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MART Therapy

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UNMC-Baker's

OBJECTIVES

MART Therapy

- Define MART therapy
- Determine appropriate MART therapy strategies for maintenance and exacerbation treatment for asthma based on severity and safety

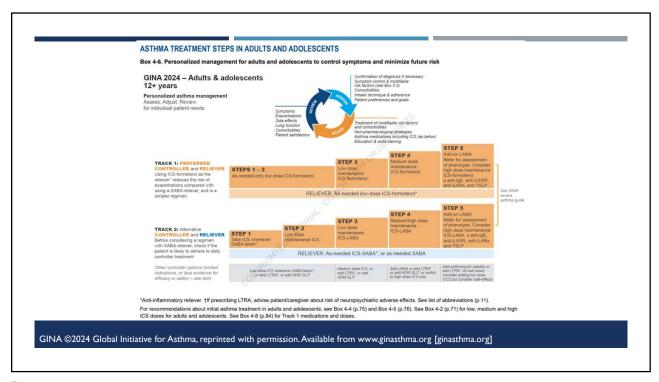
Practical Application

- Identify the primary concerns when trying to select appropriate inhaler therapy
- Recognize commercially available ICS-LABA inhalers and understand how to incorporate GINA recommendations with these inhalers practically
- Identify barriers to AIR/MART therapy and devise possible solutions

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ABBREVIATIONS

- AIR anti-inflammatory reliever
- ICS Inhaled corticosteroid
- LABA Long-acting-beta₂ agonist
- MART Maintenance-and-reliever therapy (with ICS-formoterol)
- OCS Oral Corticosteroid
- PRN as needed
- SABA Short-acting beta₂ agonist
- SMART Single-inhaler maintenance-and-reliever therapy



AIR VS SMART THERAPY

AIR

- Anti-inflammatory reliever
- Reliever containing both a low-dose ICS and a rapid-acting bronchodilator

MART

- Maintenance and Reliever Therapy
- AKA SMART
 - Single-Inhaler Maintenance-and-Reliever Therapy
- Treatment regimen that uses an ICSformoterol inhaler daily (i.e., maintenance dose), and also uses the same medication as needed for relief of symptoms (reliever doses)

AIR THERAPY

- Contains low-dose ICS and rapid-acting bronchodilator
- Includes:

Budesonide-formoterol

Beclometasone-formoterol

ICS-salbutamol combinations

- Non-formoterol LABAs in combination with ICS cannot be used as relievers
- ICS-formoterol should not be used as a reliever with maintenance ICS-non-formoterol LABAs
- Can be used as needed before exercise or allergen exposure to prevent asthma symptoms and bronchoconstriction
- Some anti-inflammatory relievers can be used PRN at Steps I-2 as a person's sole asthma treatment, without maintenance (AIR-only)
- Some ICS-formoterol combinations can be used as both maintenance and reliever therapy at Steps 3-5

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AIR THERAPYI

- Preferred treatment Track #1 Steps 1-2 for adults and adolescents
 - As-needed-only low-dose combination ICS-formoterol
- Treatment regimen is simpler patients can use a single medication for reliever and maintenance treatment if prescribed
- Dosing frequency and strength is dependent on age group

	6 - 11 years	12 - 17 years	≥18 years*
Inhalers No evidence to date	Budesonide-formoterol 200/6 mcg/ inhalation (160/4.5 mcg delivered dose)	Budesonide-formoterol 200/6 mcg/ inhalation (160/4.5 mcg delivered dose)	
Dosing Frequency for AIR (Step 1-2)		Max total 12 inhalations in any day • I inhalation as needed	Max total 12 inhalations in any day • I inhalation as needed

AIR THERAPY

Usual dose of as-needed budesonide-formoterol in mild asthma

• Single inhalation of 200/6mcg (delivered dose 160/4.5mcg), taken as needed for symptom relief

Max recommended dose of as-needed budesonide-formoterol in a single day corresponds to a total of 72 mcg formoterol (54 mcg delivered dose)

Average use around 3-4 doses per week^{2,3,4}

Rinsing the mouth is not generally needed after as-needed doses of low-dose ICS-formoterol⁵

Other ICS-formoterol formulations have not been studied for PRN use

• Beclometasone-formoterol may also be suitable based on well-established use within maintenance-and-reliever therapy, but it is not available as a combination in the USA

