Resolving Asthma Medication Access Barriers

Kelin Wheaton, PharmD, PhD

Population Health Clinical Pharmacist

Partners For Kids and Nationwide Children's Hospital

OHIO PHARMACISTS ASSOCIATION

2024 Midyear Meeting & Trade Show
November 3, 2024

Disclosure Statement

Kelin Wheaton has no relevant financial relationship(s) with ineligible companies to disclose.

and

None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

- describe barriers to asthma medication access
- apply clinical and coverage resources to identify guideline-recommended medications and avoid insurance barriers
- discuss prior authorization barriers associated with single maintenance and reliever therapy (SMART)
- describe best practices for improving asthma medication ratio (AMR).

Sunday Morning Q&A

Disclaimer

Partners For Kids members are enrolled in managed Medicaid in Ohio. Therefore, many of the asthma coverage resources reviewed today have an Ohio Medicaid formulary focus.

Partners For Kids:

- Pediatric Accountable Care Organization
- Contracted with most Ohio Medicaid Managed Care Plans within defined regions
- 440,000 pediatric patients

PFK Asthma Population Data for Children and Adolescents (0-18 yrs)

Exacerbation Events

- 43,137 Asthma Patients
- 12,188 with an oral steroid fill (28%)
- 3,355 with an ED visit (8%)
- 782 with inpatient admission (3%)

Reliever Medications

- 26,641 filled a reliever medicine (62%)
- 5,603 had 4 or more relievers filled (13%)

Controller Inhalers

- 13,054 Filled a controller inhaler (30%)
- 11,478 have PDC < 80% (88%)
- 8,326 have PDC < 50% (64%)

A Child's Journey with Asthma

Resources to take with you!

Asthma Medication Access Barriers

- Implementation of new asthma guidelines
- Formulary preferences
- Device delivery method
- Patient and family understanding of asthma action plan

Asthma Guidelines

Guidelines for the Diagnosis and Management of Asthma

Global Initiative for Asthma (GINA)

Guideline Differences

NHLBI

National (US)

EPR-1 in 1991,
EPR-2 in 1997,
EPR-3 in 2007

Focused update - 2020

GINA

International

First in 1995, updated annually since 2002

Most recent - May 2024

NHLBI: National Heart, Lung, and Blood Institute
EPR: Expert panel report
GINA: Global Initiative for Asthma

Smith T, et al. Am J Health Syst Pharm. 2024

More Focused: 2020 NHLBI Updates

In children 0-4 years with wheezing triggered by respiratory infections and no wheezing between infections, the panel recommends a short course of daily ICS at onset of infection and as needed SABA for quick-relief therapy compared to as needed SABA only

In patients 4 and older with moderate to severe persistent asthma, the panel recommends ICS-formoterol used as both controller and reliever

SABA: short-acting beta-2 agonist
ICS: Inhaled corticosteroid

Asthma Resource

To access on web browser:

- https://partnersforkids.org/resources/
- Type ‘diagnosis’ in search bar
- Bookmark asthma prescribing resource!

Asthma Prescribing Guidelines – Central Region

Topics include: A clinical pathway detailing diagnosis, treatment and follow-up recommendations for asthma patients
Updated: 01/2023

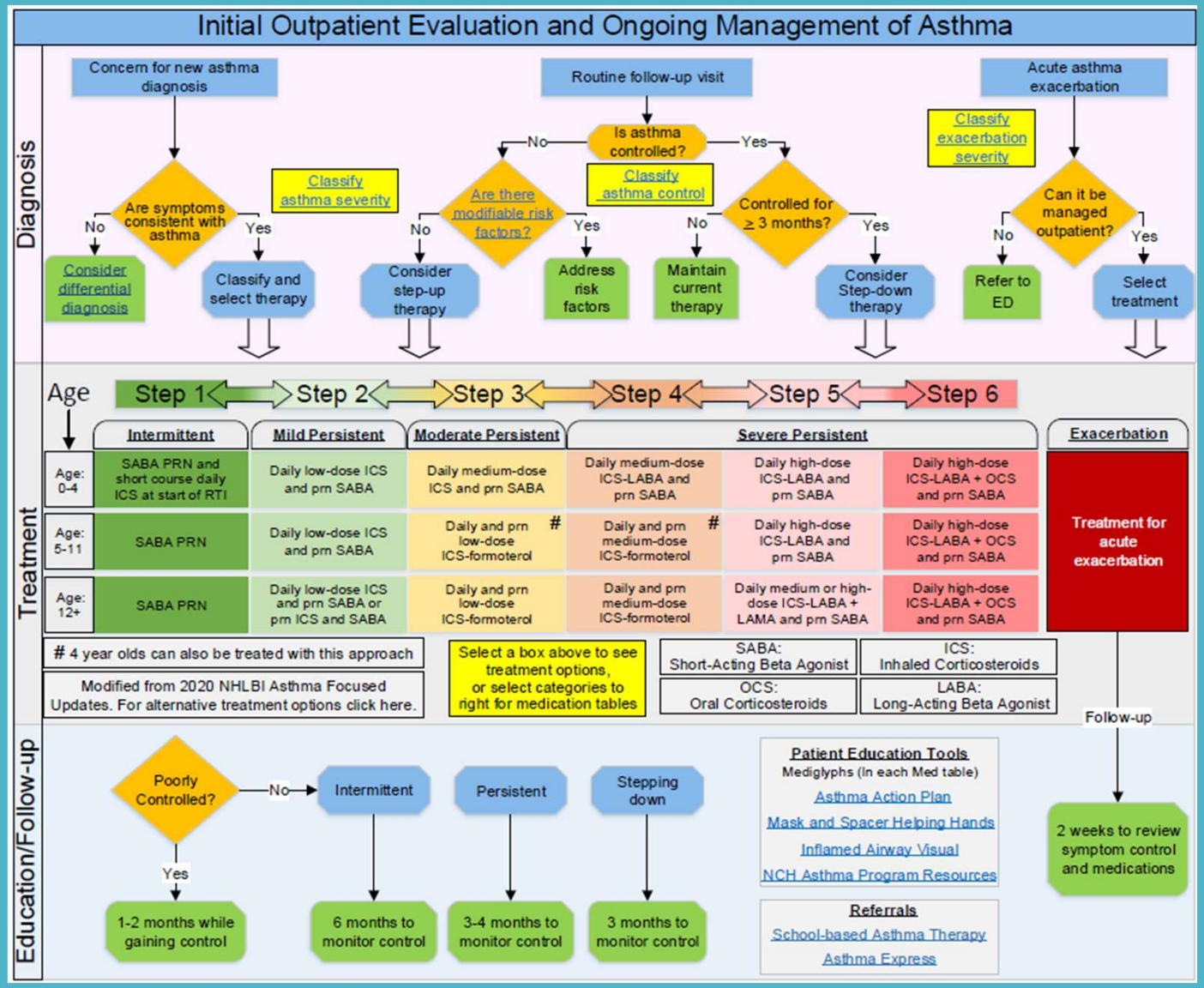
Initial Outpatient Evaluation and Ongoing Management of Asthma

Asthma Management Pathway

Diagnosis Tools:
Classifying Asthma Severity
Differential Diagnoses for Asthma
Modifiable Risk Factors
Classifying Exacerbation Severity

