Asthma Pharmacotherapy 2017: Stepwise Approach to Managing Asthma

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Global Initiative for Asthma
Asthma Pharmacotherapy

Quick-relief
- Short-acting beta-agonists
- Inhaled anticholinergics
- Systemic corticosteroids

Long-term control
- Corticosteroids
- Cromolyn sodium
  - Mast cell stabilizer
  - Only available in nebulized form
- Long-acting inhaled beta-agonists
- Theophylline
- Leukotriene Receptor Antagonists (LTRA)
Quick-Relief Medications

- Short-acting beta$_2$-agonists (SABA): albuterol (Pro-Air®, Ventolin®, Proventil®); levalbuterol (Xopenex®)
- Relax bronchial smooth muscles
- Short-acting
  - Work within 10 - 15 minutes
  - Last 4 - 6 hours
- Bind to and activate beta$_2$ receptors in cardiac and smooth muscle tissues
  - Cause bronchodilation in lungs
  - Side effects can include shakiness (tremors), tachycardia
- (Older) beta-blockers are contraindicated in asthma as they can cause the opposite effect - bronchoconstriction
- Danger of over-use
Short-acting $\beta_2$-agonists (SABA)

- Most effective medication for relief of acute symptoms

**RED FLAG**
- more than 2 canisters per year

- Regularly scheduled use not generally recommended
  - May “lower” effectiveness
  - May increase airway hyperresponsiveness
Anticholinergics

- Ipratropium bromide (Atrovent) or ipratropium bromide & albuterol (Combivent)
- Not specifically indicated for “usual” quick-relief medication in asthma
  - contrast with COPD
- Now well-studied as adjunct to beta-agonists in emergency departments
  - i.e., acute exacerbations
Long-term Control Medications

- Inhaled corticosteroids (ICS): fluticasone propionate (Flovent®, ArmonAir® RespiClick®); beclomethasone (QVAR®); budesonide (Pulmicort®); mometasone (Asmanex®); ciclesonide (Alvesco®); triamcinolone (Aerospan®), fluticasone furoate (Arnuity®)

- Combination products (inhaled corticosteroids and long-acting beta₂-agonists or ICS/LABA):
  - fluticasone & serevent (Advair®, AirDuo® RespiClick®) – BID, 3 strengths
  - budesonide & formoterol (Symbicort®) – BID, 2 strengths
  - mometasone & formoterol (Dulera®) – BID, 2 strengths
  - fluticasone furoate & vilanterol (Breo®) – once daily, 2 strengths

- Leukotriene receptor antagonist (LTRA): montelukast (Singulair®), zafirlukast (Accolate®), zileuton (Zyflo®)

- Methylxanthines: theophylline (Theo-Dur®, Slo-bid®)

- Anti-IgE blocker: omalizumab (Xolair®)
Long-term Control Medications

- Should be taken daily and chronically to maintain control of persistent asthma and to prevent exacerbations:
  - Soothes airway swelling
  - Helps prevent asthma flares - very effective for long-term control but must be taken daily
  - Often under-used
Inhaled Corticosteroids (ICS)

- Actions:
  - potentiate b-receptor responsiveness
  - reduce mucus production and hypersecretion
  - inhibit inflammatory response at all levels
- Best effects if started early after diagnosis
- Symptomatic and spirometric improvement within 2 weeks
  - maximum effects within 4-8 weeks
Inhaled Corticosteroids (ICS) (continued)

- **THE** most effective long-term control medication for persistent asthma
- Small risk for adverse events at usual doses
  - Risk can be reduced even further by:
    - Using spacer and rinsing mouth
    - Using lowest effective dose
    - Using with long-acting $\beta_2$-agonist when appropriate
    - Monitoring growth in children
Low dose ICS and the Prevention of Asthma Deaths

- ICS protects patients from asthma-related deaths
- Users of > 6 canisters/yr. had a death rate ~ 50% lower than non-users of ICS
- Death rate decreased by 21% for each additional ICS canister used during the previous year.