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AIR THERAPYI

SYGMA I study found a 64% reduction in severe exacerbations requiring oral corticosteroids, compared to SABA-only treatment³

Compared to SABA alone, as-needed low-dose ICSformoterol reduced risk of severe exacerbations requiring OCS by 55%, and reduced the risk of emergency department visits or hospitalizations by 65%

In four studies, the as-needed ICS-formoterol strategy was associated with substantially lower average ICS dose than with maintenance low-dose ICS^{2,3,4,7}

MART THERAPY¹

- Contains ICS-formoterol daily (maintenance therapy), and uses the same medication as-needed for asthma symptom relief (reliever therapy) –Preferred for Track #1 Steps 3-5
- Used <u>only</u> with combination ICS-formoterol inhalers
- Include:

Budesonide-formoterol

Beclometasone-formoterol (combo not available in US)

- Combination of ICS with non-formoterol LABAs, or ICS-SABA, cannot be used for MART
- Low-dose ICS-formoterol can be used before exercise and before expected allergen exposure
- Use of ICS-formoterol as a reliever and maintenance step simplifies the regimen with an easy transition if treatment needs to be stepped up or down, without the need for an additional medication or inhaler type

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MART THERAPY - STEP 3

- Preferred treatment Track #I Steps 3 for adolescents and adults
 - Low-dose ICS-formoterol used for both the daily maintenance treatment and an anti-inflammatory reliever for symptom relief
- Treatment regimen is simpler patients can use a single medication for reliever and maintenance treatment if prescribed
- Dosing frequency and strength is dependent on age group

	6 - Ilyears	12 - 17 years	≥18 years
Inhalers	Budesonide-formoterol 100/6 mcg/ inhalation (80/4.5 mcg delivered dose)	Budesonide-formoterol 200/6 mcg/ inhalation (160/4.5 mcg delivered dose)	Budesonide-formoterol 200/6 mcg/inhalation (160/4.5 mcg delivered dose)
Dosing Frequency for MART (Step 3)	Max total 8 inhalations in any day I inhalation once daily plus I as needed	Max total 12 inhalations in any day I inhalation twice (or once) daily plus I as needed	Max total 12 inhalations in any day I inhalation twice (or once) daily plus I as needed

MART THERAPY - STEP 3

Usual dose of MART budesonide-formoterol in Step 3

• I inhalation twice (or once) daily plus I as needed

Max total recommended dose, based on formoterol (accounting for both maintenance-and-reliever doses), is 72mcg metered dose (54mcg delivered dose)

ICS-formoterol should \underline{not} be used as a reliever for patients taking a different ICS-LABA maintenance treatment and may be associated with increased adverse effects⁸

Rinsing the mouth is not generally needed after as-needed doses of ICS-formoterol⁵

MART is an option for children 6-11 years of age in Step 3 of treatment at a lower dose

- Very low-dose budesonide-formoterol 80/4.5 mcg delivered dose
 - I inhalation once daily plus I as needed
 - · Max total 8 inhalations in any day

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MART THERAPY | STEP 3



Low-dose ICS-formoterol maintenance-and-reliever therapy reduced severe exacerbations

Also provided similar levels of asthma control at relatively low doses of ICS, compared with a fixed dose of ICS-LABA as maintenance treatment or a higher dose of ICS, both with PRN SABA⁹⁻¹⁴



switching patients with uncontrolled asthma from Step 3 treatment + SABA reliever to MART was associated with a 29% reduced risk of severe exacerbation, vs stepping up to Step 4 ICS-LABA maintenance + SABA reliever, and a 30% reduced risk compared to staying on the same step treatment with SABA reliever¹⁵

MART THERAPY | - STEP 4

Usual dose of MART budesonide-formoterol in Step 4

Max total recommended dose, based on formoterol (accounting for both maintenance-and-reliever doses), is 72mcg metered dose (54mcg delivered dose)

MART is an option for children 6-11 years of age in Step 4 of treatment at a lower dose

- Very low-dose budesonide-formoterol 80/4.5 mcg delivered dose
- · I inhalation twice daily plus I as needed
- · Max total 8 inhalations in any day