Medications Charts:
Acute Exacerbation Dosing
Short-Acting Medications
Inhaled Corticosteroids (ICS)
SMART Dosing
ICS – Long-Acting Beta Agonist

Asthma Resource

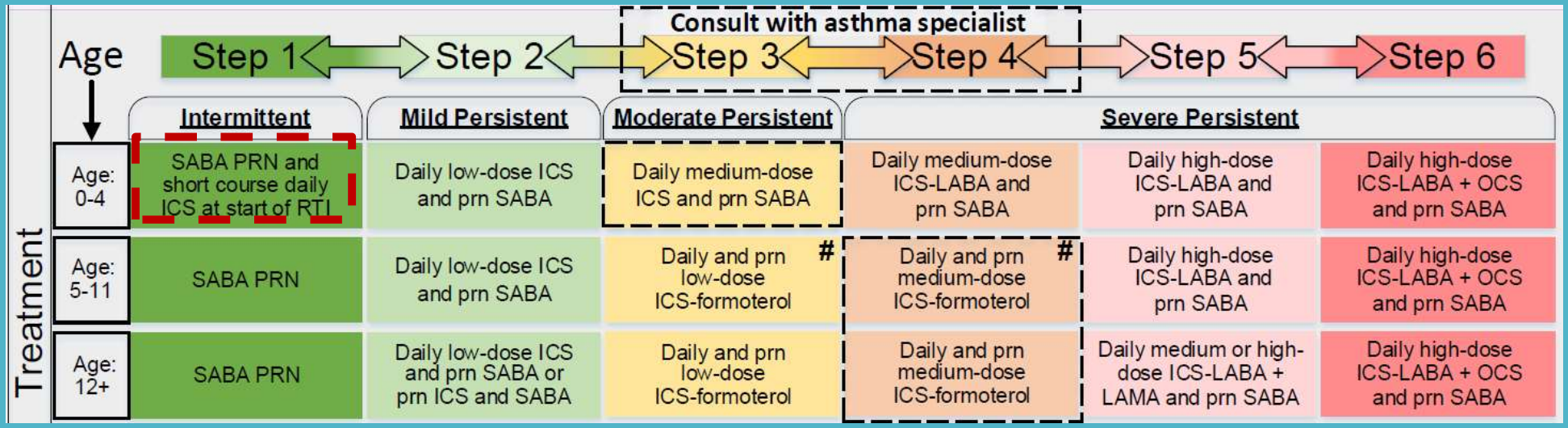


Intermittent ICS at the start of RTI

AB is a 4-year-old with intermittent asthma who has experienced multiple events where wheezing was appreciable, and these events were triggered by respiratory infections. When patient is not sick with RTI, the lungs are clear and patient does not have wheezing, shortness of breath, or cough.

Current medications: albuterol HFA 2 puffs Q4H PRN

- ☑ 3 lifetime episodes of wheezing, or 2 in the past year
- ☑ No wheezing in between episodes
- ☑ NOT on daily asthma treatment



SABA: short-acting beta-2 agonist
ICS: Inhaled corticosteroid
RTI: Respiratory tract infection

Intermittent ICS at the start of RTI

Intermittent Inhaled Corticosteroids (ICS)			
Mechanism of delivery	Drug	Strength	Dose and Frequency
Nebulizer Solution • Passive inhalation via nebulizer • Requires nebulizer device	**Pulmicort® Respules** Budesonide	1 mg/2mL solution	1 mg (1 ampule) BID for 7 to 10 days at first sign of respiratory illness
Metered-dose Inhalers (MDI) • Shake before use • Needs primed • Use with spacer	**Flovent® HFA*** Fluticasone propionate Mediglyph	110 mcg	2 puffs BID for 7 to 10 days at first sign of respiratory illness
*Flovent HFA dosing is the expert opinion of Nationwide Children's Hospital and is not described in the NHLBI guidelines			

Clinical benefit:

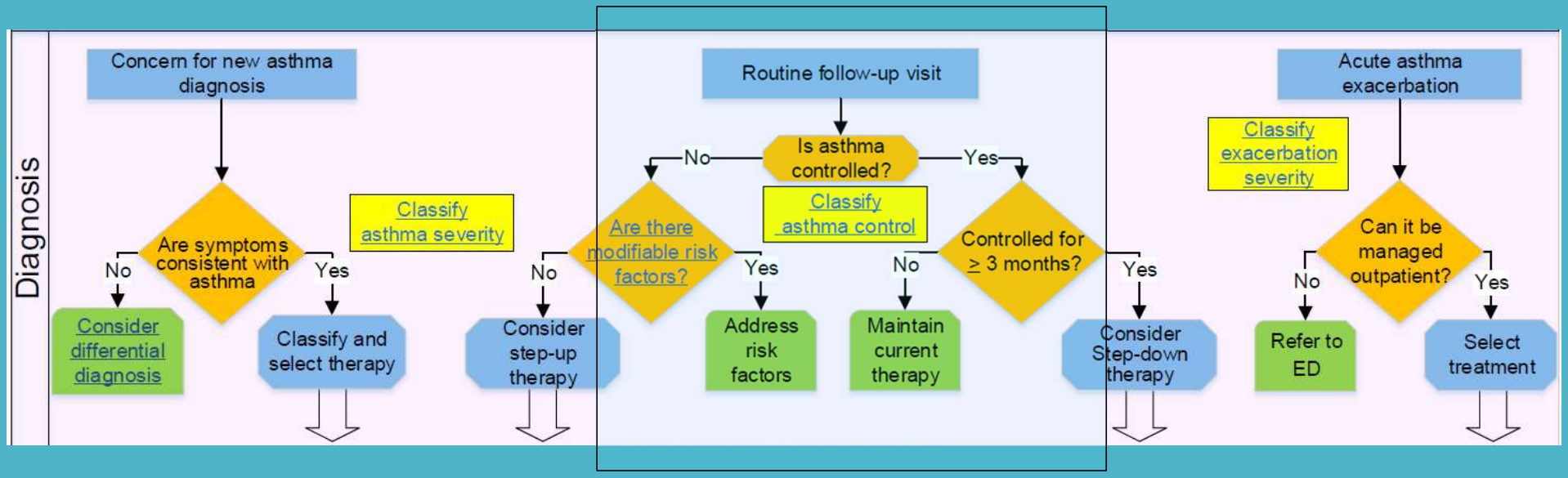
- Reduction in asthma exacerbations and oral steroids compared to albuterol alone[1]
- Non-inferior to daily inhaled steroid for patients with wheezing associated with RTI[2]

1. Ducharme et al. N Engl J Med. 2009;360(4):339-53.
2. Zeiger et al. N Engl J Med. 2011;365(21):1990-2001.

A Child's Journey with Asthma

Stepping up to Daily Controller

AB is now 5 and is visiting their pediatrician for their annual well check.



Stepping up to Daily Controller

AB has indications that their asthma is not well controlled based on asthma assessment. Asthma control test was 17.

