Managing the Difficult to Control Asthmatic and Biologics

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Disclosures

- Speakers Bureau for AstraZeneca
  - Benralizumab (Fasenra)
  - Tezepelumab (Tezspire)

- Many efforts made to mitigate potential for bias!

Objectives

- Review the definition and epidemiology of severe asthma
- Examine guideline directed management options for severe asthma
- Discuss advanced strategies for managing challenging asthma cases, including the appropriate use of biologic therapies

Definition of Asthma

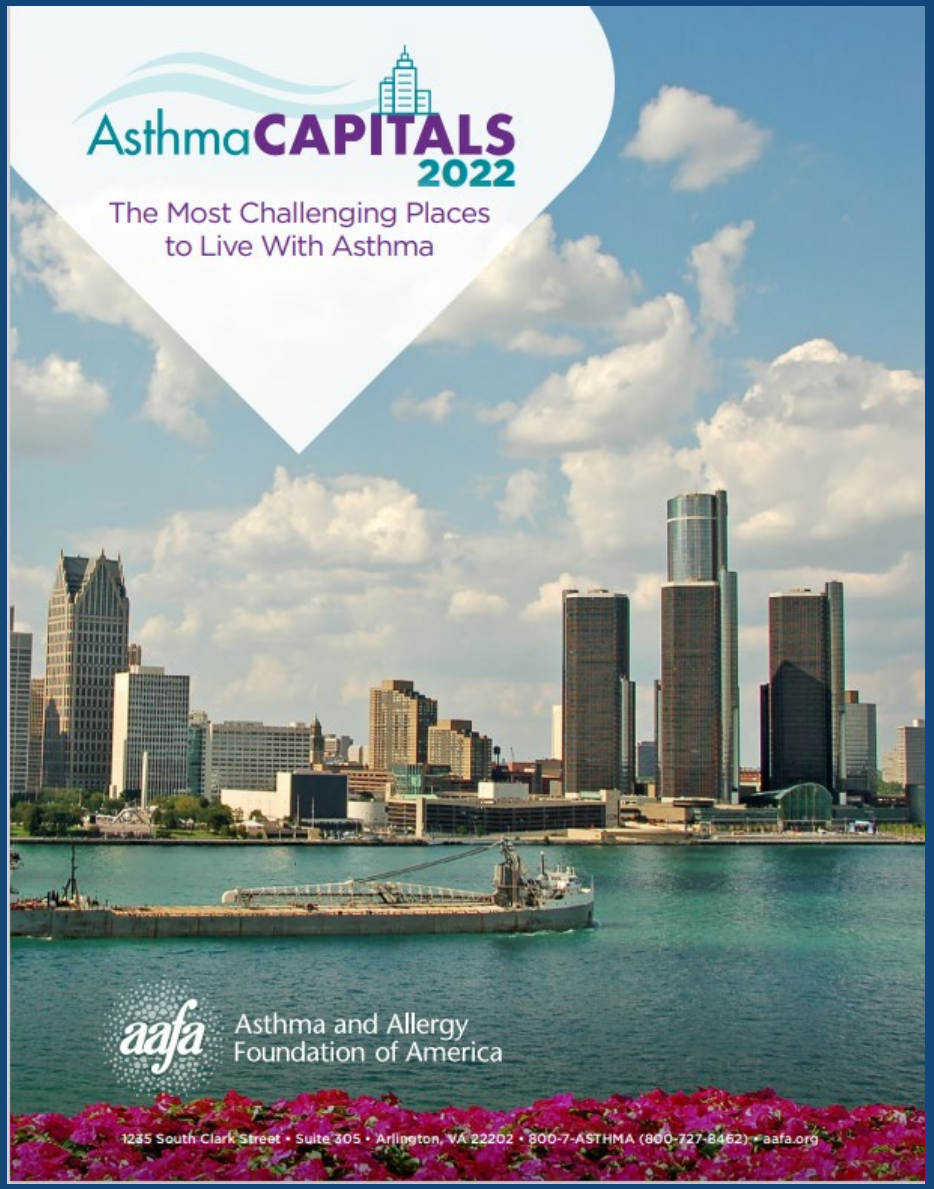
Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation.

It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation.

Burden of Asthma

- Asthma is one of the most common chronic diseases worldwide with an estimated 300 million affected individuals
- Approx 5-10% of patients with asthma meet criteria for severe asthma
- Prevalence is increasing in many countries, especially in children
- Asthma is a major cause of school and work absence
- Health care expenditure on asthma is very high

2022 AAFA Report



The Top 100 Most Challenging Places to Live With Asthma

NATIONAL RANKINGS ■ Worse Than Average ▲ Average ● Better Than Average

(Factors are not weighted equally)

2022 National Rankings	Overall	Metropolitan Area	Total Score (Avg. 63.79)	Subtotal: Estimated Asthma Prevalence	Subtotal: Crude Death Rate for Asthma	Subtotal: ED Visits for Asthma
1	■	Detroit, MI	100.00	■	■	■
2	■	Cleveland, OH	99.51	■	■	■
3	■	Allentown, PA	98.62	■	▲	■
4	■	Lakeland, FL	97.72	■	▲	■
5	■	Fresno, CA	91.36	■	■	▲
6	■	Charleston, SC	90.18	■	▲	■
7	■	Harrisburg, PA	89.06	■	■	▲
8	■	Poughkeepsie, NY	88.38	■	▲	●
9	■	Philadelphia, PA	87.50	■	■	▲
10	■	Baltimore, MD	85.84	■	■	▲
11	■	Columbus, OH	85.55	■	▲	■
12	■	Richmond, VA	83.49	▲	■	■
13	■	Cape Coral, FL	82.81	■	●	■
14	■	St. Louis, MO	82.23	▲	■	■
15	■	Orlando, FL	81.60	■	●	▲
16	■	Albany, NY	81.39	■	▲	●
17	■	Louisville, KY	81.35	■	●	■
18	■	Greenville, SC	79.73	■	●	▲
19	■	Toledo, OH	79.45	■	▲	■
20	■	Rochester, NY	77.20	■	▲	▲
21	■	New York, NY	76.95	■	■	▲
22	■	Miami, FL	76.31	■	▲	▲
23	■	Wichita, KS	75.79	●	▲	■
24	■	Dayton, OH	75.62	▲	●	■
25	■	Spokane, WA	74.64	■	▲	▲
26	■	Cincinnati, OH	74.39	▲	■	■
27	■	Tucson, AZ	74.22	▲	■	■
28	■	Chicago, IL	74.03	▲	■	▲
29	■	Indianapolis, IN	73.99	■	▲	▲
30	■	Atlanta, GA	73.79	▲	▲	■
31	▲	Jacksonville, FL	73.48	▲	▲	■
32	▲	Omaha, NE	73.16	▲	■	▲

Assessing Asthma Severity

- How?
  - Asthma severity is assessed retrospectively from the level of treatment required to control symptoms and exacerbations
- When?
  - Assess asthma severity after patient has been on controller treatment for several months
  - Severity is not static – it may change over months or years, or as different treatments become available
- Categories of asthma severity
  - *Mild asthma:* well-controlled with Steps 1 or 2 (as-needed SABA or low dose ICS)
  - *Moderate asthma:* well-controlled with Step 3 (low-dose ICS/LABA)
  - *Severe asthma:* requires Step 4/5 (moderate or high dose ICS/LABA ± add-on), or remains uncontrolled despite this treatment

Definition of Severe Asthma

Severe asthma is asthma that remains uncontrolled despite optimized treatment with high dose ICS-LABA, or that requires high dose ICS-LABA to prevent it from becoming uncontrolled

Goals of Asthma Management

- The long-term goals of asthma management are:
  1. **Symptom control**: to achieve good control of symptoms and maintain normal activity levels
  2. **Risk reduction**: to minimize future risk of exacerbations, fixed airflow limitation and medication side-effects
- Achieving these goals requires a partnership between patient and their health care providers
  - Ask the patient about their own goals regarding their asthma
  - Good communication strategies are essential
  - Consider the health care system, medication availability, cultural and personal preferences and health literacy

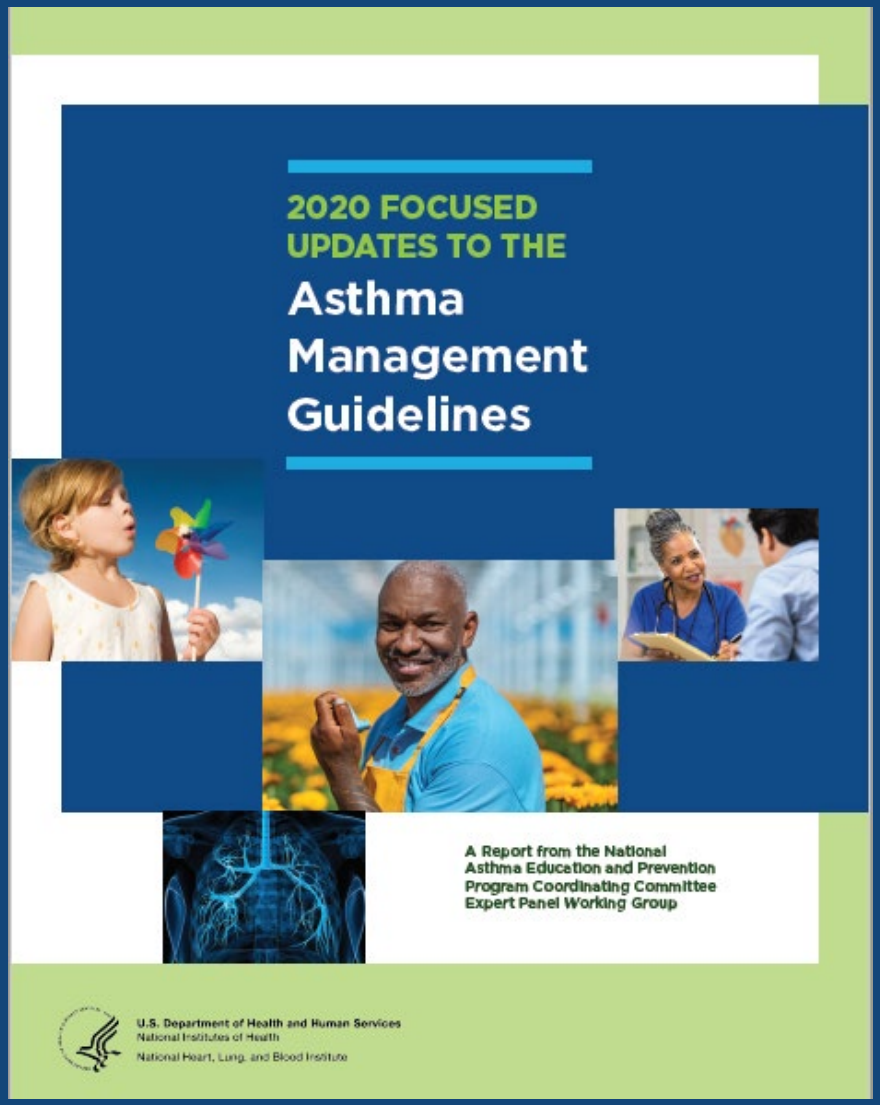
Choosing Between Controller Options – Individual Patient Decisions

