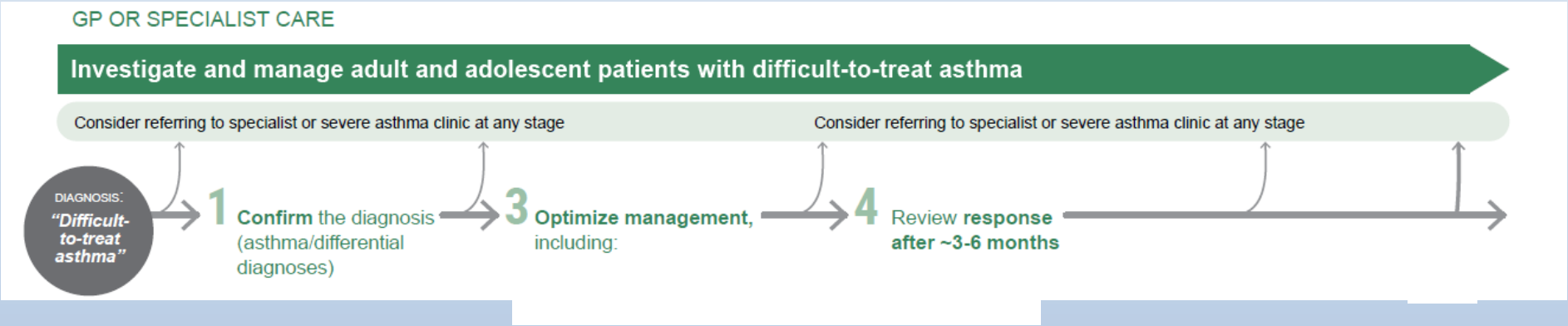
  i.e. relatively refractory to corticosteroids (rarely completely refractory)

  A retrospective definition, dependent on how thoroughly contributory factors are excluded

# Terminology

- **Phenotype**: The observable characteristics of a disease, such as morphology, development, biochemical or physiological properties, or behaviour.
  - Patients with an identified phenotype of obstructive lung disease may share a cluster of clinical, functional and/or inflammatory features, without any implication of a common underlying mechanism
  - Examples: allergic asthma, aspirin-exacerbated respiratory disease, severe eosinophilic asthma
  - Examples: emphysema due to alpha1-antitrypsin deficiency
- **Biomarker**: A defined characteristic measured as an indicator of normal biologic processes, pathogenic processes or response to an intervention
  - Potential examples: FeNO, blood eosinophils – but these may not meet quality criteria for biomarkers


Th17
• Extracellular bacteria
(skin, lining of intestine)
• Fungi
• Autoimmunity
Th17
IL-17
IL-21
IL-22
Th1
• Cell-mediated immunity and inflammation
• Intracellular pathogens
- Viruses, bacteria
• Autoimmunity
• Inflammation
Th1
IL-2
IFN-γ
TNF-α
Physical Triggers of Immune Response:
• Infections
-Bacterial, viral
-Fungal, parasitic
• Toxins
-Exogenous
-Endogenous
• Food peptides
• Allergens
• Medications
• Auto antigens
Antigen Presenting Cells
TGF-β, IL-6
IL-12, IFN-γ
Naïve T cell
Th0
TGF-β, IL-12
IL-4, IL-2
TGF-β
IL-35
IL-10
Treg
Treg
• Immune tolerance
• Lympocyte homeostasis
• Regulation of immune responses
IL-4
IL-5
IL-6
IL-10
IL-13
Th2
Th2
• Antibody-mediated immunity
• Extracellular parasites
• Asthma, allergy
Th0: Naive T cells
Th: Helper T cells
Treg: Regulatory T cells
IL: Interleukin
TNF-α: Tumor necrosis factor-alpha
IFN-γ: Interferon-gamma
TGF-β: Transforming growth factor-beta