Components of control			Classification of Asthma Control *(Modified from 2007 NHLBI guidelines)*		
		Age (yr)	Well-Controlled	Not Well-Controlled	Very Poorly Controlled
Impairment	Symptoms	All	≤ 2 days/week*	> 2 days per week#	Throughout the day
	Nighttime awakenings	0-4	≤ 1x/month	> 1x/month	>1x/week
		5 to 11	≤ 1x/month	≥ 2x/month	≥ 2x/week
		≥ 12	≤ 2x/month	1-3x/week	≥ 4x/week
	Interference with normal activity	All	None	Some limitation	Extremely limited
	Short-acting beta2-agonist use for symptom control (not prevention of EIB)	All	≤ 2 days/week	> 2 days per week	Several times per day
	FEV1 or peak flow	≥ 5	> 80% predicted/ personal best	60-80% predicted/ personal best	< 60% predicted/ personal best
	FEV1/FVC	≥ 5	> 80%	75-80%	< 75%
	Validated Questionaires – ACT	≥ 4	≥ 20	16-19	≤ 15
	Validated Questionaires – ATAQ	≥ 12	0	1-2	3-4
	Validated Questionaires – ACQ	≥ 12	≤ 0.75	≥ 1.5	N/A
Risk	Exacerbations requiring oral systemic corticosteroids¥	All	0-1/year	2-3/year	> 3/year
Recommended Action for Treatment		All	Maintain current step or consider step-down if well controlled for at least 3 months. Schedule regular follow-up in 1-6 months.	Step-up (1 step) and re-evaluate in 2-6 weeks. **Age 0-4:** If no clear benefit from stepping-up in 4-6 weeks, consider alternative diagnoses or adjust therapy.	Consider short course of oral systemic steroids, step-up (1-2 steps) and re-evaluate in 2 weeks **Age 0-4:** If no clear benefit from stepping-up in 4-6 weeks, consider alternative diagnoses or adjust therapy

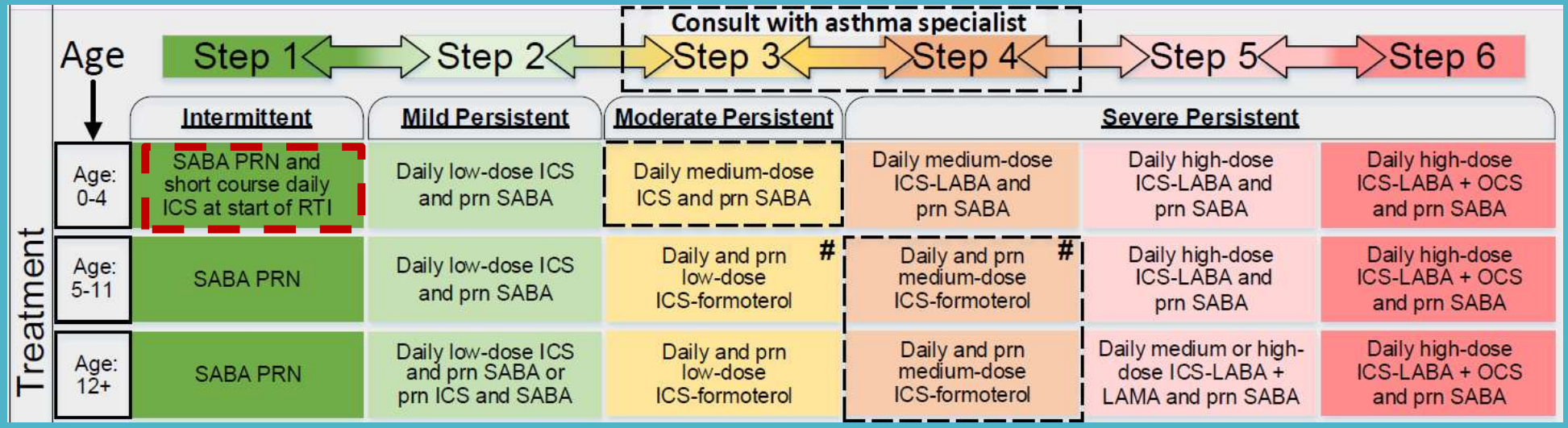
* For 5-11 yos: < 2 days/week but not more than once on each day
\# For 5-11 yos: > 2 days/ week or multiple times on < 2 days/week
¥ Consider severity and interval since last exacerbation

Before stepping-up therapy, review adherence to medications, inhaler technique and environmental control.

Suggestion for stepping down therapy:
The dose of ICS may be reduced about 25–50 percent every 3 months to the lowest dose possible required to maintain control

Return to Pathway

Stepping up to Daily Controller



SABA: short-acting beta-2 agonist
ICS: Inhaled corticosteroid
RTI: Respiratory tract infection

Asthma Resource

To access on web browser:

- https://partnersforkids.org/resources/
- Type ‘comparative’ in search bar
- Bookmark asthma prescribing resource!

Asthma Inhaled Corticosteroid Table

Each inhaled corticosteroid has comparative daily dosages listed along with typical dose frequencies, strengths available, device delivery methods, and Ohio Medicaid coverage notes.

If the medication is **BOLDED** it is covered without a prior authorization for patients on an Ohio Medicaid plan				Unless otherwise noted, doses represent the steroid component in **micrograms**					
Drug	**Delivery Method**	**Strengths Available (inhalations/device)**	**Typical Dose Frequency**	**LOW DAILY DOSE**		**MEDIUM DAILY DOSE**		**HIGH DAILY DOSE**	
				Child (5-11)^	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**
Inhaled Steroid and Long-Acting Beta Agonists: Spacer Compatible									
Budesonide/formoterol[G] (Symbicort® HFA)	Spacer compatible	80/4.5 mcg (120) 160/4.5 mcg (120)	BID	160 - 320	320	>320 - 640	640		
Fluticasone/salmeterol[G] (Advair® HFA)	Spacer compatible	45/21 mcg (120) 115/21 mcg (120) 230/21 mcg (120)	BID	90 - 180	180	460	460	920	920
Mometasone/formoterol (Dulera® HFA)	Spacer compatible	50/5 mcg (120) 100/5 mcg (120) 200/5 mcg (120)	BID	100	200	200	400	400	800
Inhaled Steroid and Long-Acting Beta Agonists: Breathe-actuated (not compatible with a spacer). Younger children may not have lung strength to obtain dose.									
Fluticasone/salmeterol[G] (Advair Diskus®)	Breath-actuated	100/50 mcg (60) 250/50 mcg (60) 500/50 mcg (60)	BID	200	200	500	500	1000	1000
Fluticasone furoate/vilanterol[G] (Breo™ Ellipta™)	Breath-actuated	50/25 mcg (30) 100/25 mcg (30) 200/25 mcg (30)	Daily	50	100	100	200		

G: Generic is available. When generic and brand are available, Ohio Medicaid prefers brand over generic (except for Flovent®, since brand not in marketplace).
HFA: Hydrofluoroalkane, a propellant most commonly used in metered dose inhalers.

*When available, these comparative dosages were obtained from the 2007 NAEPP Expert Panel Report 3 (EPR3). If not available in EPR3, the 2023 Global Initiative for Asthma guidelines were referenced.
^For patients < 5 years old there are only equivalent dose recommendations in guidelines for fluticasone propionate HFA and nebulized budesonide. Follow the recommended child (5-11) dose for these medications. For other medications, please use clinical judgement when dosing patients < 5 years old.