ICS May Help Prevent the Risk of Asthma Related Hospitalizations

Adapted from Donahue et. al. JAMA 1997;277(11):887-891.

Relative Risk of Hospitalization

Short-acting $\beta_2$-agonists

Inhaled Steroids

Total

Short-acting $\beta_2$ prescriptions dispensed per person-year

Adapted from Donahue et. al. JAMA 1997;277(11):887-891.
Inhaled Corticosteroids (ICS) (continued)

- Hypothalamic-pituitary-adrenal (HPA) suppression
  - Not seen in usual doses

- Cataracts
  - Not seen in usual doses

- Long bone growth
  - Growing understanding of this risk
  - Childhood Asthma Management Program (CAMP) study (2000)* showed small, transient reduction in growth velocity from ICS
  - Update (2012)** showed growth reduction persisted as lowered adult height (1.2 cm) – need to weigh risks & benefits

- Osteoporosis/Bone Fractures
  - Some attention at high doses, high-risk patients

- Candidiasis (thrush)

- Dysphonia (hoarseness)

Checking height in children with asthma

- Check height at least yearly, because:
  - Poorly-controlled asthma can affect growth [Pedersen 2001]
  - Growth velocity may be lower in the first 1-2 years of ICS treatment but this is not progressive or cumulative [Kelly 2012, Loke 2015].
  - The one study that examined long-term outcomes showed a difference of only 0.7% in adult height [Kelly 2012, Loke 2015]

- If decreased growth velocity is seen, also consider:
  - Poorly-controlled asthma
  - Frequent use of OCS
  - Poor nutrition
Discuss decisions about controller treatment with parents/carers
  - Discuss the relative benefits and risks of treatment/no treatment
  - Emphasize the importance of maintaining normal activity levels for normal physical and social development

ICS can have a small but usually temporary effect on growth
  - An effect of ICS on growth velocity is seen in pre-pubertal children in the first 1-2 years of treatment
  - This is not progressive or cumulative [Kelly 2012, Loke 2015].
  - The one study that examined long-term outcomes showed a difference of only 0.7% in adult height [Kelly 2012, Loke 2015]

Poorly-controlled asthma itself adversely affects adult height [Pedersen 2001]

For more detail see GINA 2017 Appendix Chapter 5B
Leukotriene Receptor Antagonists (LTRA)

- **Two mechanisms**
  - 5-lipoxygenase inhibitors
    - zileuton (Zyflo®)
  - Cysteinyl leukotriene receptor antagonists
    - zafirlukast (Accolate®), montelukast (Singulair®)

- **Indications**
  - Generally, alternative therapy in mild persistent asthma or as add-on in higher stages
    - Improve lung function
    - Decrease short-acting $\beta_2$-agonist use
    - Prevent exacerbations
Methylxanthines (Theophylline) (continued)

- Places in therapy:
  - When inhaled corticosteroids not possible
  - Patients who can’t/won’t use inhalers
  - Additive therapy at later stages

- Adverse Drug Reactions/Serum Levels
  - Therapeutic Range 5-15 mcg/mL, or 10-20 mcg/mL
  - Levels > 20 mcg/mL: nausea, vomiting, diarrhea, headache, irritability, insomnia, tachycardia
  - Levels > 30 mcg/mL: seizures, toxic encephalopathy, hyperthermia, brain damage

- Drug Interactions: PLENTY!!
Long-Acting $\beta_2$-Agonists

- Not a substitute for anti-inflammatory therapy
- Not appropriate for monotherapy