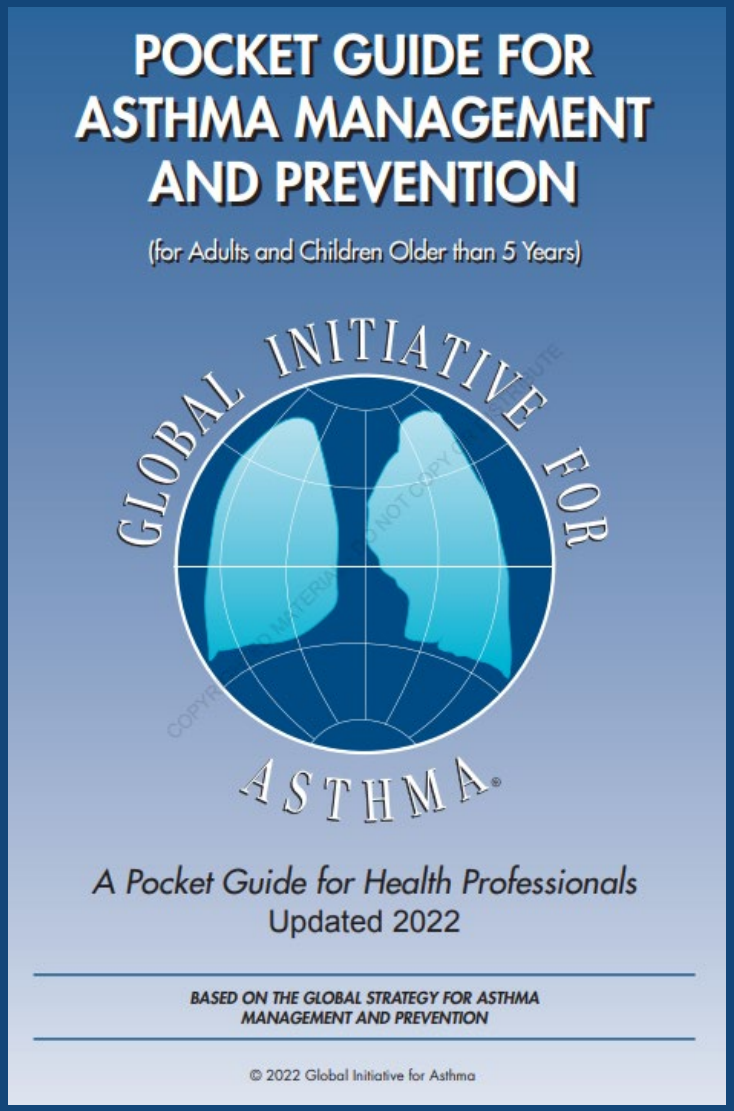
Decisions for individual patients

Use shared decision-making with the patient/parent/carer to discuss the following:

1. Preferred treatment for symptom control and for risk reduction
2. Patient characteristics (phenotype)
   - Does the patient have any known predictors of risk or response? (e.g. smoker, history of exacerbations, blood eosinophilia)
3. Patient preference
   - What are the patient's goals and concerns for their asthma?
4. Practical issues
   - Inhaler technique - can the patient use the device correctly after training?
   - Adherence: how often is the patient likely to take the medication?
   - Biologic: is the patient willing to inject a medication?
   - **Cost: can the patient afford the medication? Covered by insurance?**

Updated Guidelines





NAEPP 2020 Guidelines

Figure I.d: Stepwise Approach for Management of Asthma in Individuals Ages 12 Years and Older

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 12+ Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6■
Preferred	PRN SABA	Daily low-dose ICS and PRN SABA or PRN concomitant ICS and SABA▲	Daily and PRN combination low-dose ICS-formoterol▲	Daily and PRN combination medium-dose ICS-formoterol▲	Daily medium-high dose ICS-LABA + LAMA and PRN SABA▲	Daily high-dose ICS-LABA + oral systemic corticosteroids + PRN SABA
Alternative		Daily LTRA* and PRN SABA or Cromolyn,* or Nedocromil,* or Zileuton,* or Theophylline,* and PRN SABA	Daily medium-dose ICS and PRN SABA or Daily low-dose ICS-LABA, or daily low-dose ICS + LAMA,▲ or daily low-dose ICS + LTRA,* and PRN SABA or Daily low-dose ICS + Theophylline* or Zileuton,* and PRN SABA	Daily medium-dose ICS-LABA or daily medium-dose ICS + LAMA, and PRN SABA▲ or Daily medium-dose ICS + LTRA,* or daily medium-dose ICS + Theophylline,* or daily medium-dose ICS + Zileuton,* and PRN SABA	Daily medium-high dose ICS-LABA or daily high-dose ICS + LTRA,* and PRN SABA	
		Steps 2–4: Conditionally recommend the use of subcutaneous immunotherapy as an adjunct treatment to standard pharmacotherapy in individuals ≥ 5 years of age whose asthma is controlled at the initiation, build up, and maintenance phases of immunotherapy▲			Consider adding Asthma Biologics (e.g., anti-IgE, anti-IL5, anti-IL5R, anti-IL4/IL13)**	

Management of Severe Asthma

- Optimize dose of ICS/LABA
  - Complete resistance to ICS is rare
  - Consider therapeutic trial of higher dose
- Add-on treatments without phenotyping
  - Tiotropium - reduces exacerbations (history of exacerbations, age ≥12 years)
  - Theophylline, LTRA – limited benefit
- Phenotype-guided treatment
  - Severe allergic asthma: add-on anti-IgE (omalizumab ≥6 yrs)
  - Severe eosinophilic asthma: add-on anti-IL 5 (mepolizumab ≥12 yrs or reslizumab ≥18 yrs), or anti-IL5R (benralizumab ≥12 yrs)
  - Aspirin-exacerbated respiratory disease: consider add-on LTRA
- Non-pharmacological interventions
  - Consider bronchial thermoplasty for selected patients (with registry)
- Consider low dose maintenance oral corticosteroids
  - Monitor for and manage side-effects, including osteoporosis

Systemic Corticosteroid Complications

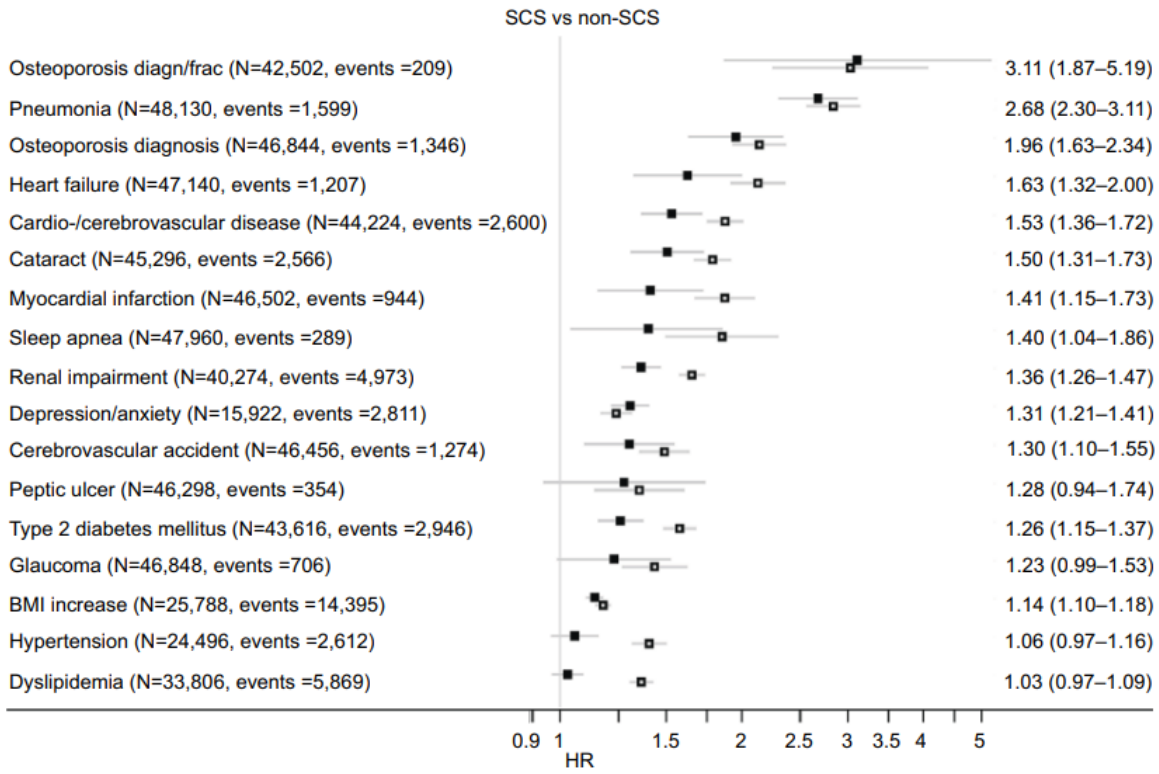


Figure 2 HR (95% CI) for each adverse outcome in the SCS arms (vs non-SCS arms). The open squares represent unadjusted, and the closed squares, adjusted results. The adjusted HRs (95% CIs) are shown on the right. See Table S3 for list of confounders.
Abbreviations: BMI, body mass index; SCS, systemic corticosteroid.

Price *et al*. Adverse outcomes from initiation of systemic corticosteroids for asthma: long-term observational study. J Asthma Allergy. 2018; 11:193-204.