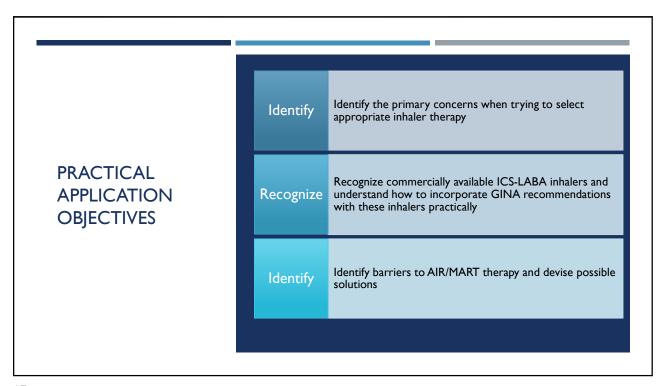
For adults and adolescents, combination ICS-formoterol as MART is more effective at reducing exacerbations than the same dose of maintenance ICS-LABA or higher doses of ICS 13 or ICS-LABA 16

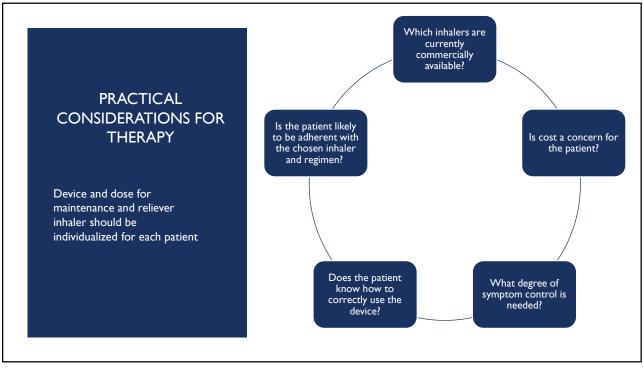
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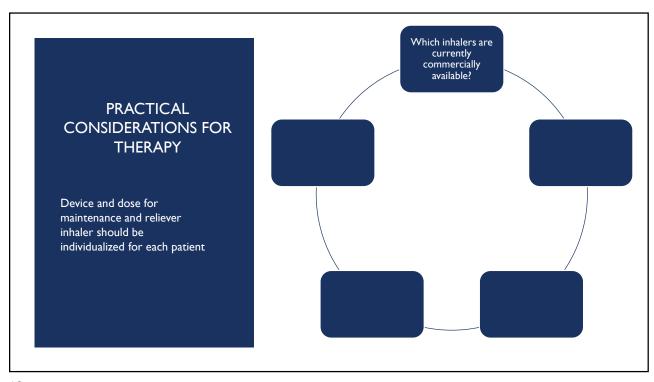
MART THERAPY - STEP 4

- Usual dose of MART budesonide-formoterol in Step 4
 - Medium-dose ICS-formoterol used for both the daily maintenance treatment and an antiinflammatory reliever for symptom relief
- Treatment regimen is simpler patients can use a single medication for reliever and maintenance treatment if prescribed
- Dosing frequency and strength is dependent on age group

	6 - Hyears	12 - 17 years	≥18 years
Inhalers	Budesonide-formoterol 100/6 mcg/inhalation (80/4.5 mcg delivered dose)	Budesonide-formoterol 200/6 mcg/inhalation (160/4.5 mcg delivered dose)	Budesonide-formoterol 200/6 mcg/inhalation (160/4.5 mcg delivered dose)
Dosing Frequency for MART (Step 4)	Max total 8 inhalations in any day I inhalation twice daily plus I as needed	Max total 12 inhalations in any day • 2 inhalations twice daily plus 1 as needed	Max total 12 inhalations in any day • 2 inhalations twice daily plus 1 as needed







Agents	Brand	Formulation		
Budesonide- <u>formoterol</u>	Symbicort®	MDI		
Mometasone- <u>formoterol</u>	Dulera®	MDI		
Fluticasone-vilanterol	Breo Ellipta®	DPI		
Fluticasone-salmeterol	Advair®	DPI, MDI		
Available ICS-LABA Inhalers MDI = meter dose inhaler DPI = dry powder inhaler				