**RED FLAG**
- Literature supporting role in addition to inhaled corticosteroids
- Not for acute symptoms or exacerbations
- Salmeterol (Serevent®) first of class in US (in Advair®)
- Newer LABAs: formoterol (Foradil®) & vilanterol (in Breo®)
  - Newer long-acting beta-agonists
  - Have rapid onset and long duration
  - Formoterol is available in combination with inhaled steroid in Symbicort® & Dulera® (BID dosing), vilanterol is in Breo® (qd dosing)
Long-Acting $\beta_2$-Agonists

- Salmeterol Multicenter Asthma Research Trial (SMART)
- A comparison of usual pharmacotherapy for asthma or usual pharmacotherapy plus salmeterol.
The Salmeterol Multicenter Asthma Research Trial*  
A Comparison of Usual Pharmacotherapy for Asthma or Usual Pharmacotherapy Plus Salmeterol  

Harold S. Nelson, MD; Scott T. Weiss, MD, MS; Eugene R. Bleecker, MD; Steven W. Yancey, MS; and Paul M. Dorinsky, MD; and the SMART Study Group
Long-Acting $\beta_2$-Agonists (LABAs)

- Patients $> 12$ years old with asthma
- Sought to evaluate the effects of salmeterol or placebo added to usual asthma care on
  - respiratory and asthma related deaths
  - life-threatening episodes
- Initial aim to enroll 30,000 patients; later changed with aim to enroll 60,000
Long-Acting $\beta_2$-Agonists (LABAs)

- Increase in adverse events in salmeterol group during SMART trial:
  - Particularly in those recruited in Phase 1
  - Particularly among African-Americans who were noted to have markers of more severe asthma and less likely to be using ICS

- Increase in adverse events in salmeterol group:
  - Due to adverse effect of salmeterol?
  - Due to inappropriate bronchodilator use? (affected patients were more severe at baseline and less likely to be using ICS)
FDA Safety Requirements for Long-Acting $\beta_2$-Agonists (LABAs) in Asthma

- The use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid. Single-ingredient LABAs should only be used in combination with an asthma controller medication; they should not be used alone.

- LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications.

- LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication.

- Pediatric and adolescent patients who require the addition of a LABA to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA, to ensure compliance with both medications.

~ February 2010
Conclusions:

- Black Box warning
- Do not use long-acting bronchodilators alone
- Always use with inhaled corticosteroids

Newer Data:

- LABAs when used with inhaled corticosteroids are helpful. Multiple reviews/meta-analyses suggest that long-acting beta-agonists + inhaled corticosteroids reduce asthma hospitalizations compared to inhaled corticosteroids alone.

- Emphasize the weakness of the primary data in terms of statistical strength, simply because asthma-related deaths and intubations are so rare.

Patients Are Candidates for Maintenance Therapy if The “RULES OF TWO”™* Apply…

- They are **using a quick-relief inhaler** more than **2 times per week**
- They **awaken at night due to asthma** more than **2 times per month**
- They **refill a quick-relief inhaler Rx** more than **2 times per year**

*“RULES OF TWO”™ is a trademark of the Baylor Health Care System.
Out of Control!

Rules of Two™

- If your patient can answer “YES” to ANY of these questions, his/her asthma is probably not under good control.

- These rules define persistent asthma.
Asthma Severity

- Intermittent
- Mild Persistent
- Moderate Persistent
- Severe Persistent
### Components of Severity

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Classification of Asthma Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Impairment</strong></td>
<td><strong>Intermittent</strong></td>
</tr>
<tr>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td>Symptoms</td>
<td>≤2 days/week</td>
</tr>
<tr>
<td>Nighttime Awakenings</td>
<td>≤2x/month</td>
</tr>
<tr>
<td>SABA use for sx control</td>
<td>≤2 days/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>none</td>
</tr>
<tr>
<td>Lung Function</td>
<td>•Normal FEV₁ between exacerbations</td>
</tr>
<tr>
<td></td>
<td>• FEV₁ &gt; 80%</td>
</tr>
</tbody>
</table>

### Risk

| Relative annual risk of exacerbations may be related to FEV₁ |
| Frequency and severity may vary over time for patients in any category |

### Recommended Step for Initiating Treatment

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4 or 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>In 2 - 6 weeks, evaluate asthma control that is achieved and adjust therapy accordingly</td>
<td>Consider short course of oral steroids</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Asthma Control

The purpose of periodic assessment and ongoing monitoring is to determine whether the goals of asthma therapy are being achieved and asthma is controlled.