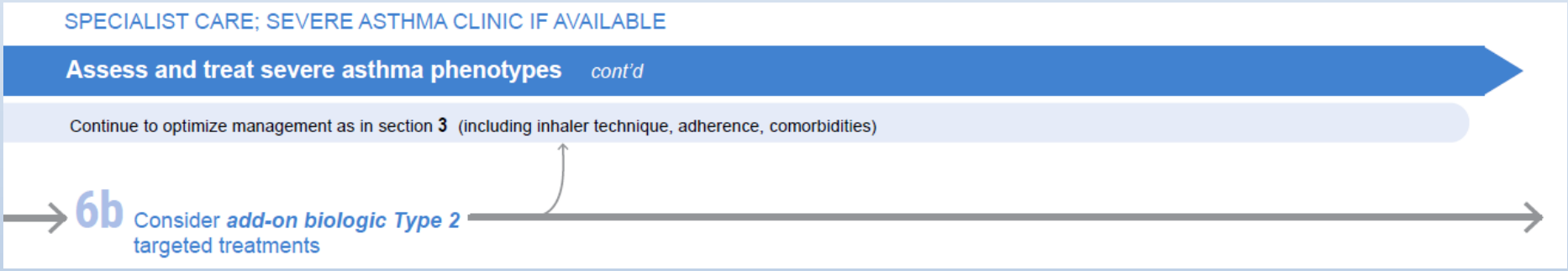
SPECIALIST CARE; SEVERE ASTHMA CLINIC IF AVAILABLE

**Assess and treat severe asthma phenotypes**

Continue to optimize management as in section **3** (including inhaler technique, adherence, comorbidities)

**5** Assess the **severe asthma phenotype** and factors contributing to symptoms, quality of life and exacerbations

**6a** Consider ***non-biologic*** treatments



SPECIALIST CARE; SEVERE ASTHMA CLINIC IF AVAILABLE

## Assess and treat severe asthma phenotypes

Continue to optimize management as in section **3** (including inhaler technique, adherence, comorbidities)

**5** Assess the **severe asthma phenotype** and factors contributing to symptoms, quality of life and exacerbations

***Assess the severe asthma phenotype during high dose ICS treatment*** *(or lowest possible dose of OCS)*

**Type 2 inflammation**

*Could patient have Type 2 airway inflammation?*

- Blood eosinophils ≥150/µl and/or
- FeNO ≥20 ppb and/or
- Sputum eosinophils ≥2%, and/or
- Asthma is clinically allergen-driven and/or
- Need for maintenance OCS

(Repeat blood eosinophils and FeNO up to 3x, on lowest possible OCS dose)

*Note: these are not the criteria for add-on biologic therapy (see* **6b***)*

*yes*

*no*

***Investigate for comorbidities/differential diagnoses*** *and treat/refer as appropriate*

- Consider: CBC, CRP, IgG, IgA, IgM, IgE, fungal precipitins; CXR and/or HRCT chest; DLCO
- Skin prick testing or specific IgE for relevant allergens, if not already done
- Other directed testing (e.g. ANCA, CT sinuses, BNP, echocardiogram) based on clinical suspicion

***Consider need for social/psychological support***

***Involve multidisciplinary team care (if available)***

***Invite patient to enroll in registry (if available) or clinical trial (if appropriate)***

**6a** Consider ***non-biologic*** treatments

- Consider adherence tests
- Consider increasing the ICS dose for 3-6 months
- Consider AERD, ABPA, chronic rhinosinusitis, nasal polyposis, atopic dermatitis (clinical Type 2 phenotypes with specific add-on treatment)

*Is add-on Type 2 biologic therapy available/ affordable?*

*no*

***If add-on Type 2 biologic therapy is NOT available/affordable***

- Consider higher dose ICS, if not used
- Consider non-biologic add-on therapy (e.g. LABA, tiotropium, LM/LTRA, macrolide*)
- Consider add-on low dose OCS, but implement strategies to minimize side-effects
- Stop ineffective add-on therapies

***If no evidence of Type 2 inflammation:***

- Review the basics: differential diagnosis, inhaler technique, adherence, comorbidities, side-effects
- Avoid exposures (tobacco smoke, allergens, irritants)
- Consider investigations (if available and not done)
  - Sputum induction
  - High resolution chest CT
  - Bronchoscopy for alternative/additional diagnoses
- Consider add-on treatments
  - Trial of tiotropium or macrolide* (if not already tried)
  - Consider add-on low dose OCS, but implement strategies to minimize side-effects
  - Stop ineffective add-on therapies
- Consider bronchial thermoplasty (+ registry)