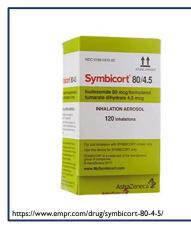
SELECTING AN INHALER



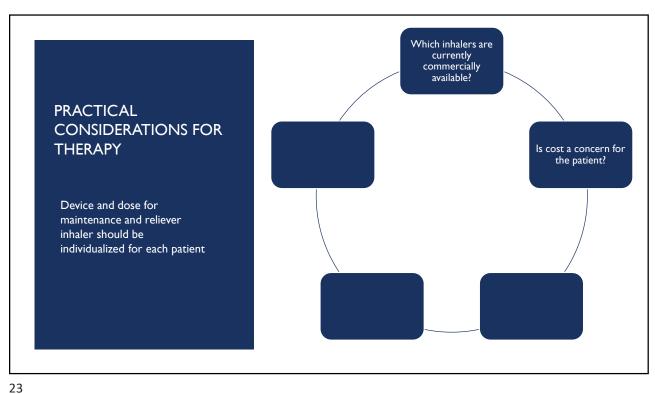
- AIR/MART studies recommend ICS-formoterol combination inhalers for symptom relief and maintenance
- Is mometasone-formoterol an appropriate alternative to budesonide-formoterol?
 - o Currently no MART studies with mometasone-formoterol
 - GINA cautions against extrapolating data to other ICSformoterol inhalers

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SELECTING AN INHALER



- Is AIR/MART therapy appropriate for both adults and children?
 - o AIR and MART therapy are recommended for adolescents and adults
 - AIR therapy not studied extensively in children ages 6-11; therefore, use in this age group is not recommended at this time
 - o MART is an option for children ages 6-11; initiate at a lower dose
- Potential barrier: AIR/MART therapy with ICS-formoterol DPI is not an approved regimen by the US FDA
 - o Most studies for MART looked at the Symbicort DPI
 - o In the US, only Symbicort MDI is available



COST AND COVERAGE

- Generic budesonide-formoterol became available March 2022
- Most insurance companies do not have formularies that support MART therapy, and may have quantity limits that would limit additional inhalations for rescue use
 - Cost differences between available SABAs and ICS-formoterol
 - Lack of FDA approval

Symbicort

- 120 inhalations
- \$300-400

Budesonideformoterol

- 120 inhalations
- \$150-250

Albuterol

- 90 inhalations
- \$30-60

COST AND COVERAGE

- MART therapy reduces severe exacerbations compared to SABA alone; cost of MART therapy may be offset by decreases in health care costs
 - o Decreased number of emergency room visits, urgent care visits
- o MART/AIR therapy reduces the number of inhalers a patient requires
 - Fewer medications = less copays
 - o A single device reduces the potential for waste
 - Expiring albuterol inhalers
- Major differences and options for government insurance and private insurance



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COST AND COVERAGE – MEDICARE TODAY

In 2024 in Nebraska, there are 22 Part D Prescription Drug Plans available

Deductible

Patient pays 100% of drug costs up to a maximum of \$545

Initial Coverage

Patient pays between \$0 to 50% coinsurance of the drug's full price

Coverage Gap (Donut Hole)

After patient and plan combined spend \$5030, patient pays 25% of the drug's full price

Catastrophic Coverage

After the out-ofpocket spending reaches \$8000, patient pays \$0

COST AND COVERAGE – MEDICARE IN 2025



The coverage gap will be eliminated

The initial coverage phase will extend to the maximum annual out-of-pocket threshold, at which point the catastrophic phase will begin

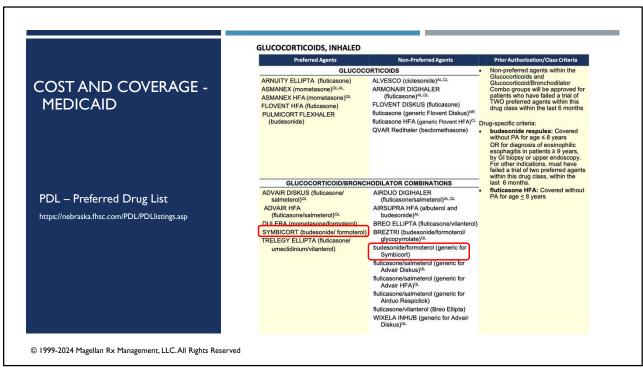


Out-of-pocket cap

The out-of-pocket limit for 2025 is set at \$2000, after which Medicare will cover the remaining costs

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Coverage Gap Initial Catastrophic Deductible (Donut Hole) Coverage Coverage Patient pays After patient and Patient pays 100% After the out-ofbetween \$0 plan combined spend of drug costs up to pocket spending \$5030, patient pays 25% of the to 50% reaches \$8000, a maximum coinsurance of the patient pays \$0 of \$545 drug's full price drug's full price Catastrophic Initial Deductible Coverage Coverage Patient pays 25% After the out-of-Patient can pay coinsurance of pocket spending up to a reaches \$2000, covered drug's maximum of \$590 full price patient pays \$0