- **Well Controlled**
- **Not Well Controlled**
- **Very Poorly Controlled**
### Classification of Asthma Control

<table>
<thead>
<tr>
<th>Components of Control</th>
<th>Well Controlled</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IMPAIRED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>≤ 2 days/week</td>
<td>&gt; 2 days/week</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>≤ 2/month</td>
<td>1-3/week</td>
<td>≥ 4/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>none</td>
<td>Some limitation</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>SABA use</td>
<td>≤ 2 days/week</td>
<td>&gt; 2 days/week</td>
<td>Several times/day</td>
</tr>
<tr>
<td>FEV_{1} or peak flow</td>
<td>&gt; 80% predicted/ personal best</td>
<td>60-80% predicted/ personal best</td>
<td>&lt;60% predicted/ personal best</td>
</tr>
<tr>
<td>Validated questionnaires</td>
<td>0/≥ 20</td>
<td>1-2/16-19</td>
<td>3-4/≤ 15</td>
</tr>
<tr>
<td>ATAQ/ACT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exacerbations</td>
<td>0- 1 per year</td>
<td>2 - 3 per year</td>
<td>&gt; 3 per year</td>
</tr>
<tr>
<td>Progressive loss of lung function</td>
<td>Evaluation requires long-term follow up care</td>
<td>Consider in overall assessment of risk</td>
<td></td>
</tr>
<tr>
<td>Rx-related adverse effects</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Recommended Action

- **Well Controlled**: Maintain current step. Consider step down if well controlled at least 3 months.
- **Not Well Controlled**: Step up 1 step. Reevaluate in 2 - 6 weeks.
- **Very Poorly Controlled**: Consider oral steroids. Step up (1-2 steps) and reevaluate in 2 weeks.

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**EPR-3, p77, 345**
Stepwise management - pharmacotherapy

**Not for children <12 years**

*For children 6-11 years, the preferred Step 3 treatment is medium dose ICS

#For patients prescribed BDP/formoterol or BUD/formoterol maintenance and reliever therapy

† Tiotropium by mist inhaler is an add-on treatment for patients ≥12 years with a history of exacerbations

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

**Diagnosis**
- Symptom control & risk factors (including lung function)
- Inhaler technique & adherence
- Patient preference

**Step 1**
- Low dose ICS

**Step 2**
- Consider low dose ICS
- Leukotriene receptor antagonists (LTRA)
- Low dose theophylline*

**Step 3**
- Med/high ICS/LABA
- Med/high ICS + LTRA (or + theoph*)

**Step 4**
- Med/high ICS/LABA
- Add tiotropium†
- Add low dose OCS

**Step 5**
- Refer for add-on treatment e.g. tiotropium, anti-IgE, anti-IL5*

**PREFERRED CONTROLLER CHOICE**

**Other controller options**

**RELEIVER**

- As-needed short-acting beta²-agonist (SABA)
- As-needed SABA or low dose ICS/formoterol†
**REMEMBER TO**

- Provide guided self-management education
- Treat modifiable risk factors and comorbidities
- Advise about non-pharmacological therapies and strategies
- Consider stepping up if … uncontrolled symptoms, exacerbations or risks, but check diagnosis, inhaler technique and adherence first
- Consider adding SLIT in adult HDM-sensitive patients with allergic rhinitis who have exacerbations despite ICS treatment, provided FEV₁ is 70% predicted
- Consider stepping down if … symptoms controlled for 3 months + low risk for exacerbations. Ceasing ICS is not advised.