Stepping up to Daily Controller

If the medication is **BOLDED** it is covered without a prior authorization for patients on an Ohio Medicaid plan				Unless otherwise noted, doses represent the steroid component in **micrograms**					
Drug	**Delivery Method**	**Strengths Available (inhalations/device)**	**Typical Dose Frequency**	**LOW DAILY DOSE**		**MEDIUM DAILY DOSE**		**HIGH DAILY DOSE**	
				Child (5-11)^	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**
Inhaled Steroids: Spacer compatible									
Fluticasone propionate[G] (Flovent® HFA)	Spacer compatible	44 mcg (120) 110 mcg (120) 220 mcg (120)	BID	88 - 176	88 - 264	>176 - 440	>264 - 660	>440	>660
Mometasone (Asmanex® HFA)	Spacer compatible	50 mcg (120) 100 mcg (120) 200 mcg (120)	BID	100	200	200	400	400	>400
Ciclesonide (Alvesco® HFA)	Spacer compatible	80 mcg (60) 160 mcg (60)	BID	80	160	160	320	>160	640
Inhaled Steroids: Breathe-actuated (not compatible with a spacer). Younger children may not have lung strength and proper technique to obtain dose.									
Beclomethasone (QVAR® Redihaler™)	Breath-actuated	40 mcg (120) 80 mcg (120)	BID	80 - 160	80 - 240	>160 - 320	>240 - 480	>320	>480
Budesonide[G] (Pulmicort Flexhaler™)	Breath-actuated	90 mcg (60) 180 mcg (120)	BID	180 - 360	180 - 540	>360 - 720	>540 - 1,080	>720	>1,080
Fluticasone propionate[G] (Flovent® Diskus®)	Breath-actuated	50 (60) 100 (60) 250 (60)	BID	100 - 200	100 - 300	>200 - 400	>300 - 500	>400	>500
Fluticasone furoate (Arnuity™ Ellipta™)	Breath-actuated	50 mcg (30) 100 mcg (30) 200 mcg (30)	Daily	50	100	100	200		
Mometasone (Asmanex® Twisthaler®)	Breath-actuated	110 mcg (multiple) 220 mcg (multiple)	Daily	110	220	220	>220 - 440	440	>440
Inhaled Steroids: Nebulizer Solution									
Budesonide[G] (Pulmicort Respules®)	Nebulized	0.25 mg/2 mL 0.5 mg/2 mL 1 mg/2 mL	Daily	0.5 mg		1 mg		2 mg	

Stepping up to Daily Controller

Fluticasone Propionate
44 mcg 2 puffs BID

Insurance no longer prefers fluticasone propionate!!

Stepping up to Daily Controller

Fluticasone Propionate
44 mcg 2 puffs BID

Insurance no longer prefers fluticasone propionate!!

Insurance prefers
Pulmicort Flexhaler™

Should they switch??

Stepping up to Daily Controller

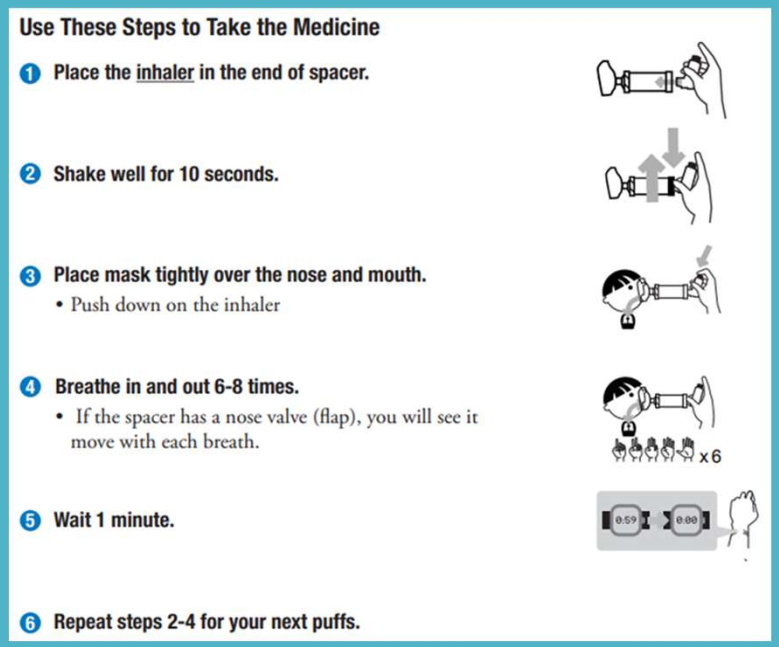
If the medication is **BOLDED** it is covered without a prior authorization for patients on an Ohio Medicaid plan				Unless otherwise noted, doses represent the steroid component in **micrograms**					
Drug	**Delivery Method**	**Strengths Available (inhalations/device)**	**Typical Dose Frequency**	**LOW DAILY DOSE**		**MEDIUM DAILY DOSE**		**HIGH DAILY DOSE**	
				Child (5-11)^	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**
Inhaled Steroids: Spacer compatible									
Fluticasone propionate[G] (Flovent® HFA)	Spacer compatible	44 mcg (120) 110 mcg (120) 220 mcg (120)	BID	88 - 176	88 - 264	>176 - 440	>264 - 660	>440	>660
Mometasone (Asmanex® HFA)	Spacer compatible	50 mcg (120) 100 mcg (120) 200 mcg (120)	BID	100	200	200	400	400	>400
Ciclesonide (Alvesco® HFA)	Spacer compatible	80 mcg (60) 160 mcg (60)	BID	80	160	160	320	>160	640
Inhaled Steroids: Breathe-actuated (not compatible with a spacer). Younger children may not have lung strength and proper technique to obtain dose.									
Beclomethasone (QVAR® Redihaler™)	Breath-actuated	40 mcg (120) 80 mcg (120)	BID	80 - 160	80 - 240	>160 - 320	>240 - 480	>320	>480
Budesonide[G] (Pulmicort Flexhaler™)	Breath-actuated	90 mcg (60) 180 mcg (120)	BID	180 - 360	180 - 540	>360 - 720	>540 - 1,080	>720	>1,080
Fluticasone propionate[G] (Flovent® Diskus®)	Breath-actuated	50 (60) 100 (60) 250 (60)	BID	100 - 200	100 - 300	>200 - 400	>300 - 500	>400	>500
Fluticasone furoate (Arnuity™ Ellipta™)	Breath-actuated	50 mcg (30) 100 mcg (30) 200 mcg (30)	Daily	50	100	100	200		
Mometasone (Asmanex® Twisthaler®)	Breath-actuated	110 mcg (multiple) 220 mcg (multiple)	Daily	110	220	220	>220 - 440	440	>440
Inhaled Steroids: Nebulizer Solution									
Budesonide[G] (Pulmicort Respules®)	Nebulized	0.25 mg/2 mL 0.5 mg/2 mL 1 mg/2 mL	Daily	0.5 mg		1 mg		2 mg	