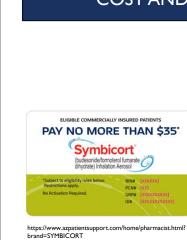


COST AND COVERAGE - COMMERCIAL INSURANCE

- Highly variable
 - Preferred products, preferred pharmacy
 - Eligibility for savings programs
 - May require prior authorization
- Savings program eligible patients save and spend \$35
 - Cannot use with government-issued insurance (Tricare, VA, Medicare, Medicaid)
 - Pay as low as \$35 for each 30-day supply (one inhaler); patient out-of- pocket expenses may vary
 - Maximum savings limit for the program is \$200 per inhaler
 - The coupon is valid for use 12 times only



 $https://www.azpatientsupport.com/home/pharmacist.html?\\brand=SYMBICORT$



COST AND COVERAGE - COMMERCIAL INSURANCE

- Mail order rebate
 - For patients with a mail-order option can complete the Savings Card reimbursement form and mail it with proof of purchase to receive a savings refund
- AZ&ME savings discount program provided by AstraZeneca
 - o Patients with no insurance or Medicare Part D may be eligible
 - Need to make a certain income or lower to qualify and receive a manufacturer coupon

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ADDITIONAL OPTIONS

Independent patient assistance programs

Additional Affordability Resources

Here are some additional resources that may help you gain access to the medicines or services you need. This is not a complete list and is provided as a public service for health care providers, caregivers, and low-income patients.

complete list and is provided as a public service for health Area Agencies on Aging (Electora) Local area agencies on aging may be able to help patients age 65 years and older who cannot infort wheir medicines. To contact your local area agency on aging, call 1-300-877-1116 or vital twaveldercare.acl.gov. Association of Clinicians for the Underserved (ACU) The ACU is an operation that works to help clinicians better serve the needs of low-income patients. For more information, visit www.clinicians.org.

For more information, visit www.clinicians.org.

BenefitsCheckUp?

The National Council on Aging (NCOA) aponsors this website. It offers confidential assistance online for seniors and caregivers by searching more than 1,100 federal, state, and private prescription drug programs and determining those for which the senior may be eligible. For more information, visit www.benefitscheckup.org.

Health Resources and Services Administration (HRSA)

HESA cliens information about community health centres that HESA cliens information. The community of the control o

more information, call 1-888-ASK-HRSA or visit www.hrsa.gov. Inside Rs.SM Express Scripts has introduced a prescription drug discount program called inside/its and AstraZeneca is one of several pharmacoulcula companies participating. This program pharmacy including those who don't have insurance, or who are in the deductible phase of a high-deductible commercial insurance plan. Through this program, many AstraZeneca products can be accessed at a discounted price, providing savings that are realized immediately at the pharmacy. For a list of participating pharmacies, medications, and other important infections.

information about the program, visit www.lnaideRv.com. Medicine Assistance Tool (MAT) is a search engine designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaeuticinal industry programs. MAT is not to own patient assistance program but rather a search engine for many of the patient assistance resources that the biopharmaeutical industry offers. For more information, visit www.mat.org.

Medicare
This official Medicare website can help patients, caregivers, and doctors find information about public and private prescription drug assistance programs in their area, including eligibility requirements and covered services. For more information, visit www.medicare.gov.

www.medicare.gov.

The My Medicare Matters

The My Medicare Matters website is designed to help individuals beam more about Medicare prescription drug coverage. The website was developed using materials from the Centers for Medicare and Medicals Services, as well as materials developed by the National Council on Aging (NCOA), the Access to Berefits Coatilition (Agi., and AstraZeneca. For more information, visit www.mymedicarematters.org.

more information, was www.www.more information, was developed in RecdyMeds is devoted to helping people in need find assistance programs to help them afford their medications and costs related to health care. The NeedyMeds website provides information on company patient assistance programs, free and low-cost clinics, government programs and other was all ow-cost clinics, government programs and other www.needymeds.org.

www.nedymeds.org.

Rx Outreach

1234 (1-88-7/B*-1/2-yr)

RASsist

RASsist test you search for information on patient assistance
Programs by company, brand name, generic name, or type of
medicine. RAAssist provides information on ways to get free
and low-cost medications. The site sto provides a guickreference chart that lists drug assistance programs by state.
For more information, visit www.rxassist.org.