*Not currently eligible for biologics*

**Off-label*

SPECIALIST CARE; SEVERE ASTHMA CLINIC IF AVAILABLE

## Assess and treat severe asthma phenotypes *cont'd*

Continue to optimize management as in section **3** (including inhaler technique, adherence, comorbidities)

**6b** Consider ***add-on biologic Type 2*** targeted treatments

- Consider add-on Type 2-targeted biologic for patients with exacerbations or poor symptom control on high dose ICS-LABA, who:
  - have eosinophilic or allergic biomarkers, or
  - need maintenance OCS
- Consider **local payer eligibility criteria** and **predictors of response** when choosing between available therapies
- Also consider cost, dosing frequency, route (SC or IV), patient preference

*Check local eligibility criteria for specific biologic therapies as these may vary from those listed*

SPECIALIST CARE; SEVERE ASTHMA CLINIC IF AVAILABLE

## Assess and treat severe asthma phenotypes *cont'd*

Continue to optimize management as in section **3** (including inhaler technique, adherence, comorbidities)

**6b** Consider ***add-on biologic Type 2*** targeted treatments

- Consider add-on Type 2-targeted biologic for patients with exacerbations or poor symptom control on high dose ICS-LABA, who:
  - have eosinophilic or allergic biomarkers, or
  - need maintenance OCS
- Consider **local payer eligibility criteria** and **predictors of response** when choosing between available therapies
- Also consider cost, dosing frequency, route (SC or IV), patient preference

*Which biologic is appropriate to start first?*

**Anti-IgE**

*Is the patient eligible for **anti-IgE** for severe allergic asthma?*

- Sensitization on skin prick testing or specific IgE
- Total serum IgE and weight within dosage range
- Exacerbations in last year

*no* / *no*

**Anti-IL5 / Anti-IL5R**

*Is the patient eligible for **anti-IL5 / anti-IL5R** for severe eosinophilic asthma?*

- Exacerbations in last year
- Blood eosinophils ≥300/µl

*no* / *no*

**Anti-IL4R**

*Is the patient eligible for **anti-IL4R***

*… for severe eosinophilic/Type 2 asthma?*

- Exacerbations in last year
- Blood eosinophils ≥150/µl or FeNO ≥25 ppb

*… or because of need for maintenance OCS?*

*Eligible for none?*
*Return to section* **6a**

*Check local eligibility criteria for specific biologic therapies as these may vary from those listed*

SPECIALIST CARE; SEVERE ASTHMA CLINIC IF AVAILABLE

## Assess and treat severe asthma phenotypes *cont'd*

Continue to optimize management as in section **3** (including inhaler technique, adherence, comorbidities)

### 6b Consider *add-on biologic Type 2* targeted treatments

- Consider add-on Type 2-targeted biologic for patients with exacerbations or poor symptom control on high dose ICS-LABA, who:
  - have eosinophilic or allergic biomarkers, or
  - need maintenance OCS
- Consider **local payer eligibility criteria** and **predictors of response** when choosing between available therapies
- Also consider cost, dosing frequency, route (SC or IV), patient preference

*Which biologic is appropriate to start first?*

**Anti-IgE**

*Is the patient eligible for **anti-IgE** for severe allergic asthma?*

- Sensitization on skin prick testing or specific IgE
- Total serum IgE and weight within dosage range
- Exacerbations in last year

*What factors may predict good asthma response to anti-IgE?*

- Blood eosinophils ≥260/µl ++
- FeNO ≥20 ppb +
- Allergen-driven symptoms +
- Childhood-onset asthma +

*no* / *no*

**Anti-IL5 / Anti-IL5R**

*Is the patient eligible for **anti-IL5 / anti-IL5R** for severe eosinophilic asthma?*

- Exacerbations in last year
- Blood eosinophils ≥300/µl

*What factors may predict good asthma response to anti-IL5/5R?*

- Higher blood eosinophils +++
- More exacerbations in previous year +++
- Adult-onset of asthma ++
- Nasal polyposis ++