Assessments for proper delivery technique

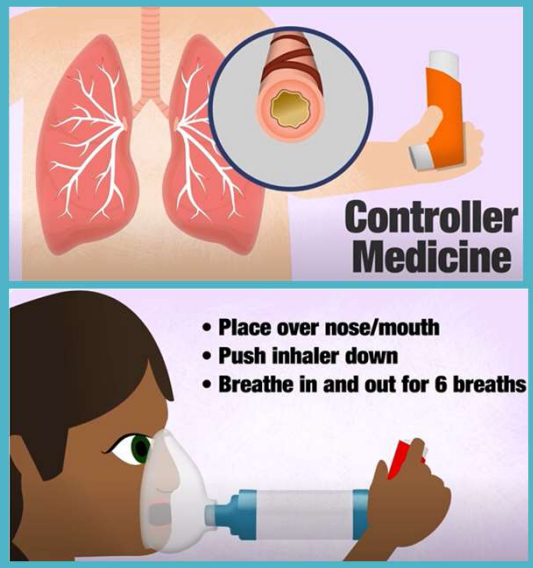
Will the patient be able to use a breath-actuated inhaler?	• Most patients less than 8-years old typically do not have the lung strength
Will the patient need a mask or is a mouthpiece, okay?	• Most patients less than 5 years old will need a mask to help with coordinating breaths
Does the mask fit?	• A tight seal around nose and mouth is important • Each mask brand may have different age ranges for small, medium, large, etc..
Does the patient/family understand the technique?	• Review asthma action plan • Use patient handouts and teach back to confirm

Example Patient Education Tools

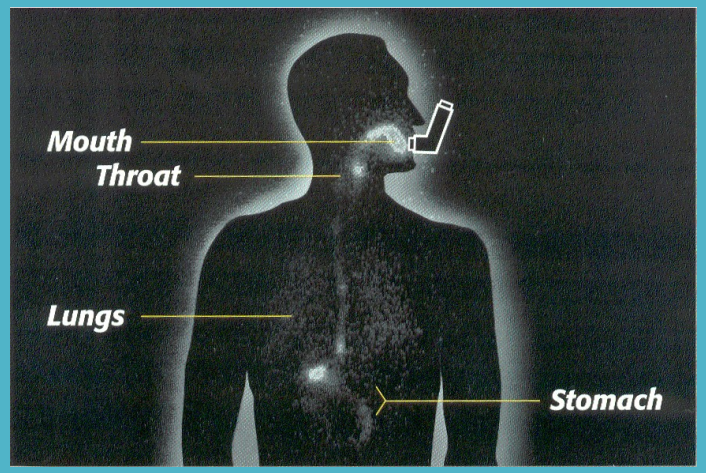
Mediglyphs: Inhaler education handouts



Asthma video for patients/families

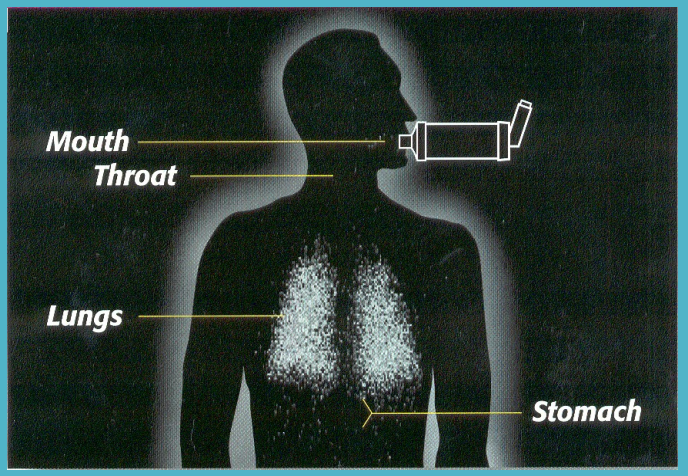


Why use a Spacer with an Inhaler?



Inhaler alone

When an inhaler is used alone, medicine ends up in the mouth, throat, stomach and lungs.



Inhaler used with spacer device

When an inhaler is used with a spacer device, more medicine is delivered to the lungs.

"Comparative respiratory deposition of ^{99m}Tc labeled particles of albuterol using a metered dose inhaler, a metered does inhaler with Aerochamber® spacer and OptiChamber® spacer in healthy human volunteers using gamma-scintigraphy," R. Beihn, PhD, Scintiprox, Inc., Indianapolis, IN and D. Doherty, MD, Dept. of Pulmonology, University of Kentucky Medical Center, Lexington, KY, 1997.

Images kindly provided by Respironics HealthScan Inc.

Allies Against Asthma, Center for Pediatric Research, 855 W. Brambleton Ave., Norfolk, VA 23510, 757-668-6435

Stepping up to Daily Controller

Fluticasone Propionate 44 mcg 2 puffs BID

Insurance no longer prefers fluticasone propionate!!

Insurance prefers Pulmicort Flexhaler™

Should they switch?? No.

Submit prior authorization for spacer-compatible inhaler

Sample prior authorization language for child needing spacer-compatible inhaler

Children do not have the lung strength and therefore the inspiratory flow to properly deliver medication from a breath-actuated inhaler to their lungs[1]. Asthma clinical guidelines confer that children need to use a metered dose inhaler with a spacer to appropriately treat asthma[2,3]. Please approve a PA for _____.

1.Amirav I et al. Pediatr Pulmonol. 2005 May;39(5):447-51.

2.Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2007. National Heart, Lung, and Blood Institute.

3.Global Initiative for Asthma. Global Strategy for Asthma Management and. Prevention, 2023. Available from: www.ginasthma.org.

Adjusting controller therapy

Fluticasone propionate HFA

Mometasone HFA

If the medication is **BOLDED** it is covered without a prior authorization for patients on an Ohio Medicaid plan				Unless otherwise noted, doses represent the steroid component in **micrograms**					
Drug	**Delivery Method**	**Strengths Available (inhalations/device)**	**Typical Dose Frequency**	**LOW DAILY DOSE**		**MEDIUM DAILY DOSE**		**HIGH DAILY DOSE**	
				Child (5-11)^	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**	**Child (5-11)^**	**Teen/Adult (12 and older)**
Inhaled Steroids: Spacer compatible									
Fluticasone propionate[G] (Flovent® HFA)	Spacer compatible	44 mcg (120) 110 mcg (120) 220 mcg (120)	BID	88 - 176	88 - 264	>176 - 440	>264 - 660	>440	>660
Mometasone (Asmanex® HFA)	Spacer compatible	50 mcg (120) 100 mcg (120) 200 mcg (120)	BID	100	200	200	400	400	>400
Ciclesonide (Alvesco® HFA)	Spacer compatible	80 mcg (60) 160 mcg (60)	BID	80	160	160	320	>160	640
Inhaled Steroids: Breathe-actuated (not compatible with a spacer). Younger children may not have lung strength and proper technique to obtain dose.									
Beclomethasone (QVAR® Redihaler™)	Breath-actuated	40 mcg (120) 80 mcg (120)	BID	80 - 160	80 - 240	>160 - 320	>240 - 480	>320	>480
Budesonide[G] (Pulmicort Flexhaler™)	Breath-actuated	90 mcg (60) 180 mcg (120)	BID	180 - 360	180 - 540	>360 - 720	>540 - 1,080	>720	>1,080
Fluticasone propionate[G] (Flovent® Diskus®)	Breath-actuated	50 (60) 100 (60) 250 (60)	BID	100 - 200	100 - 300	>200 - 400	>300 - 500	>400	>500
Fluticasone furoate (Arnuity™ Ellipta™)	Breath-actuated	50 mcg (30) 100 mcg (30) 200 mcg (30)	Daily	50	100	100	200		
Mometasone (Asmanex® Twisthaler®)	Breath-actuated	110 mcg (multiple) 220 mcg (multiple)	Daily	110	220	220	>220 - 440	440	>440
Inhaled Steroids: Nebulizer Solution									
Budesonide[G] (Pulmicort Respules®)	Nebulized	0.25 mg/2 mL 0.5 mg/2 mL 1 mg/2 mL	Daily	0.5 mg		1 mg		2 mg	