Systemic Corticosteroid Complications

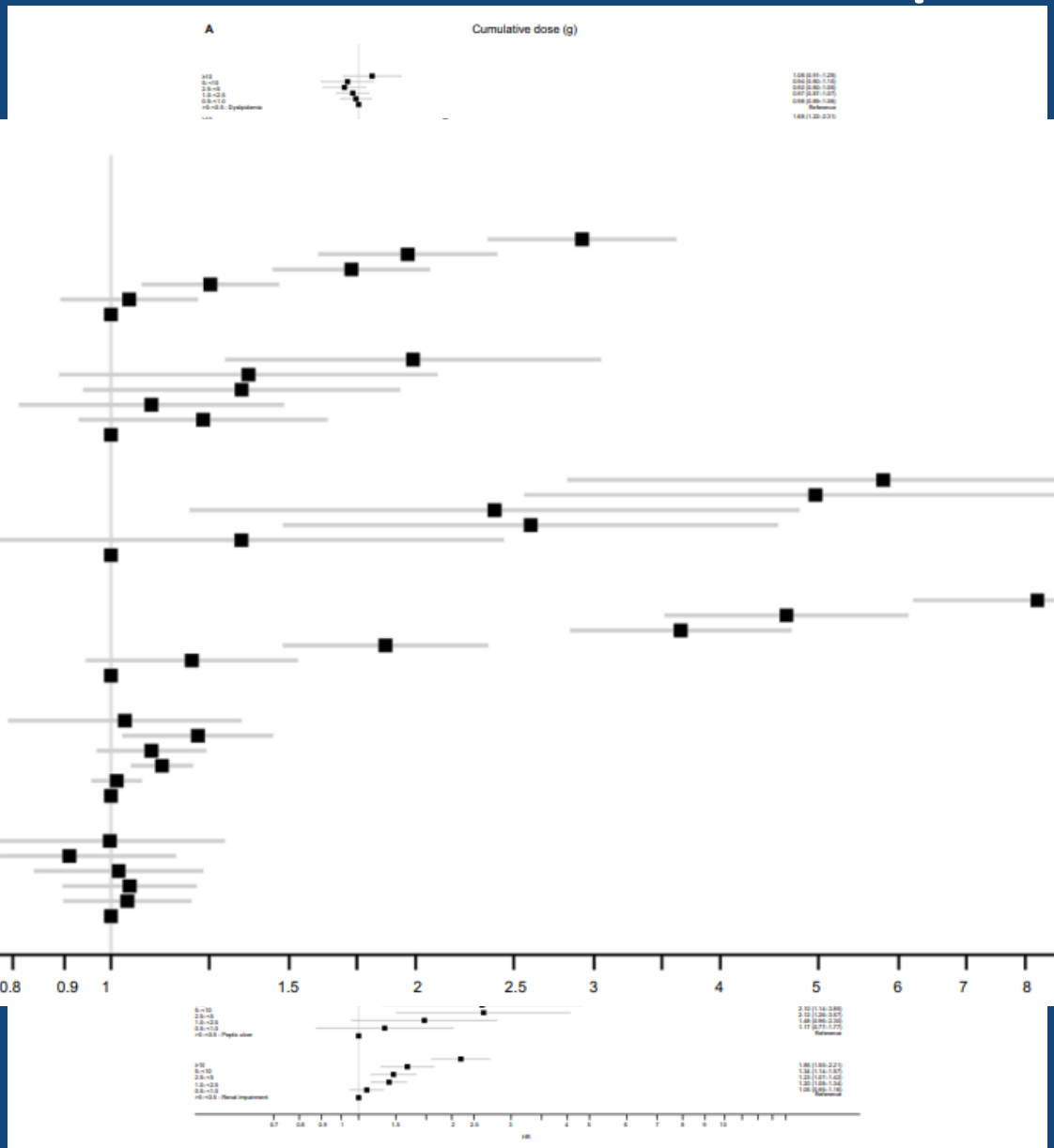
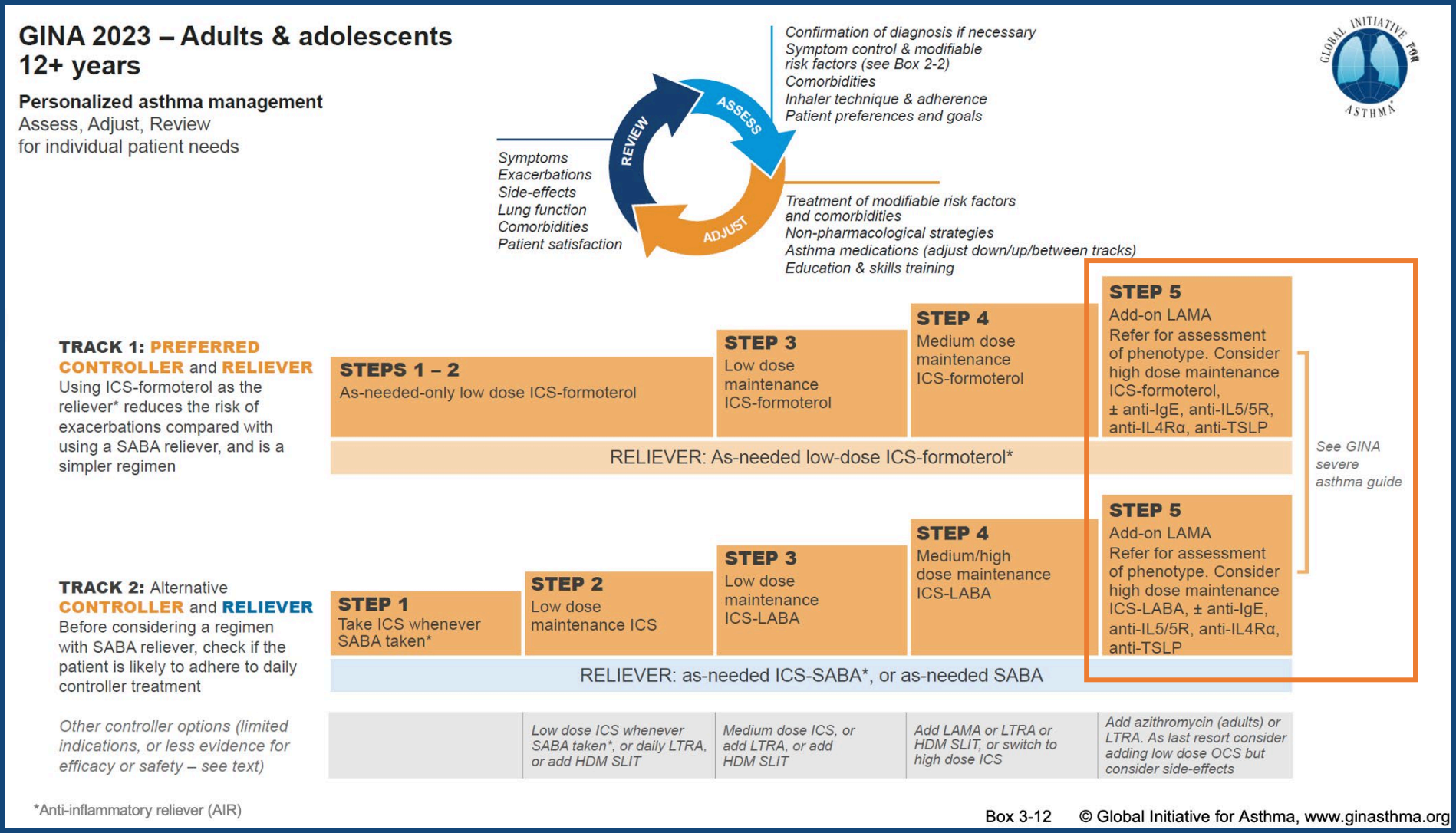


Figure 3 (A–C) Adjusted hazard ratio (95% CI) for each adverse outcome in the SCS arms for categorized, cumulative SCS exposures, compared with the reference category of >0 to <0.5-g cumulative exposure. See Table S3 for list of confounders.
Abbreviations: BMI, body mass index; SCS, systemic corticosteroid.