*no* / *no*

**Anti-IL4R**

*Is the patient eligible for **anti-IL4R***

*… for severe eosinophilic/Type 2 asthma?*

- Exacerbations in last year
- Blood eosinophils ≥150/µl or FeNO ≥25 ppb

*… or because of need for maintenance OCS?*

*What factors may predict good asthma response to anti-IL4R?*

- Higher blood eosinophils +++
- Higher FeNO +++

*Anti-IL4R may also be used to treat*

- Moderate/severe atopic dermatitis
- Nasal polyposis

*Eligible for none?*
*Return to section* **6a**

*Check local eligibility criteria for specific biologic therapies as these may vary from those listed*

SPECIALIST CARE; SEVERE ASTHMA CLINIC IF AVAILABLE

## Assess and treat severe asthma phenotypes *cont'd*

Continue to optimize management as in section **3** (including inhaler technique, adherence, comorbidities)

**6b** Consider ***add-on biologic Type 2*** targeted treatments

- Consider add-on Type 2-targeted biologic for patients with exacerbations or poor symptom control on high dose ICS-LABA, who:
  - have eosinophilic or allergic biomarkers, or
  - need maintenance OCS
- Consider **local payer eligibility criteria** and **predictors of response** when choosing between available therapies
- Also consider cost, dosing frequency, route (SC or IV), patient preference

*Which biologic is appropriate to start first?*

### Anti-IgE

*Is the patient eligible for **anti-IgE** for severe allergic asthma?*

- Sensitization on skin prick testing or specific IgE
- Total serum IgE and weight within dosage range
- Exacerbations in last year

*no* / *no*

*What factors may predict good asthma response to anti-IgE?*

- Blood eosinophils ≥260/µl ++
- FeNO ≥20 ppb +
- Allergen-driven symptoms +
- Childhood-onset asthma +

### Anti-IL5 / Anti-IL5R

*Is the patient eligible for **anti-IL5 / anti-IL5R** for severe eosinophilic asthma?*

- Exacerbations in last year
- Blood eosinophils ≥300/µl

*no* / *no*

*What factors may predict good asthma response to anti-IL5/5R?*

- Higher blood eosinophils +++
- More exacerbations in previous year +++
- Adult-onset of asthma ++
- Nasal polyposis ++