A Child's Journey with Asthma

More Focused: 2020 NHLBI Updates

In children 0-4 years with wheezing triggered by respiratory infections and no wheezing between infections, the panel recommends a short course of daily ICS at onset of infection and as needed SABA for quick-relief therapy compared to as needed SABA only

In patients 4 and older with moderate to severe persistent asthma, the panel recommends ICS-formoterol used as both controller and reliever

SABA: short-acting beta-2 agonist
ICS: Inhaled corticosteroid

S INGLE

M AINTENANCE

A ND

R ELIEVER

T HERAPY

- ICS-Formoterol daily and PRN
- For use with ***Formoterol*** ONLY
- **F**ormoterol is **F**ast acting
- Benefits: Decreases exacerbations, improves asthma control, and improves QOL

Advantages of SMART

As needed ICS

- Inflammation is dynamic, and so should the amount of inhaled steroid[1]
- Quicker treatment of airway inflammation[2]

As needed Formoterol

- As quick acting but longer duration of action than albuterol[4]
- Lower frequency of reliever inhalations needed[5]
- Fewer exacerbations compared to SABA when used as relief medication[5]

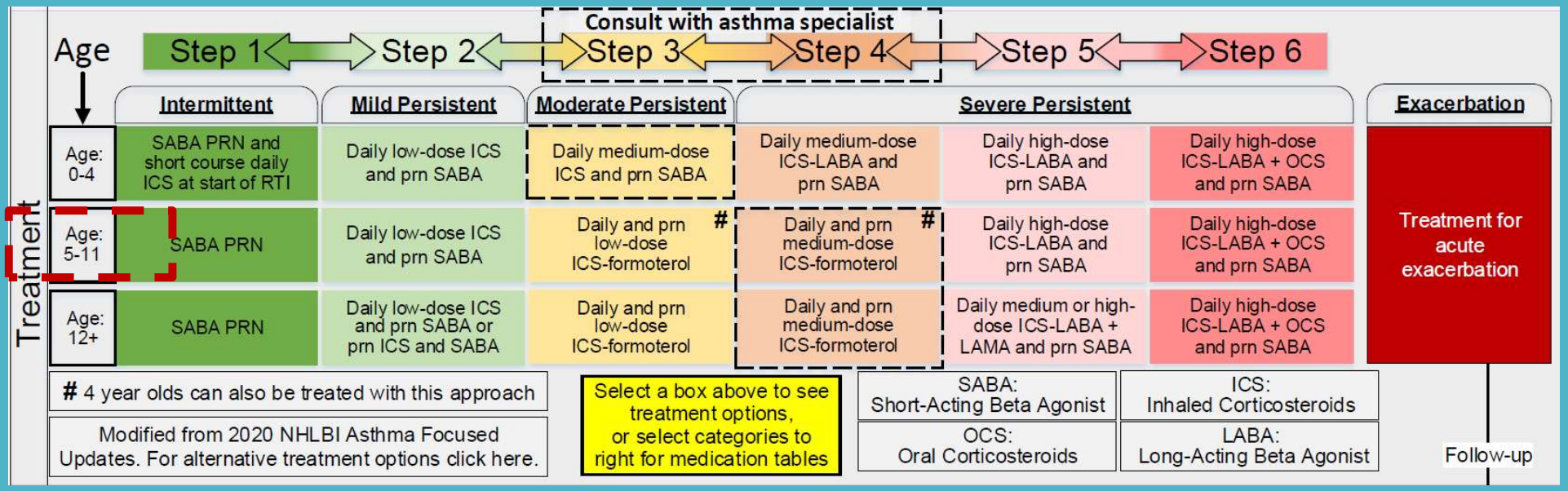
ICS-Formoterol Daily and As Needed

- ICS-LABA reduces exacerbations compared to increasing ICS dose and lowers overall steroid dose [3,6]
- ICS and formoterol work better together as a reliever[7]
- Simplified regimen and asthma action plan

1. Oppenheimer JJ, Peters SP. Ann Allergy Asthma Immunol. 2010 Feb;104(2):112-7.
2. Partridge MR et al. BMC Pulm Med. 2006 Jun 13;6:13.
3. Papi A et al. N Engl J Med. 2007 May 17;356(20):2040-52.
4. van der Woude HJ et al. Pulm Pharmacol Ther. 2004;17(2):89-95.
5. Pauwels RA et al. Eur Respir J. 2003 Nov;22(5):787-94.
6. O'Byrne PM et al. Am. J. Respir. Crit. Care Med. 2001;164: 1392–7
7. Rabe KF et al. Lancet. 2006 Aug 26;368(9537):744-53.

Single maintenance and reliever therapy

AB is now 6 and is following-up with PCP from an ED visit for an asthma exacerbation



Single Maintenance And Reliever Therapy (SMART)

ICS + Long-Acting Beta Agonist (LABA) **BOLD** = Preferred, no PA required for Medicaid patients						
Inhaler Mechanism	Drug	Age (years)	Low Dose Inhaler Strength	Medium Dose Inhaler Strength	Dose and Frequency	Max Dose
Metered-dose Inhalers (MDI) • Aerosolized inhalation that is pushed to activate • Shake before use • Needs primed • Use with spacer	**Symbicort® HFA** **Budesonide / formoterol**	4-11	80-4.5 mcg	160-4.5 mcg	1 to 2 puffs BID and 1 puff PRN	8 puffs
		≥ 12				12 puffs
	Dulera® HFA Mometasone / formoterol	4-11	50-5 mcg	100-5 mcg	1 to 2 puffs BID and 1 puff PRN	8 puffs
		≥ 12				12 puffs

Example Prescription – Low Dose ICS + LABA			
Age (years)	Drug	Strength	Directions
4-11	**Symbicort® HFA** Budesonide / formoterol	80-4.5 mcg	Inhale 2 puffs twice a day. May also inhale 1 puff as needed for symptoms (Max: 8 puffs per day). Dispense 2 inhalers for 30-day supply.
≥ 12	**Symbicort® HFA** Budesonide / formoterol	80-4.5 mcg	Inhale 2 puffs twice a day. May also inhale 1 puff as needed for symptoms (Max: 12 puffs per day). Dispense 2 inhalers for 30 day supply.

Reddel HK, et al. A Practical Guide to Implementing SMART in Asthma Management. J Allergy Clin Immunol Pract.