GINA 2023 Treatment Figure



Box 3-12

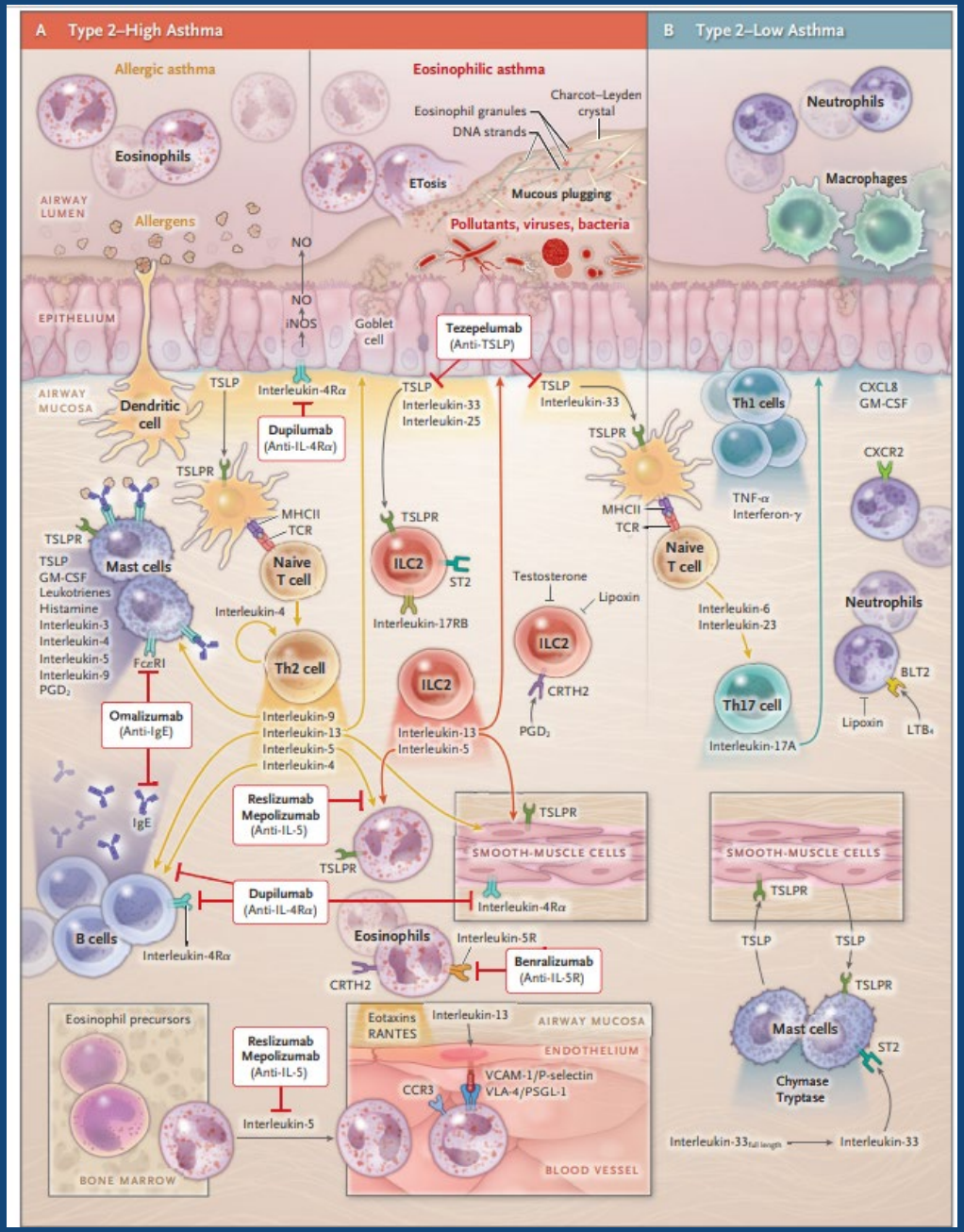
Available Asthma Biologics

Table 1. Food and Drug Administration-approved biologics in asthma

Medication	Mechanism	Current indications	Potential indications	Administration
Omalizumab	Anti-IgE	Asthma ≥6 w/↑ IgE Chronic urticaria ≥12 CRSwNP ≥18	AERD ABPA Co-immunotherapy Food allergy	Subcutaneous Q2–4 weeks Home
Mepolizumab	Anti-IL5	Eos asthma ≥6 CRSwNP ≥18 EGPA ≥18 HES ≥2	AERD	Subcutaneous Q4 weeks Home
Reslizumab	Anti-IL5	Eos asthma ≥18	–	Intravenous Q4 weeks Infusion Center
Benralizumab	Anti-IL5R	Eos asthma ≥12	HES CRSwNP	Subcutaneous Q8 weeks Home
Dupilumab	Anti-IL4 Anti-IL13	Eos asthma ≥6 Atopic dermatitis ≥6 CRSwNP ≥18	AERD ABPA Food allergy EoE	Subcutaneous Q2 weeks Home
Tezepelumab	Anti-TSLP	Asthma ≥12		Subcutaneous Q4 weeks Medical facility

ABPA, allergic bronchopulmonary aspergillosis; AD, Atopic dermatitis; AERD, aspirin-exacerbated respiratory disease; CRSwNP, chronic rhinosinusitis with nasal polyps; EGPA, eosinophilic granulomatosis with polyangiitis; EoE, eosinophilic esophagitis; Eos asthma, eosinophilic asthma; HES, hypereosinophilic syndrome; IgE, immunoglobulin E; IL13, interleukin-13; IL4, interleukin-4; IL5, interleukin-5; IL5R, interleukin-5 receptor; TSLP, thymic stromal lymphopoietin.

Mustafa *et al*. Use of Biologics for the Treatment of Moderate or Severe Asthma: The age of Personalized Medicine. COPM. 2022; 28:266-273.



Brusselle *et al*. Biologic Therapies for Severe Asthma. NEJM 2022;386:157-171.

Improved Outcomes with Biologics

US Food and Drug Administration-Approved Biologic Therapeutics

Mechanism of action	Drug	Approved indications in US	Age approved for asthma (y)	Dosing and frequency		Route	Phase 3 clinical trial results			Real-world study results		
							Exacerbation reduction	Increased FEV1	mOCS reduction	Exacerbation reduction	Increased FEV1	mOCS reduction
Anti-IgE	Omalizumab	2003 Asthma 2016 CSU 2020 Nasal polyps	≥ 6	75-375 mg (based on weight, IgE level, age)	Q2W Q4W	s.q. Office Home	✔	Minimal increase		✔	✔	✔
Anti–IL-5	Mepolizumab	2015 Asthma 2019 EGPA 2020 HES 2021 CRSwNP	≥ 6	100 mg 300 mg (EGPA and HES)	Q4W	s.q. Office Home (for > 11 y.o.)	✔	✔	✔	✔	✔	✔
	Reslizumab	2016 Asthma	≥ 18	3.0 mg/kg	Q4W	i.v. Clinic/infusion center	✔	✔	✔(Not done prospectively but post hoc analysis)	✔	✔	✔
Anti–IL-5Rα	Benralizumab	2018 Asthma	≥ 12	30 mg	Q4W (× 3) → Q8W	s.q. Office Home	✔	✔	✔	✔	✔	✔
IL-4Rα (impacts IL-4 and IL-13)	Dupilumab	2017 AD 2018 Asthma 2019 CRSwNP	≥ 6	200 mg or 300 mg 300 if OCS-dependent	Q2W	s.q. Home	✔	✔	✔	✔	✔	✔

Abbreviations: CRSwNP, chronic rhinosinusitis with nasal polyp; CSU, chronic spontaneous urticaria; EGPA, eosinophilic granulomatosis polyangiitis; FEV1, forced expiratory volume in 1 second; HES, hypereosinophilic syndrome; IgE, immunoglobulin E; IL, interleukin; mOCS, maintenance oral corticosteroid; OCS, oral corticosteroid; s.q., subcutaneous.

Wang *et al*. A rational approach to compare and select biologic therapeutics in asthma. Ann Allergy Asthma Immunol. 2022; 128 379-398.

Improved Outcomes with Biologics

TABLE I. RCT data on effects of antialarmin therapy and downstream cytokine blockade on pulmonary function, asthma control, annualized exacerbation rate, type 2 biomarkers, and airway hyperresponsiveness for severe asthma patients compared with placebo

Biologic	Anti-TSLP	Anti-IL-4rα	Anti-IL-5(rα)
FEV_1 (L)	↑	↑	↑
FEF_{25-75} (L/s)	N/A	↑	N/A
ACQ	↓	↓	↓
AER	↓	↓	↓
PBE (cells/μL)	↓	↑/↔	↓↓
FeNO (ppb)	↓	↓	↔
Total IgE (IU/mL)	↓	↓	↔
OCS sparing	↔	↓	↓
AHR	↓	N/A	N/A

ACQ, Asthma Control Questionnaire; *AER*, annualized exacerbation rate; *AHR*, airway hyperresponsiveness; *FeNO*, fractional exhaled nitric oxide; FEF_{25-75}, forced expiratory flow rate between 25% and 75% of full vital capacity; FEV_1, forced expiratory volume in 1 second; *N/A*, not applicable; *OCS*, oral corticosteroid; *PBE*, peripheral blood eosinophils; *RCT*, randomized controlled trial; *TSLP*, thymic stromal lympoietin.

Chan *et al*. Targeting downstream T2 cytrokines or upstream epithelial alarmins for severe asthma. J Allergy Clin Immunol Prac. 2022;10:1497-505.

How Do You Determine The Most Probable Type of Inflammation Driving Severe Asthma?

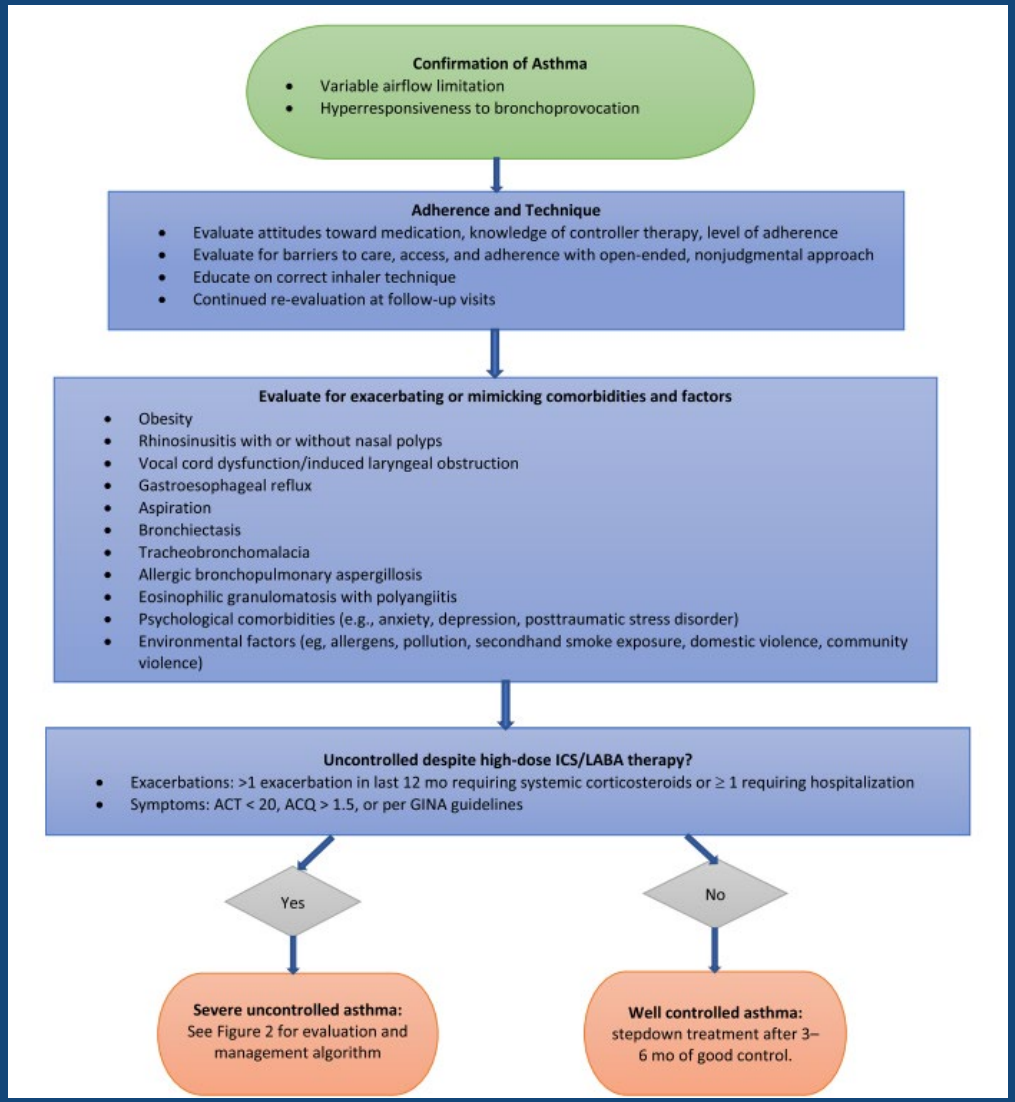
Precision Medicine
Phenotypes, Endotypes, and Biomarkers

- **Precision medicine** guides selection of biologic therapeutics
- **Phenotyping** integrates biological and clinical features—from molecular, cellular, morphologic, and functional to patient-oriented characteristics—to describe the outward manifestations of disease (i.e. Eosinophillic asthma, atopic asthma, etc)
- **Endotypes** reflect identifiable mechanistic pathways that lead to the phenotypes (i.e. T2 high or T2 low)
- A **Biomarker** is an objective measure of biological or pathogenic processes that may inform an endotype or may reflect prediction of or pharmacologic response to an intervention (i.e. AEC, IgE, FeNO, etc)

Complexities of Precision Medicine

- Asthma phenotypes and endotypes may not be static attributes and instead may vary over time owing to natural history of the disease or as a consequence of different treatments or exposures
- Some patients may have dominance of only 1 biomarker vs another, reflecting the diversity within this endotype: (1) allergic, (2) eosinophilic, and (3) FeNO predominant
- Most people with T2 endotype asthma have mixed features

Evaluation of Asthma



Wang *et al*. A rational approach to compare and select biologic therapeutics in asthma. Ann Allergy Asthma Immunol. 2022; 128 379-398.