### Anti-IL4R

*Is the patient eligible for **anti-IL4R***

*… for severe eosinophilic/Type 2 asthma?*

- Exacerbations in last year
- Blood eosinophils ≥150/µl or FeNO ≥25 ppb

*… or because of need for maintenance OCS?*

*What factors may predict good asthma response to anti-IL4R?*

- Higher blood eosinophils +++
- Higher FeNO +++

*Anti-IL4R may also be used to treat*

- Moderate/severe atopic dermatitis
- Nasal polyposis

*Eligible for none?*
*Return to section* **6a**

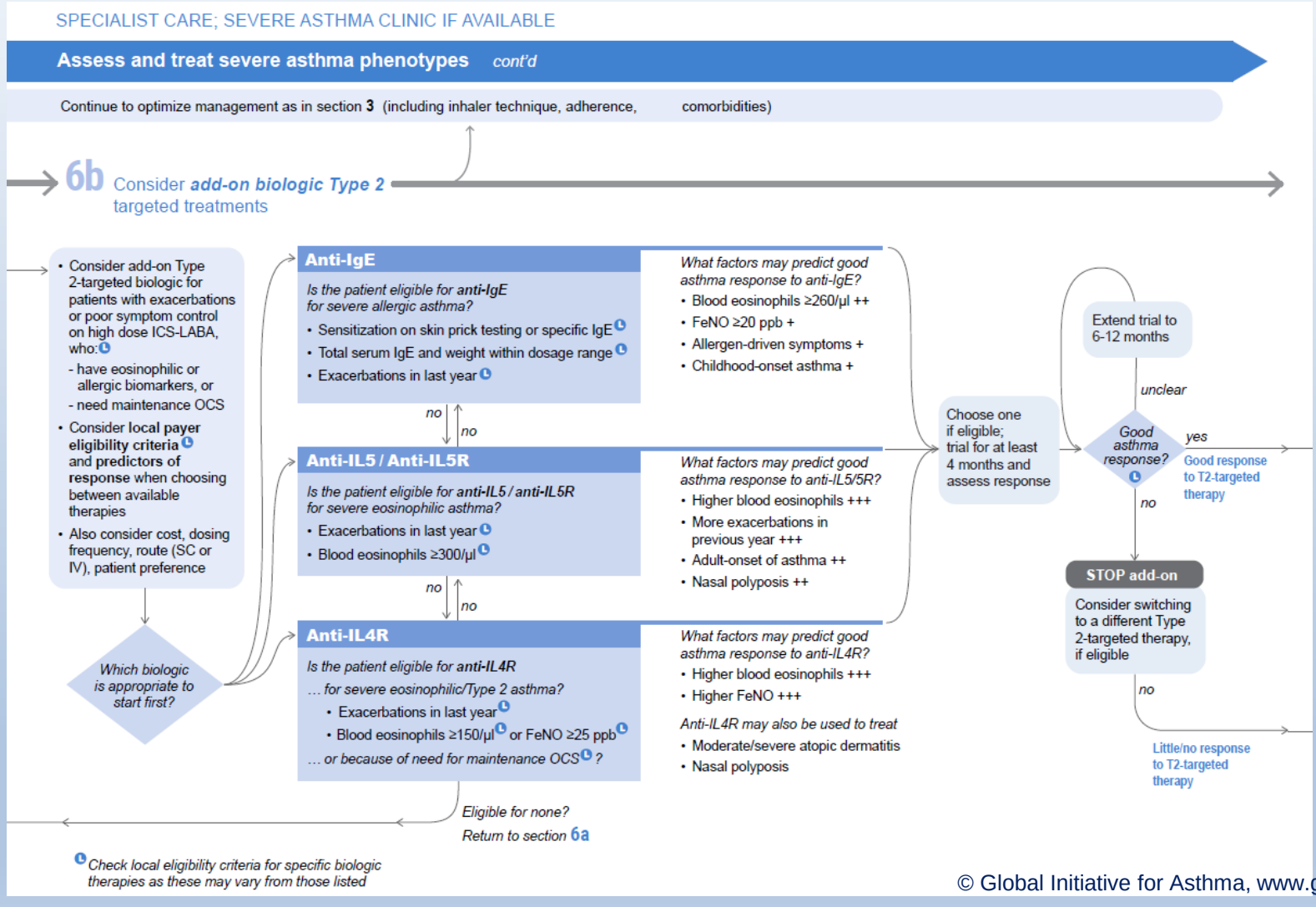
Choose one if eligible; trial for at least 4 months and assess response

*Good asthma response?*

*yes* — Good response to T2-targeted therapy

*no* — *unclear* — Extend trial to 6-12 months

*Check local eligibility criteria for specific biologic therapies as these may vary from those listed*



SPECIALIST AND PRIMARY CARE IN COLLABORATION

## Monitor / Manage severe asthma treatment

Continue to optimize management

### 7 Review **response**

- Asthma: symptom control, exacerbations, lung function
- Type 2 comorbidities e.g. nasal polyposis, atopic dermatitis
- Medications: treatment intensity, side-effects, affordability
- Patient satisfaction

SPECIALIST AND PRIMARY CARE IN COLLABORATION

## Monitor / Manage severe asthma treatment

Continue to optimize management

### 7 Review response

- Asthma: symptom control, exacerbations, lung function
- Type 2 comorbidities e.g. nasal polyposis, atopic dermatitis
- Medications: treatment intensity, side-effects, affordability
- Patient satisfaction

yes

***If good response to Type 2-targeted therapy***

- Re-evaluate the patient every 3-6 months
- For **oral treatments:** consider decreasing/stopping OCS first, then stopping other add-on medication
- For **inhaled treatments:** consider decreasing after 3-6 months; continue at least moderate dose ICS
- Re-evaluate need for ongoing biologic therapy
- Order of reduction of treatments based on observed benefit, potential side-effects, cost and patient preference