Asthma Action Plan

Good Control

All of these are true:

- No cough
- No wheeze
- No trouble breathing
- Asthma doesn't bother sleep or exercise

Take budesonide/formoterol with a spacer every morning and evening to control asthma.

✖ Budesonide/formoterol 80/4.5 mcg take ___ puff(s) twice daily

☐ Budesonide/formoterol 160/4.5 mcg take ___ puff(s) twice daily

Other: _____

Warning: Symptoms starting

You have any of these:

- Coughing
- Wheezing
- Shortness of breath
- Chest tightness
- Waking up at night due to asthma

Keep taking daily controller budesonide/formoterol **plus** take budesonide/formoterol with a spacer to relieve asthma symptoms.

Take 1 puff as needed. Repeat if symptoms do not improve.

4 – 11 years old: Do not use more than 8 **total** controller + reliever puffs per day.

12 years and older: Do not use more than 12 **total** controller + reliever puffs per day.

Call your doctor If using reliever puffs more than 2 times a week.

Call your doctor if asthma symptoms worsen, your medicine is not helping, or if you are taking more than the total puffs per day outlined in the yellow zone. If you can't reach your doctor, go to an Urgent Care or Emergency Room.

Danger: Get help now!

Breathing is bad:

- Lips are blue
- Trouble speaking
- Breathing hard and fast
- Ribs show when breathing
- Neck or stomach sink in

Call 9-1-1 or go to the closest Emergency Room!

Take budesonide/formoterol while you are waiting for help to arrive.

Take 1 puff as needed. Wait 1 to 3 minutes. Repeat if symptoms do not improve.

https://partnersforkids.org/news-updates/asthma-toolkit-for-primary-care/

Common barriers to implementing SMART

Budesonide-formoterol HFA is off-label when used as needed for relief

- Budesonide-formoterol Turbohaler® was used for international studies
- Guidelines and studies support use as single maintenance and reliever therapy

Commercial insurance may not cover two inhalers per 30-days*

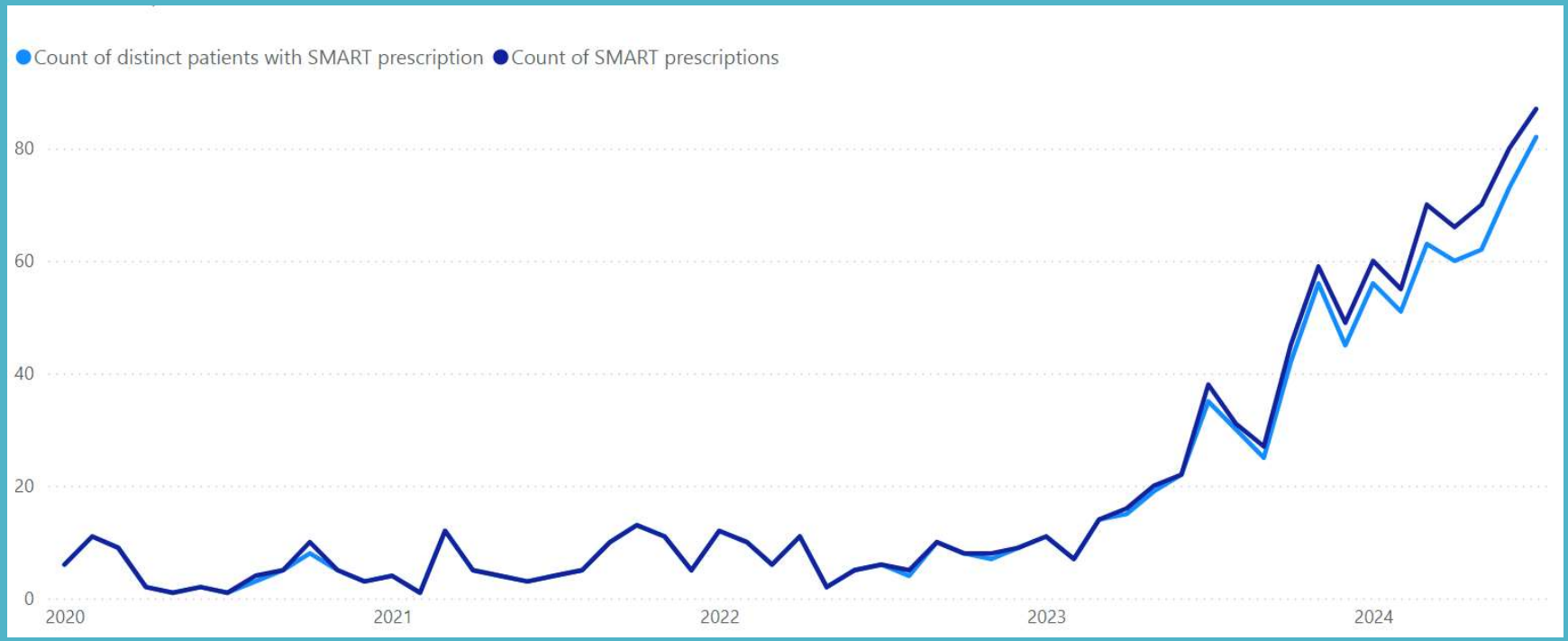
- Ohio Medicaid does cover 2 Symbicort inhalers (Brand preferred) per 30-days
- Pharmacist may need to place high dose override if pharmacy system warns

Lack of comfortability and time to educate within healthcare team

- New approach that requires time to educate patient and family
- Patient/family concerns that budesonide-formoterol won't work as well as albuterol
- Takes time for prescribers and payors to adapt to new guidance

Example PA language for SMART denials: This is a moderate persistent asthma patient that needs two Symbicort inhalers for 30-days to use BID as a controller AND prn as a reliever inhaler. This approach aligns with national asthma guidelines and reduces exacerbations.

PFK SMART Prescription Data for Children and Adolescents (4-18 yrs)



Unpublished data from Partners For Kids claims database

Quality Measure Spotlight: Asthma Medication Ratio (AMR)

OAK: Outcomes Acceleration for Kids

Comprised of:

- Ohio pediatric ACOs
- Ohio children's hospitals
- Medicaid MCOs
- Ohio Department of Medicaid

Quality Measures

- Well care
- Behavioral health follow-up
- Sickle Cell Disease
- Asthma Medication Ratio (AMR)

Compliance Threshold for AMR

$$\frac{Controller}{Controller + Reliever}$$

If ratio is > 0.5 patients are compliant

3 fluticasone propionate and 6 albuterol

AMR = 0.33

4 fluticasone propionate and 2 albuterol

AMR = 0.67

Controller Medications

Medication Category	Medications	
Biologics	Omalizumab Benralizumab Reslizumab	Dupilumab Mepolizumab
Leukotriene modifiers	Montelukast Zileuton	Zafirlukast
Inhaled steroids and long-acting beta agonists	Budesonide-formoterol Mometasone-formoterol	Fluticasone-salmeterol Fluticasone-vilanterol
Inhaled steroids	Beclomethasone Ciclesonide Fluticasone	Budesonide* Flunisolide Mometasone
Methylxanthines	Theophylline	
*Budesonide ampules for nebulizer are not included in medication list		

Reliever Medications

Medication Category	Medications	
Short-acting, inhaled beta-2 agonists*	Albuterol	Levalbuterol
*Ampules for nebulizers are not included in medication list		