Severe Uncontrolled Asthma Confirmed

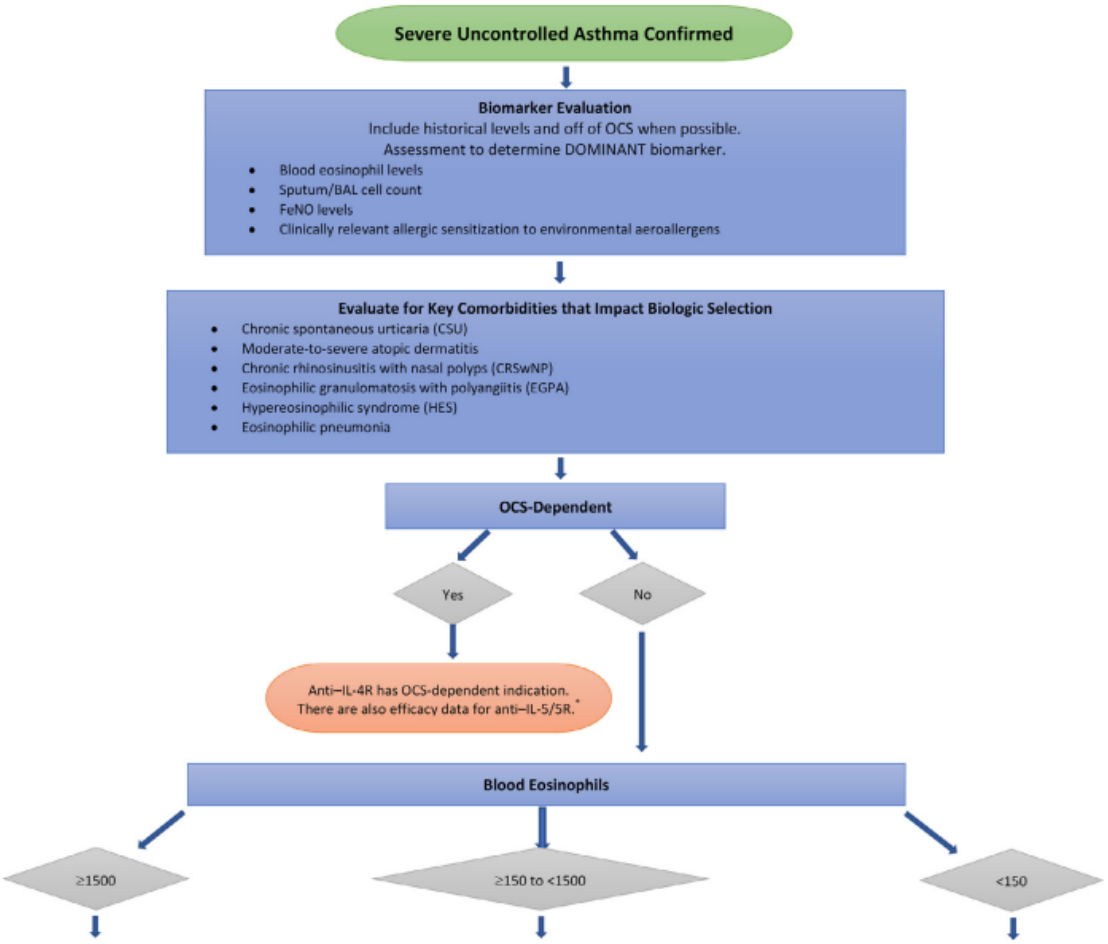


Figure 2. Evaluation and management algorithm for confirmed severe uncontrolled asthma. *Final assessment may indicate more than 1 option. Consider re-evaluation for potential switch if insufficient response after trial of a biologic for 4 to 6 mo. BAL, bronchoalveolar lavage; BT, bronchial thermoplasty; CRSwNP, chronic rhinosinusitis with nasal polyps; CSU, chronic spontaneous urticaria; EGPA, eosinophilic granulomatosis with polyangiitis; FeNO, fractional exhaled nitric oxide; HES, hypereosinophilic syndrome; IgE, immunoglobulin E; IL, interleukin; OCS, oral corticosteroid; R, receptor; TSLP, thymic stromal lymphopoietin.

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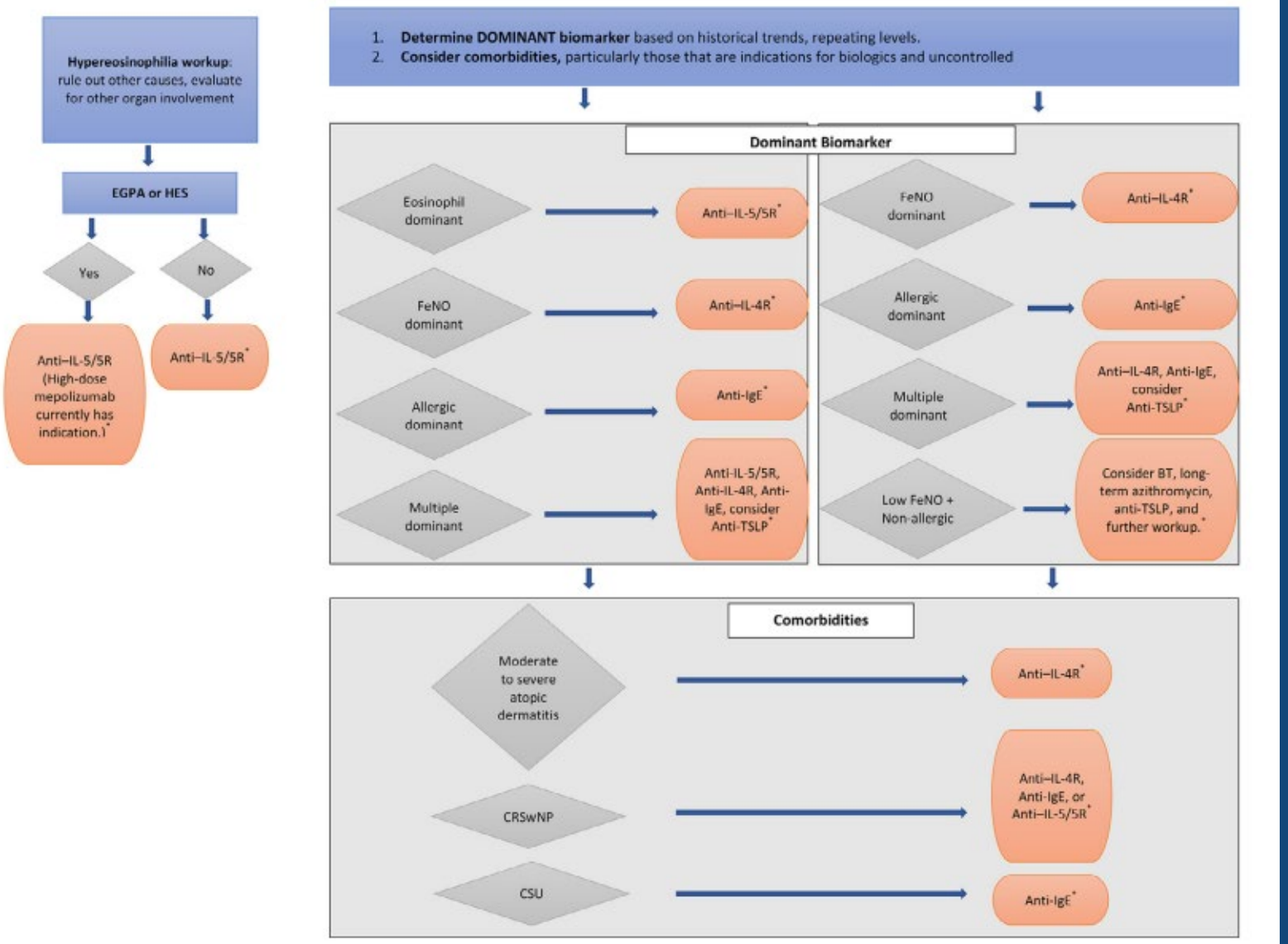
≥1500