SPECIALIST AND PRIMARY CARE IN COLLABORATION

## Monitor / Manage severe asthma treatment

Continue to optimize management

### 7 Review response

- Asthma: symptom control, exacerbations, lung function
- Type 2 comorbidities e.g. nasal polyposis, atopic dermatitis
- Medications: treatment intensity, side-effects, affordability
- Patient satisfaction

yes →

***If good response to Type 2-targeted therapy***

- Re-evaluate the patient every 3-6 months
- For **oral treatments:** consider decreasing/stopping OCS first, then stopping other add-on medication
- For **inhaled treatments:** consider decreasing after 3-6 months; continue at least moderate dose ICS
- Re-evaluate need for ongoing biologic therapy
- Order of reduction of treatments based on observed benefit, potential side-effects, cost and patient preference

no →

***If no good response to Type 2-targeted therapy***

- Stop the biologic therapy
- Review the basics: differential diagnosis, inhaler technique, adherence, comorbidities, side-effects, emotional support
- Consider high resolution chest CT (if not done)
- Reassess phenotype and treatment options
  - Induced sputum (if available)
  - Consider add-on macrolide*
  - Consider add-on low dose OCS, but implement strategies to minimize side-effects
  - Consider bronchoscopy for alternative/additional diagnoses
  - Consider bronchial thermoplasty (+ registry)
- Stop ineffective add-on therapies
- Do not stop ICS

**Off-label*

SPECIALIST AND PRIMARY CARE IN COLLABORATION

## Monitor / Manage severe asthma treatment

Continue to optimize management

### 7 Review **response**

- Asthma: symptom control, exacerbations, lung function
- Type 2 comorbidities e.g. nasal polyposis, atopic dermatitis
- Medications: treatment intensity, side-effects, affordability
- Patient satisfaction

*yes*

***If good response to Type 2-targeted therapy***

- Re-evaluate the patient every 3-6 months
- For **oral treatments:** consider decreasing/stopping OCS first, then stopping other add-on medication
- For **inhaled treatments:** consider decreasing after 3-6 months; continue at least moderate dose ICS
- Re-evaluate need for ongoing biologic therapy
- Order of reduction of treatments based on observed benefit, potential side-effects, cost and patient preference

*no*

***If no good response to Type 2-targeted therapy***

- Stop the biologic therapy
- Review the basics: differential diagnosis, inhaler technique, adherence, comorbidities, side-effects, emotional support
- Consider high resolution chest CT (if not done)
- Reassess phenotype and treatment options
  - Induced sputum (if available)
  - Consider add-on macrolide*
  - Consider add-on low dose OCS, but implement strategies to minimize side-effects
  - Consider bronchoscopy for alternative/additional diagnoses
  - Consider bronchial thermoplasty (+ registry)
- Stop ineffective add-on therapies
- Do not stop ICS

**Off-label*

### 8 Continue to **optimize management** as in section **3**, including:

- Inhaler technique
- Adherence
- Comorbidity management
- Patients' social/emotional needs
- Two-way communication with GP for ongoing care

**Notes:**

Allergy & Asthma Network

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Price: $3.00

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## Epinephrine Treatments (8 1/2" x 11")

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Price: $3.00

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Respiratory Treatments
CHEST

# Asthma Action Plan for Home & School

Allergy & Asthma NETWORK

**Name:** **Birthdate:**

**Asthma Severity:** ☐ Intermittent ☐ Mild Persistent ☐ Moderate Persistent ☐ Severe Persistent
☐ He/she has had many or severe asthma attacks/exacerbations

## ☺ Green Zone

Have the child take these medicines every day, even when the child feels well.

Always use a spacer with inhalers as directed.

Controller Medicine(s): _____

_____

Controller Medicine(s) Given in School: _____

Rescue Medicine: Albuterol/Levalbuterol _____ puffs every four hours as needed

Exercise Medicine: Albuterol/Levalbuterol _____ puffs 15 minutes before activity as needed

## 😐 Yellow Zone

Begin the sick treatment plan if the child has a cough, wheeze, shortness of breath, or tight chest. Have the child take all of these medicines when sick.

Rescue Medicine: Albuterol/Levalbuterol _____ puffs every 4 hours as needed

Controller Medicine(s):

☐ Continue Green Zone medicines: _____

☐ Add: _____

_____

☐ Change: _____

If the child is in the **yellow** zone more than **24** hours or is getting worse, follow **red** zone and call the doctor right away!