Independent Charitable Patient Assistance Foundations

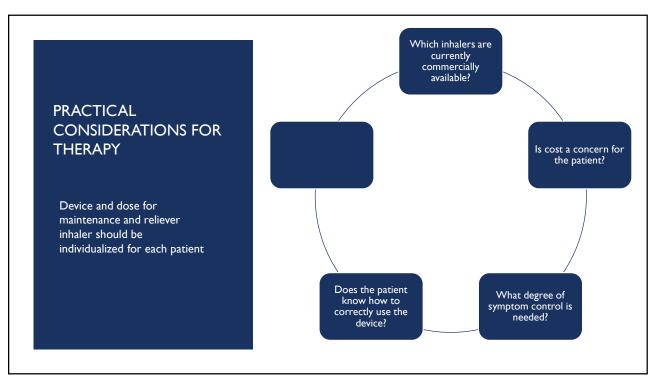
- Leukemia & Lymph www.lls.org 1-800-955-4572
- Patient Access Network F www.PANfoundation.org 1-866-316-7263

AstraZeneca 🕏

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Which inhalers are currently commercially available? **PRACTICAL CONSIDERATIONS FOR THERAPY** Is cost a concern for the patient? Device and dose for maintenance and reliever inhaler should be individualized for each patient What degree of symptom control is needed?





PERFECTING TECHNIQUE¹⁹ – PRIMING A SYMBICORT® INHALER

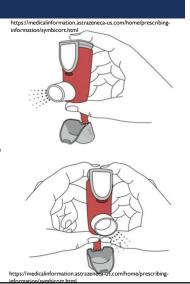


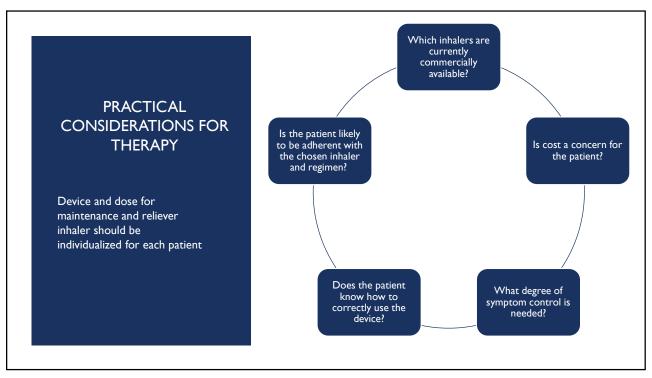
- Take the inhaler out of the foil pouch
- If using it for the first time, shake inhaler for 5 seconds, then release a test spray
 - Also, if > 7 days since last use
- Shake it again for 5 seconds and release a second test spray

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DIRECTIONS FOR USE¹⁹

- Shake inhaler for 5 seconds
- 2. Remove the mouthpiece cover by squeezing gently at both sides, then pull off
- 3. Hold inhaler upright. Breathe out fully, then place the mouthpiece into mouth and close lips around it
- 4. Inhale deeply and slowly while pressing down firmly on the top of the counter on the inhaler
- 5. Hold breath for about 10 seconds (or as long as comfortable.)
- 6. Release your finger from the top of the counter
- 7. Keep the inhaler upright and remove from mouth, then breathe out





FACTORS CONTRIBUTING TO POOR ADHERENCE

Difficulties using inhaler

- Dexterity
- Problems coordinating breathing with actuation
 - Spacer

Burdensome regimen

· Multiple times a day

Misunderstanding instructions

• More complicated regimen than scheduled maintenance doses

Cost

Concerns about side effects

NEW DEVELOPMENTS - AIRSUPRA Airsupra = budesonide-albuterol (ICS-SABA) ■ FDA has approved Airsupra for as-needed treatment for patients 18+ years with asthma 0.35 o First product containing an ICS to be approved as a 0.25 0.20 Efficacy - evaluated in adult patients with moderate to 0.15 severe asthma in the MANDALA study²⁰ (randomized, double-blind, multicenter study) o Primary endpoint - time to first severe asthma attack 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 Time from randomization (weeks) o Airsupra demonstrated a 28% reduction in the risk of a severe asthma attack as compared to albuterol https://www.airsuprahcp.com/exacerbation-study

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