≥150 - <1500

<150



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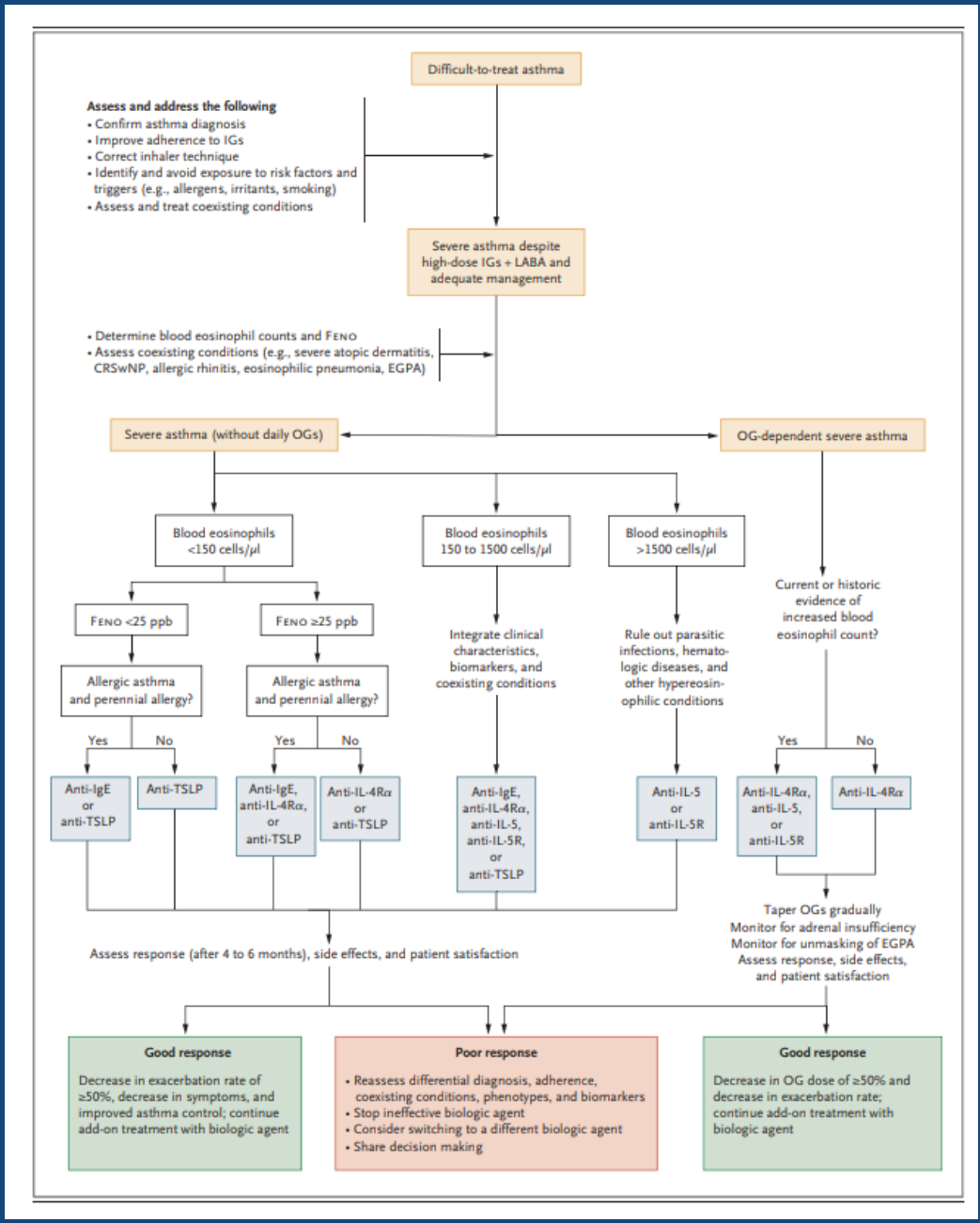


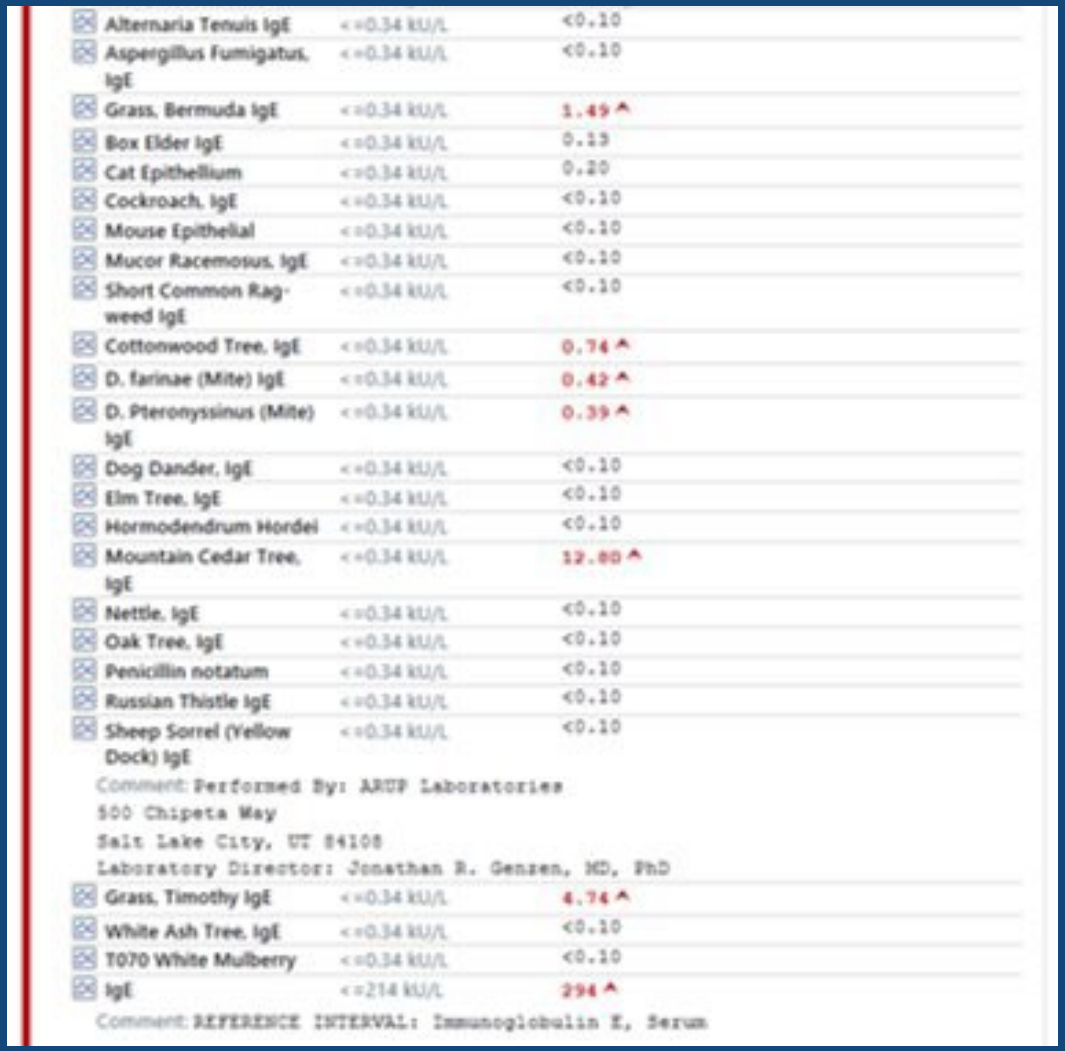
Brusselle *et al*. Biologic Therapies for Severe Asthma. NEJM 2022;386:157-171.

Patient 1

- 22 year-old female with history of childhood asthma
- Poor control over past several years, especially in spring/fall
- PCP had recently increased her fluticasone/salmeterol to 500/50 1 puff twice daily given 2 recent exacerbations
- Additional Medications: Flonase, cetirizine, montelukast