SLIT: sublingual immunotherapy
The control-based asthma management cycle

**Diagnosis**
- Symptom control & risk factors (including lung function)
- Inhaler technique & adherence
- Patient preference

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

**Asthma medications**
- Non-pharmacological strategies
- Treat modifiable risk factors

**Review Response**

**Assess**

**Adjust Treatment**
General principles for stepping down controller treatment

- **Aim**
  - To find the lowest dose that controls symptoms and exacerbations, and minimizes the risk of side-effects

- **When to consider stepping down**
  - When symptoms have been well controlled and lung function stable for ≥3 months
  - No respiratory infection, patient not travelling, not pregnant

- **Prepare for step-down**
  - Record the level of symptom control and consider risk factors
  - Make sure the patient has a written asthma action plan
  - Book a follow-up visit in 1-3 months

- **Step down through available formulations**
  - Stepping down ICS doses by 25–50% at 3 month intervals is feasible and safe for most patients *(Hagan et al, Allergy 2014)*
  - See GINA 2017 report Box 3-7 for specific step-down options

- Stopping ICS is not recommended in adults with asthma because of risk of exacerbations *(Rank et al, JACI 2013)*
Current Therapy

- Use Asthma Guidelines as a guide
- Poor adherence with inhaled therapy
- No curative therapy
- Many patients remain poorly controlled
- Recognition of different phenotypes of asthma
New/Upcoming Asthma Therapies

- Recognition that there are different phenotypes or endotypes of asthma
  - Phenotype – observable characteristics or clinical presentation (e.g., transient vs. persistent wheezing)
  - Endotype – a subtype of a condition defined by a distinct pathophysiological mechanism

- As treatments become more specific, targeting specific inflammatory cells (such as blockade of specific cytokines or kinases) may be effective in the treatment of asthma

- Because new therapies are likely to be very expensive (especially antibodies) it will become increasingly important to recognize responder patients
New Long-Acting Bronchodilators

- Prevention and relief of bronchoconstriction
- LABAs offered 12 hour action
  - Salmeterol (Serevent®), formoterol (Foradil®)
- Now Ultra-LABAs in development with 24-hour action
  - indacaterol, carmoterol, vilanterol and olodaterol.
Risks of LABAs

- Increased risk of overall death if monotherapy
- Evidence supports LABA + ICS in a single inhaler device for patient with mod/severe asthma

Thorax 2012; 67: 67 342-349
ProAir RespiClick®
albuterol sulfate dry powder inhaler

- Breath actuated
Side Effects

- Back pain
- Body aches and pains
- Upset stomach
- Heart racing
- Urinary tract infection
- Shakiness
Arnuity Ellipta®
fluticasone furoate

- Approved August 2014
- Once daily maintenance therapy of asthma in those 12 and older
- Normal dose is one inhalation daily
- Starting dose is 100mcg
- May increase to 200mcg after 2 weeks
Side Effects

- Upper infections
- Nasopharyngitis
- Headache
- Bronchitis
- Oral candidiasis
LABA/Corticosteroid

- New products aimed for ease of use and adherence to therapy
- One inhalation/once daily
Breo Ellipta®
fluticasone furoate/vilanterol

- FDA approval 4/30/2015 for ages 18 and older
- LABA warning continues
- Once daily inhalation therapy for individuals with asthma
- Side Effects - Headache, nasopharyngitis, pneumonia, fractures
Respimat®  
New Inhalation Device  
SMI (Soft Mist Inhaler)  

Respimat Medications:  

- Combivent®  
  - albuterol and ipratropium (quick-relief)  
- Spiriva®  
  - Tiotropium (LAMA)  
- Stiolto®  
  - Tiotropium/olodaterol (LAMA/LABA)
Spiriva Respimat® (tiotropium)