Persistent Asthma Patient HEDIS Definition

Member with *at least one* of the following criteria[1]:
≥ 1 ED visit *or* acute inpatient encounter (principal diagnosis asthma)
≥ 4 outpatient *or* telehealth visits[2] (any diagnosis of asthma) *and* ≥ 2 asthma medication dispensing events[3]
≥ 4 asthma medication dispensing events[3,4]

[1]During the measurement year and the year prior to the measurement year (criteria does not need to be the same across both years)
[2]Visits on different dates of service
[3]Any controller or reliever medication
[4]If leukotriene modifiers or antibody inhibitors were the sole medication dispensed, must have ≥ 1 diagnosis of asthma in the same year the drug was dispensed

Evidence for AMR Utility as a Pediatric Population Health Measure

Correlation of Care Process Measures with Childhood Asthma Exacerbations

- Population: 528 children ages 5 – 17 years with persistent asthma
- Endpoints: Asthma exacerbation[2]
- Results:
  - Patients with AMR < 0.5 have a higher risk of exacerbation
  - Patients with 0 controller medications vs. ≥1 have a higher risk of exacerbation

[2]ED visit, hospitalization, or outpatient visit with oral steroid prescription

Vernacchio L, et al. *Pediatrics*. 2013

Asthma Medication Ratio Predicts Emergency Department Visits and Hospitalizations in Children with

- Population: 19,512 children ages 2 – 18 years with persistent asthma
- Endpoints: ED visits and hospitalizations[1]
- Results:
  - Patients with AMR < 0.5 are 60% more likely to have ER visit
  - AMR can predict ED visits and hospitalizations over short (3-months) and long time periods (12-months) of time

[1]Over 3-, 6-, and 12-month periods

Andrews LA, et al. *Medicare & Medicaid Research Review. 2013*

Strategies to Improve AMR

- Resolve medication access barriers
- Review asthma action plan
- Review asthma control and follow guidelines to step-up or step-down therapy
- S.M.A.R.T.
- Patient education

Asthma Medication Resources Reviewed

Access Asthma Toolkit on web browser:

- https://partnersforkids.org/news-updates/asthma-toolkit-for-primary-care/

Asthma Prescribing Pathway

Step therapy decision guidance

Inhaled Steroid Comparison Table

Comparative doses by age-group

Available doses and delivery devices

Spacer-compatible Inhaler Decision Guidance

Steps to ensure patient access to a metered dose inhaler

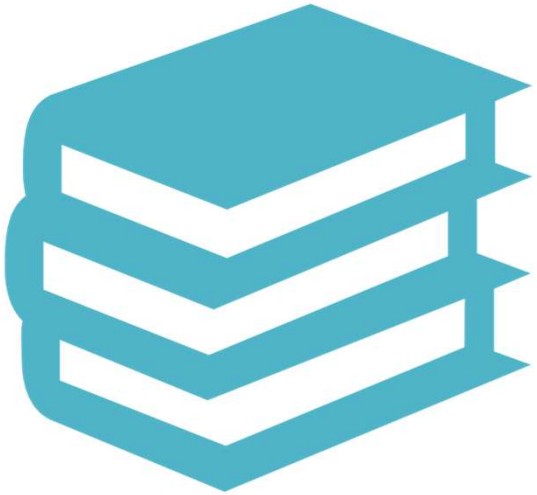
Prior authorization language to communicate with payers

Inhaler Patient Assistance Program Tool

For underinsured or uninsured

Mediglyphs

Pediatric patient education handouts for common inhalers



References

1. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC); Cloutier et at. 2020 Focused Updates to the Asthma Management Guidelines. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270.
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available from: www.ginasthma.org
3. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma-Summary Report 2007. J Allergy Clin Immunol 120(5 Suppl): S94-138.
4. Asthma Toolkit for Primary Care. Partners For Kids. Updated May 2024. Available from: https://partnersforkids.org/news-updates/asthma-toolkit-for-primary-care/
5. Andrews AL, Simpson AN, Basco WT Jr, Teufel RJ 2nd. Asthma medication ratio predicts emergency department visits and hospitalizations in children with asthma. Medicare Medicaid Res Rev. 2013 Dec 16;3(4).
6. O'Byrne PM, Barnes PJ, Rodriguez-Roisin R, Runnerstrom E, Sandstrom T, Svensson K, Tattersfield A. Low dose inhaled budesonide and formoterol in mild persistent asthma: the OPTIMA randomized trial. Am J Respir Crit Care Med. 2001 Oct 15;164(8 Pt 1):1392-7.
7. Oppenheimer JJ, Peters SP. Is the maintenance and reliever approach the answer? Ann Allergy Asthma Immunol. 2010 Feb;104(2):112-7.
8. Papi A, Canonica GW, Maestrelli P, Paggiaro P, Olivieri D, Pozzi E, Crimi N, Vignola AM, Morelli P, Nicolini G, Fabbri LM; BEST Study Group. Rescue use of beclomethasone and albuterol in a single inhaler for mild asthma. N Engl J Med. 2007 May 17;356(20):2040-52.
9. Partridge MR, van der Molen T, Myrseth SE, Busse WW. Attitudes and actions of asthma patients on regular maintenance therapy: the INSPIRE study. BMC Pulm Med. 2006 Jun 13;6:13. doi: 10.1186/1471-2466-6-13.
10. Pauwels RA, Sears MR, Campbell M, Villasante C, Huang S, Lindh A, Petermann W, Aubier M, Schwabe G, Bengtsson T; RELIEF Study investigators. Formoterol as relief medication in asthma: a worldwide safety and effectiveness trial. Eur Respir J. 2003 Nov;22(5):787-94.
11. Rabe KF, Atienza T, Magyar P, Larsson P, Jorup C, Lalloo UG. Effect of budesonide in combination with formoterol for reliever therapy in asthma exacerbations: a randomised controlled, double-blind study. Lancet. 2006 Aug 26;368(9537):744-53.
12. Reddel HK, Bateman ED, Schatz M, Krishnan JA, Cloutier MM. A Practical Guide to Implementing SMART in Asthma Management. J Allergy Clin Immunol Pract. 2022 Jan;10(1S):S31-S38.
13. Smith T, Mills K, Cober MP, Fenn NE 3rd, Hill C, King M, Pauley JL, Eiland L, Sierra C, Omecene NE. Updates in the treatment of asthma in pediatrics: A review for pharmacists. Am J Health Syst Pharm. 2024 Apr 19;81(9):e210-e219.
14. van der Woude HJ, Boorsma M, Bergqvist PB, Winter TH, Aalbers R. Budesonide/formoterol in a single inhaler rapidly relieves methacholine-induced moderate-to-severe bronchoconstriction. Pulm Pharmacol Ther. 2004;17(2):89-95.
15. Vernacchio L, Trudell EK, Muto JM. Correlation of care process measures with childhood asthma exacerbations. Pediatrics. 2013 Jan;131(1):e136-43.

Need More Information?

Kelin Wheaton, PharmD, PhD
Kelin.wheaton@nationwidechildrens.org

OHIO PHARMACISTS ASSOCIATION

2024 Midyear Meeting & Trade Show
November 3, 2024