Patient 1

- AEC 100
- FeNO 17 PPM
- Region 9

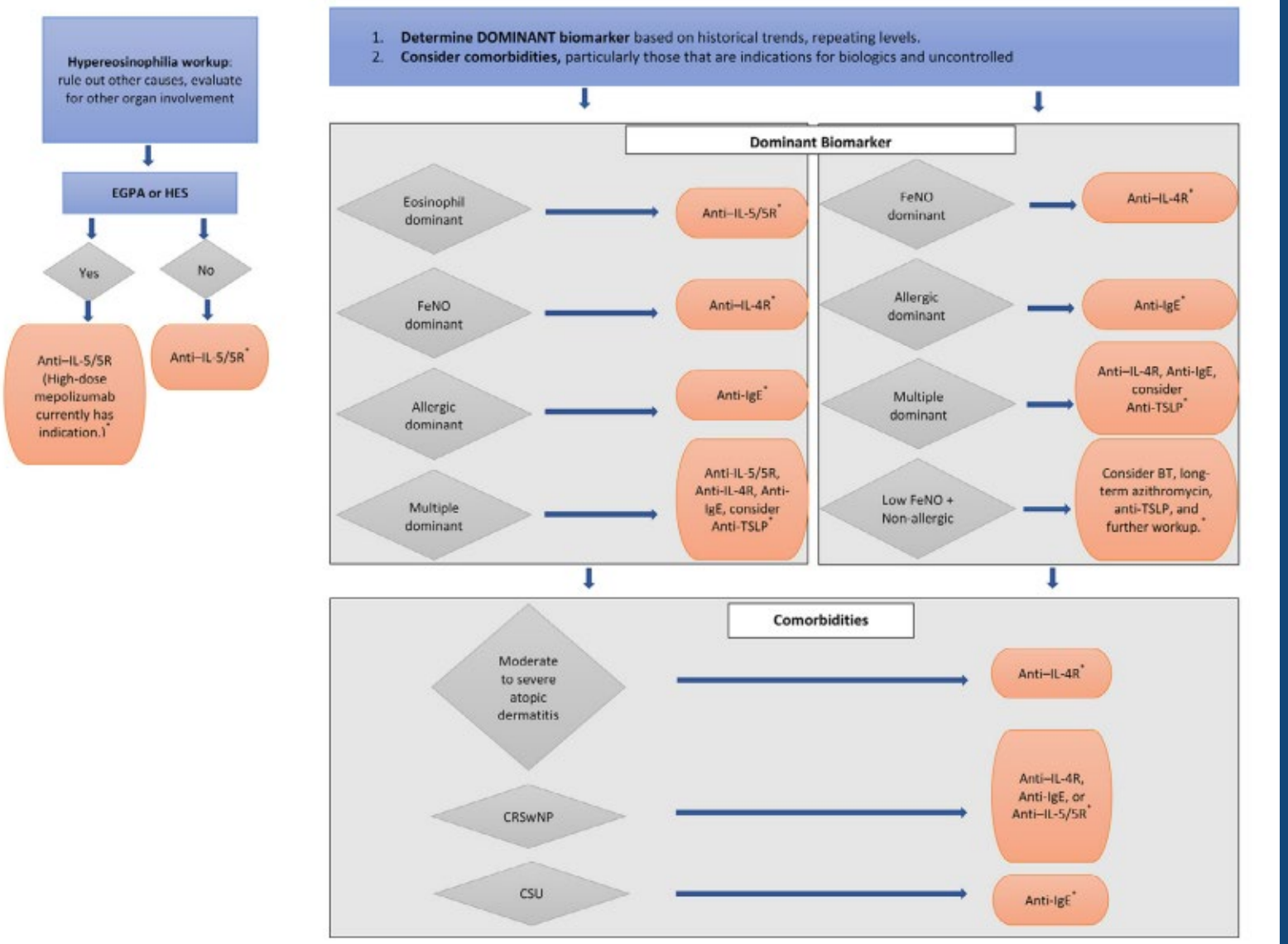


Alternaria Tenuis IgE	<=0.34 kU/L	<0.10
Aspergillus Fumigatus, IgE	<=0.34 kU/L	<0.10
Grass, Bermuda IgE	<=0.34 kU/L	1.49 ^
Box Elder IgE	<=0.34 kU/L	0.13
Cat Epithellium	<=0.34 kU/L	0.20
Cockroach, IgE	<=0.34 kU/L	<0.10
Mouse Epithelial	<=0.34 kU/L	<0.10
Mucor Racemosus, IgE	<=0.34 kU/L	<0.10
Short Common Ragweed IgE	<=0.34 kU/L	<0.10
Cottonwood Tree, IgE	<=0.34 kU/L	0.74 ^
D. farinae (Mite) IgE	<=0.34 kU/L	0.42 ^
D. Pteronyssinus (Mite) IgE	<=0.34 kU/L	0.39 ^
Dog Dander, IgE	<=0.34 kU/L	<0.10
Elm Tree, IgE	<=0.34 kU/L	<0.10
Hormodendrum Hordei	<=0.34 kU/L	<0.10
Mountain Cedar Tree, IgE	<=0.34 kU/L	12.80 ^
Nettle, IgE	<=0.34 kU/L	<0.10
Oak Tree, IgE	<=0.34 kU/L	<0.10
Penicillin notatum	<=0.34 kU/L	<0.10
Russian Thistle IgE	<=0.34 kU/L	<0.10
Sheep Sorrel (Yellow Dock) IgE	<=0.34 kU/L	<0.10
Comment: Performed By: ARUP Laboratories 500 Chipeta Way Salt Lake City, UT 84108 Laboratory Director: Jonathan R. Genzen, MD, PhD		
Grass, Timothy IgE	<=0.34 kU/L	4.74 ^
White Ash Tree, IgE	<=0.34 kU/L	<0.10
T070 White Mulberry	<=0.34 kU/L	<0.10
IgE	<=214 kU/L	294 ^
Comment: REFERENCE INTERVAL: Immunoglobulin E, Serum		

≥1500

≥150 - <1500

<150



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Patient 1 Resolution

- Patient started on omalizumab
- Within months noted improvement in both nasal and asthma symptoms/exacerbations

Patient 2

- 62 y/o male referred for second opinion regarding cough syncope (early 2016)
- Prior pulmonologist told him was related to COPD (Smoked for 10 years, stopped 10 years ago)
- Ongoing episodes despite maximal COPD regimen, especially walking in freezer in grocery store

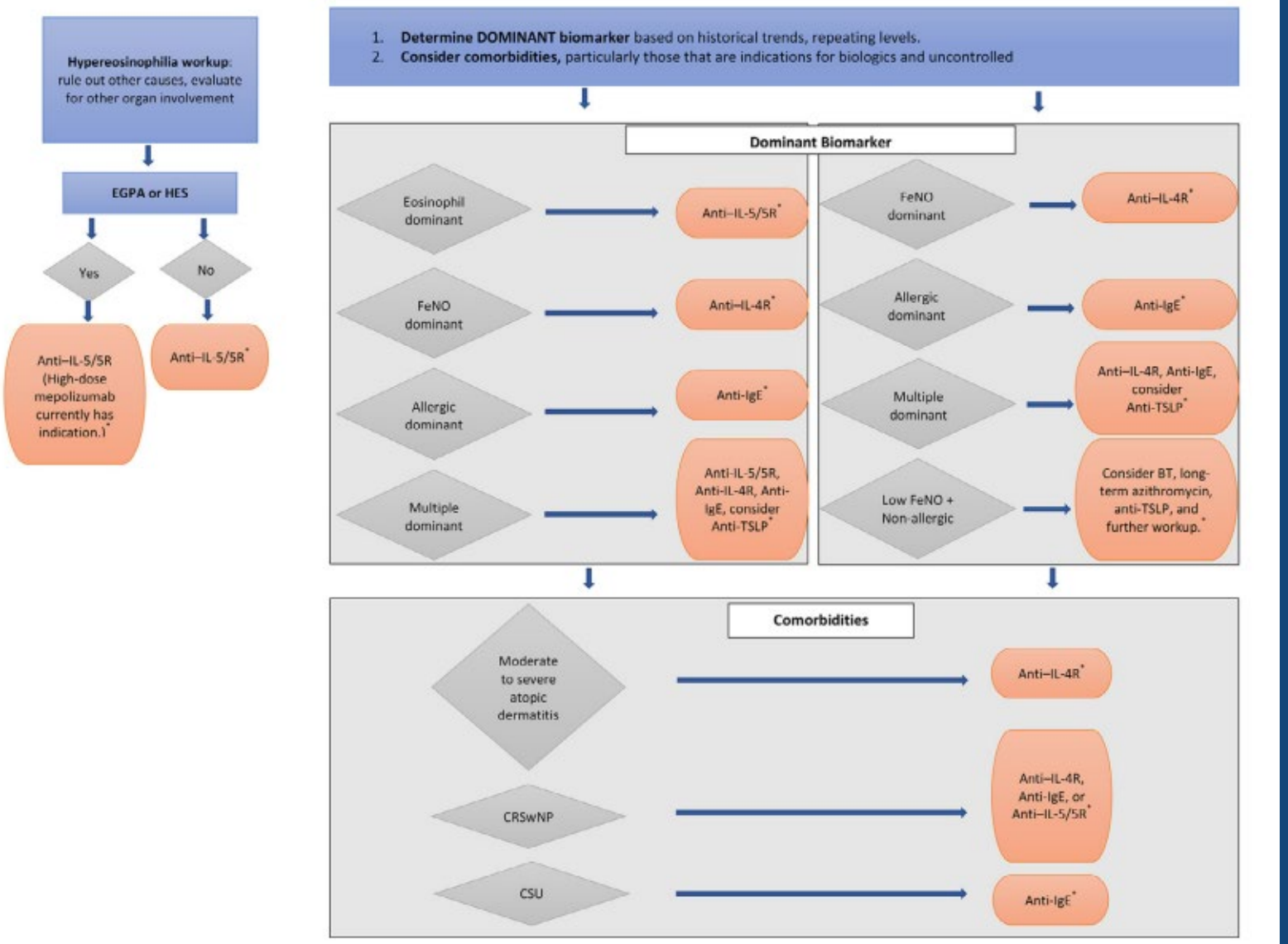
Patient 2

- Other provoking factors: heat, humidity, dust, smoke
- Current regimen: budesonide/formoterol, tiotropium, montelukast, roflumilast, albuterol prn
- AEC 400
- FeNO 15 ppm
- Region 9 panel negative

≥1500

≥150 - <1500

<150



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Patient 2 Resolution

- Started on mepolizumab
- Significant improvement in daily symptoms and no further syncope episodes
- Remains on mepolizumab to date

Patient 3

- 67 y/o female patient with oxygen dependent COPD (FEV1 32%)
- 2-3 acute exacerbations annually despite fluticasone/umeclidinium/vilanterol 100 mcg daily, roflumilast 500 mcg daily, and albuterol prn
- Seen twice in last 6 months in ENT for severe rhinitis/nasal congestion complicating her oxygen, found to have nasal polyps

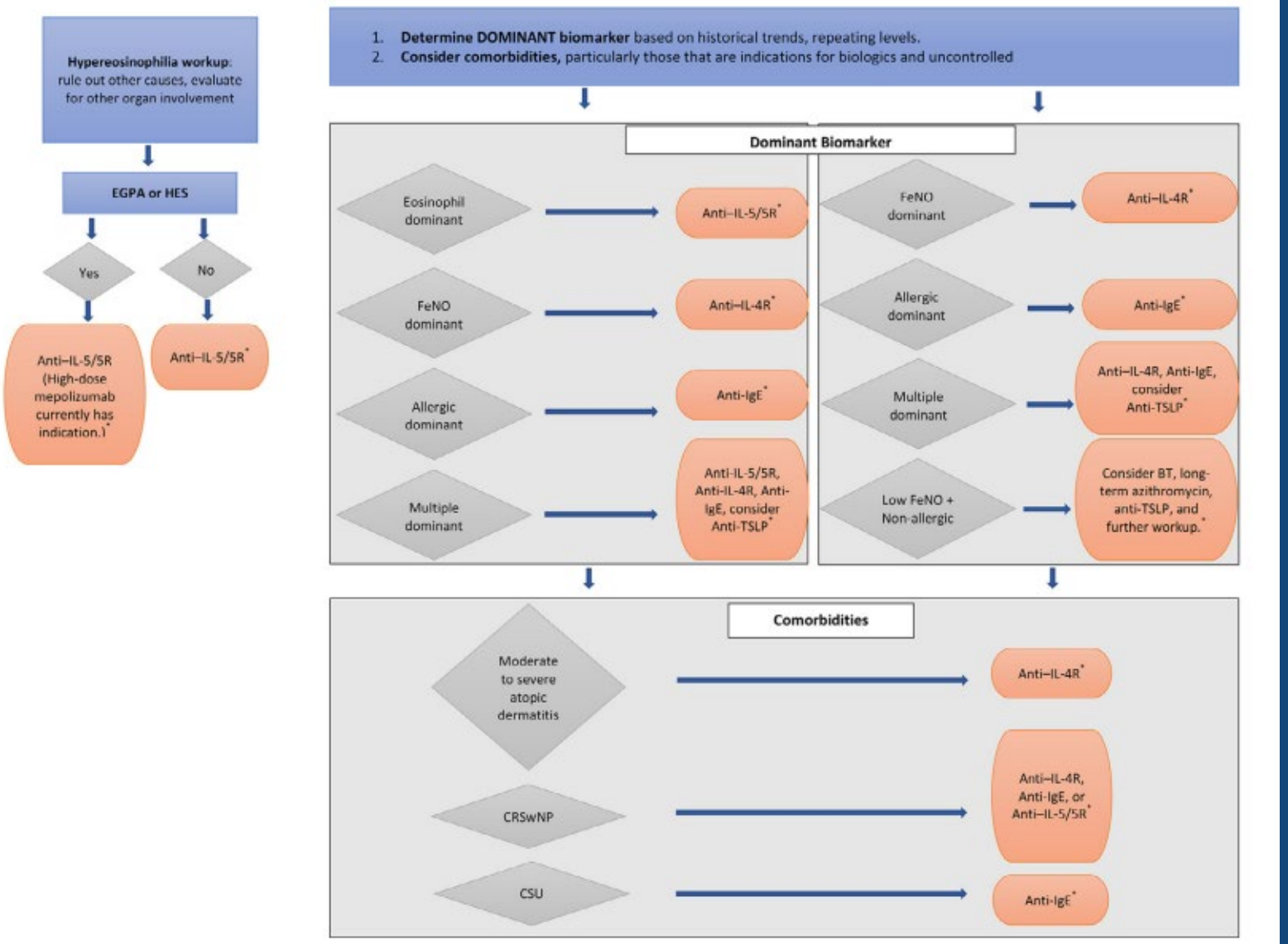
Patient 3

- AEC 300
- FeNO 10 PPM
- Region 9 panel negative

≥1500

≥150 - <1500

<150



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Patient 3 Resolution

- Dupilumab approved for Chronic Rhinosinusitis w Nasal Polyposis (CRSwNP), starting next week
- (First of 2 studies for Eosinophilic COPD published. Sister study results available early 2024)