- New indication for asthma
- Dose 1.25mcg/actuation = 2 actuations once daily
- Add-on maintenance bronchodilator treatment
- Once-daily maintenance treatment for patients with asthma > 6 years (new age indication)
- Not for the relief of acute bronchospasm
- Can be used in patients who remain symptomatic on ICS/LABA
- Adverse reactions: pharyngitis, cough, headache, palpitations, dizziness, dysphonia
### Choosing an inhaler device for children ≤5 years

<table>
<thead>
<tr>
<th>Age</th>
<th>Preferred device</th>
<th>Alternate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–3 years</td>
<td>Pressurized metered dose inhaler plus dedicated spacer with face mask</td>
<td>Nebulizer with face mask</td>
</tr>
<tr>
<td>4–5 years</td>
<td>Pressurized metered dose inhaler plus dedicated spacer with mouthpiece</td>
<td>Pressurized metered dose inhaler plus dedicated spacer with face mask, or nebulizer with mouthpiece or face mask</td>
</tr>
</tbody>
</table>

GINA 2017, Box 6-7
Device Selection in Children (2017)

- Inhaled therapy is cornerstone of asthma treatment
- Tidal breathing in young children with spacer/face mask
- Takes 5-10 breaths to empty spacer depending on child’s tidal volume and spacer volume (passive)
- Place face mask tightly around mouth and nose
- Nebulizers are reserved for minority of children who cannot be taught effective use of a spacer device (use with mouthpiece to avoid medication reaching the eyes) – never use blow-by technique!
Biologics: Xolair® (omalizumab)
Anti-IgE Therapy

- Biologic antibody therapy binds IgE in the circulation and prevents it from activating mast cells and basophils.

- In moderate to severe asthma, anti-IgE therapy reduced exacerbation rate and reduced steroid dose needed.

- Anti IgE therapy is recommended as an add-on to optimized standard therapy in individuals 12 years and older who need continuous or frequent treatment with oral corticosteroids.

- Elevated serum IgE 30-700 IU/ml

- Positive allergy test
Xolair® Indication

- Omalizumab (Xolair) is indicated for adults and adolescents 12 years of age and above
  - With moderate to severe, persistent asthma
  - Who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen
  - Whose symptoms are inadequately controlled with inhaled corticosteroids
  - Elevated serum immunoglobulin E (IgE) level (≥ 30-700 IU/mL)

- Xolair has been shown to decrease the incidence of asthma exacerbations in these patients

- Safety and efficacy have not been established in other allergic conditions
Biologics: Nucala® (mepolizumab)

- Indicated for the maintenance treatment of asthma in people over 12 years whose asthma is not otherwise controlled on current asthma medicines
- For patients with an eosinophilic phenotype – eosinophils are responsible for airway inflammation in asthma
- Helps prevent exacerbations
- Reduces blood eosinophils in patients with severe eosinophilic asthma (>150 cells/microliters at start or >300 anytime in past 12 months).
- Dose: 100 mg subcutaneously q 4 weeks
Nucala® (mepolizumab)

- Anti-interleukin 5 (IL-5) targeted therapy for individuals with severe asthma with an eosinophilic phenotype
- Patients 12 years and older with severe asthma who have:
  - Current therapy (high dose ICS and additional controller(s))
  - Exacerbation history ≥2 in prior 12 months*
  - Blood eosinophil levels ≥150 cells/µL
  - Obtain CBC with differential
- Once-monthly fixed dose SC injection
- Adverse reactions: anaphylaxis, headache, dizziness, back pain, local reaction at injection site

*Oral steroids, hospitalization(s) or ED visit(s)
Biologics: Cinqair® (reslizumab)

- Anti-interleukin-5 monoclonal antibody
- Intravenous infusion
- Indicated for maintenance treatment of patients with severe asthma 18 years and older
- Binds to human IL-5 and prevents it from binding to IL-5 receptor, thereby reducing eosinophilic inflammation
- Dose is 3 mg/kg every 4 weeks
- Adverse reactions: anaphylaxis, cancer and muscle pain
Bronchial Thermoplasty