## ☹ Red Zone

If breathing is hard and fast, ribs sticking out, trouble walking, talking, or sleeping.
**Get Help Now**

**Take rescue medicine(s) now**

Rescue Medicine: Albuterol/Levalbuterol _____ puffs every _____

Take: _____

_____

**If the child is not better right away, call 911**
Please call the doctor any time the child is in the red zone.

**Asthma Triggers:** (List)

**School Staff**: Follow the Yellow and Red Zone plans for rescue medicines according to asthma symptoms.
Unless otherwise noted, the only controllers to be administered in school are those listed as "given in school" in the green zone.

☐ Both the asthma provider and the parent feel that the child may carry and self-administer their inhalers
☐ School nurse agrees with student self-administering the inhalers

| Asthma Provider Printed Name and Contact Information: | Asthma Provider Signature:<br>Date: |
|---|---|

**Parent/Guardian:** I give written authorization for the medications listed in the action plan to be administered in school by the nurse or other school members as appropriate. I consent to communication between the prescribing health care provider/clinic, the school nurse, the school medical advisor and school-based health clinic providers necessary for asthma management and administration of this medication.

| Parent/guardian signature: | School Nurse Reviewed: |
|---|---|

# An Asthma Action Plan:

https://www.allergyasthmanetwork.org/cms/wp-content/uploads/2014/07/Asthma-Action-Plan-English.pdf

# Inhaler technique videos:

https://www.bing.com/videos/search?q=how+to+use+a+ventolin+inhaler+properly&&view=detail&mid=42D0422123954963F5E942D0422123954963F5E9&&FORM=VRDGAR

https://www.bing.com/videos/search?q=how+to+use+a+spacer+with+inhaler&&view=detail&mid=4ADA5870C49C9363B0D44ADA5870C49C9363B0D4&&FORM=VRDGAR

# COVID-19 and asthma *(as at April 3, 2020)*

- Advise patients with asthma to continue taking their prescribed asthma medications, particularly *inhaled corticosteroids* (ICS), and oral corticosteroids (OCS) if prescribed
  - Asthma medications should be continued as usual. Stopping ICS often leads to potentially dangerous worsening of asthma
  - For patients with severe asthma: continue biologic therapy, and do not suddenly stop OCS if prescribed
- Make sure that all patients have a *written asthma action plan* with instructions about:
  - Increasing controller and reliever medication when asthma worsens
  - Taking a short course of OCS for severe asthma exacerbations
  - When to seek medical help
  - See the GINA 2020 report for more information about treatment options for asthma action plans.
- *Avoid nebulizers* where possible
  - Nebulizers increase the risk of disseminating virus to other patients AND to health care professionals
  - Pressurized metered dose inhaler via a spacer is the preferred treatment during severe exacerbations, with a mouthpiece or tightly fitting face mask if required

# COVID-19 and asthma *(as at March 30, 2020)*

- *Avoid spirometry* in patients with confirmed/suspected COVID-19
  - Spirometry can disseminate viral particles and expose staff and patients to risk of infection
  - While community transmission of the virus is occurring in your region, postpone spirometry and peak flow measurement within health care facilities unless there is an urgent need
  - Follow contact and droplet precautions
- *Follow strict infection control procedures* if aerosol-generating procedures are needed
  - For example: nebulization, oxygen therapy (including with nasal prongs), sputum induction, manual ventilation, non-invasive ventilation and intubation
  - World Health Organization (WHO) infection control recommendations are found here: www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125
- *Follow local health advice* about hygiene strategies and use of personal protective equipment, as new information becomes available in your country or region

# Other resources for COVID-19 *(as at March 30, 2020)*

- Information for health professionals
  - World Health Organization (WHO) recommendations for infection control www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125
  - Centers for Disease Control and Prevention (CDC) www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html,
- Information for patients
  - CDC: https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Information for health systems
  - www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance
- Follow local health advice about hygiene strategies and use of personal protective equipment as new information becomes available in your country or region

# OHMYGOSHWEAREDONE!

Thank you!!

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