- Indicated for treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and LABAs

- Performed with a bronchoscope – involves the delivery of controlled, therapeutic radiofrequency energy to the airway wall

- This results in heating of the tissue and reduces the amount of smooth muscle present in the airway way

- Requires 3 separate bronchoscopic procedures

- Reduces asthma exacerbations, ER visits and hospitalizations
Timothy Grass Extract
Grastek®

- Used for grass pollen-induced allergic rhinitis confirmed by positive allergy testing
- Dose one tablet sublingual daily
- First dose in allergy office (observed for 30 minutes), then taken once daily at home
- Leave under tongue for at least 1 minute
- Start 12 weeks before grass season
- Ages 5 - 65
- Do not use in severe or uncontrolled asthma
Timothy Grass Extract
Grastek®

- Side effects
  - Throat irritation
  - Itchy ears
  - Oral itching
  - Mouth edema
  - Headache

- Stop taking if trouble breathing, throat tightness or swelling, trouble swallowing, dizziness, rapid heartrate, severe stomach symptoms

- Possibility of systemic (anaphylactic) reaction (lower risk than immunotherapy injections)

- Offer an EpiPen for home use
Grass Pollen Extract
Oralair®

- Used for treatment of grass pollen-induced allergic rhinitis confirmed by positive allergy testing
- 5 grass species included
- Dose: one sublingual tab daily
- Ages 10 - 65
- Do not use in uncontrolled asthma
Grass Pollen Extract
Oralair®

- Side Effects
  - Oral itching
  - Throat irritation
  - Ear itching
  - Edema mouth

- Stop taking if trouble breathing, throat tightness or swelling, trouble swallowing, dizziness, rapid heart rate, severe stomach symptoms

- Possibility of systemic (anaphylactic) reaction (lower risk than immunotherapy injections)

- Offer an EpiPen for home use
Short Ragweed Pollen Extract
Ragwitek®

- Indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis confirmed by positive allergy testing
- Dose one tablet sublingual daily
- Start 12 weeks prior to season
- Ages 18 - 65
- Do not use in severe or uncontrolled asthma
Short Ragweed Pollen Extract
Ragwitek®

- Side Effects
  - Throat irritation
  - Ear itching
  - Oral itching
  - Mouth tingling
  - Mouth edema

- Stop taking if throat tightness or swelling, trouble breathing, trouble swallowing, dizziness, rapid heart rate, severe stomach problems

- Possibility of systemic (anaphylactic) reaction (lower risk than immunotherapy injections)

- Offer an EpiPen for home use
Asthma & Allergy Pipeline

- SLIT – Dust mite or cat allergy
- Generic version of Advair – may be up to 8 generic versions in the pipeline, all using different devices
- 3M’s Intelligent Control Inhaler (2016) – provides data on inspiratory flow, integrated patient instructions, profiles to help monitor disease progression
- Novartis’ Breezhaler digital inhaler device integrated with smart phone
- Generic albuterol – expected by end of 2017
- New biologics: Anti-IgE antibodies, Anti-IL-13 antibodies and Anti-IL-13/Anti-IL-4 receptor antibodies – show real promise
- Triple therapy – ICS/LABA/LAMA
What is Success: How do we measure it and how do we get there?

- Begin therapy based on *Severity*

- Monitor and adjust therapy based on *Control* and *Risk* and *Responsiveness to Therapy*

- Use routine standardized multifaceted measures

- The goal of therapy is to achieve control

- Individualize therapy based on likelihood of response and patient needs, desires and goals
Questions?

- Contact Information:
  - Phone: 616-464-4816
  - E-mail: Karen.Meyerson@priorityhealth.com

- Download the NIH Guidelines at:

- Download the GINA Guidelines at:
  - [http://ginasthma.org/](http://ginasthma.org/)