ORIGINAL ARTICLE

Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts

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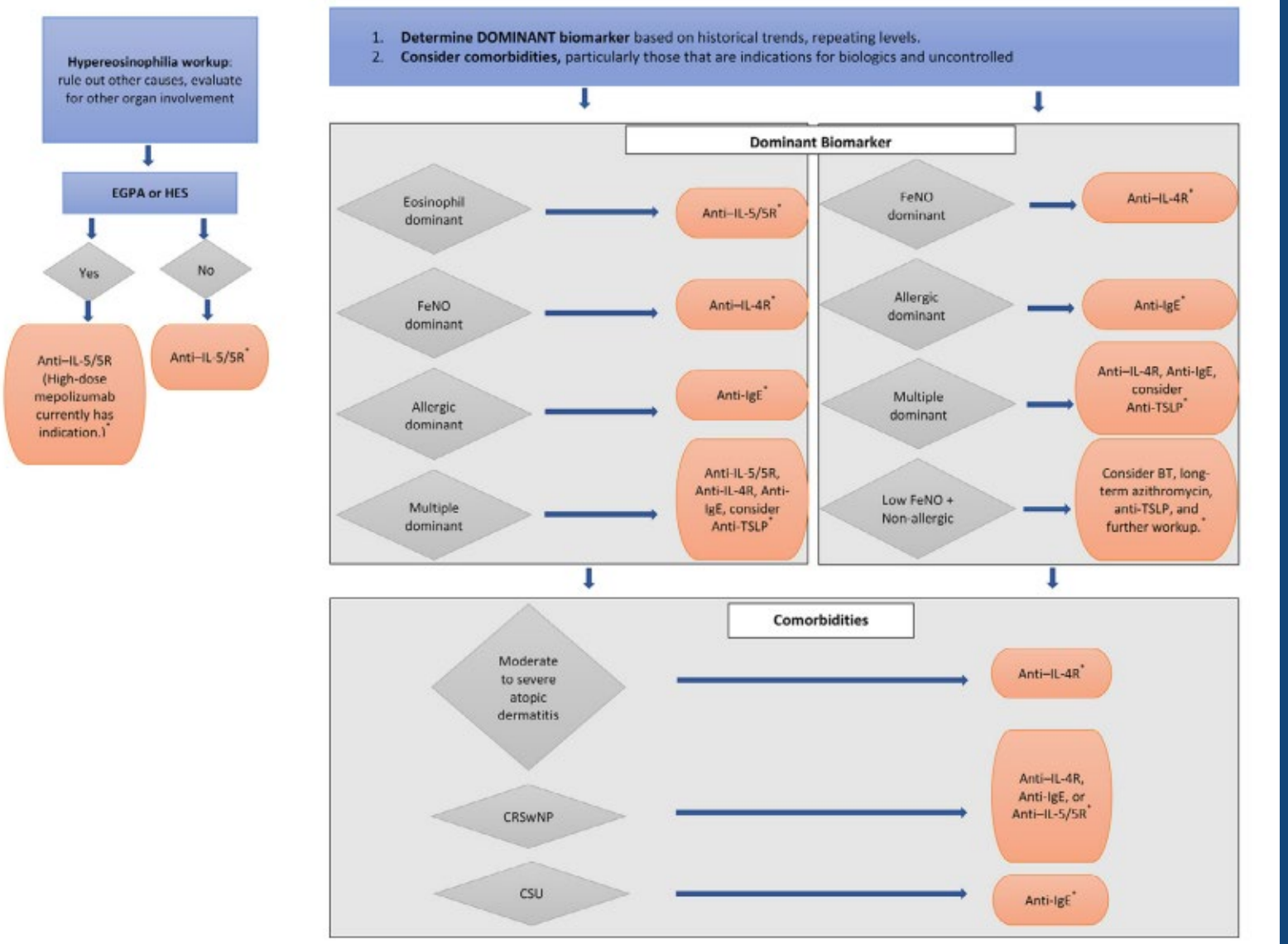
Patient 4

- 65 y/o female referred by PCCM partner for management of severe COPD
- 6 acute exacerbations in past 12 months, started on 10 mg prednisone daily 3 months prior
- Successfully stopped smoking 9 months prior
- Wheelchair bound, weight 310 lbs
- Reported long-standing hx of childhood asthma
- PFT - FEV1 1.07 L (40%), 31% BD improvement, RV 139%, DLCO 57%
- CT with mild upper lobe predominant emphysema
- AEC 600, FeNO 30, IgE 53

≥1500

≥150 - <1500

<150



Wang *et al*. A rational approach to compare and select biologic therapeutics in asthma. Ann Allergy Asthma Immunol. 2022; 128 379-398.

Patient 4 Resolution

- Recently seen in 6-month follow-up
- Another 6 months of excellent asthma control (ACT 24) and no acute exacerbations, on medium-dose ICS/LABA/LAMA and benralizumab
- Another 30-pound weight loss (110 lb total!)
- PFT FEV1 1.63 L (62%) (prior 1.07 L)
- Back to work – Panera (full-time) – employee of the month her first month!

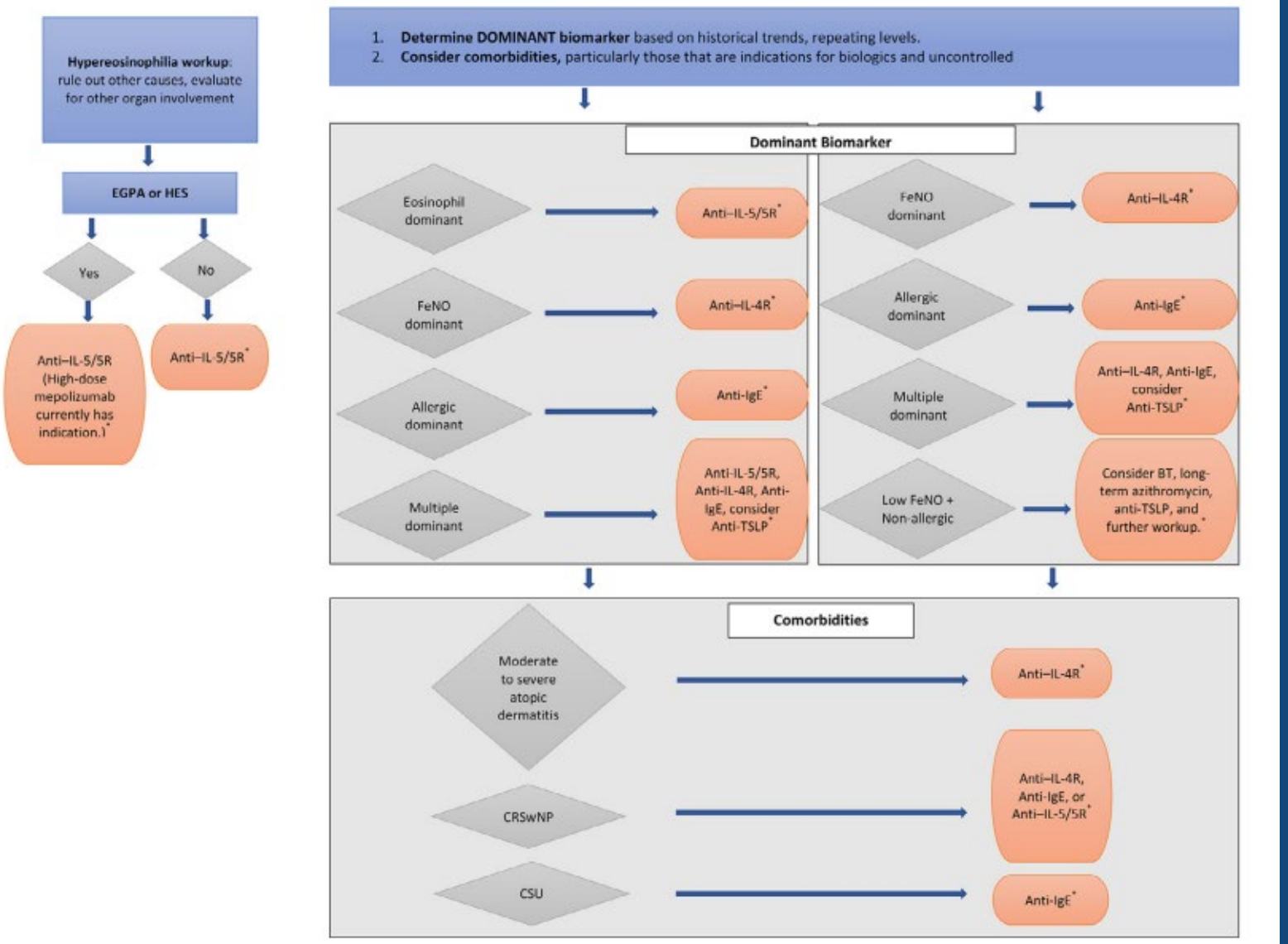
Patient 5

- 67 y/o male former smoker of 30 pack years (quit 20 yrs ago) with lifelong history of asthma
- In addition to inhalers, montelukast, allergy regimen he has tried and failed omalizumab, mepolizumab, and is currently on dupilumab
- Remains on 10 mg prednisone and has required 2 prednisone bursts last 4 months
- AEC 300, FeNO 40 PPM, IgE 57

≥1500

≥150 - <1500

<150



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Patient 5 Resolution

- Patient transitioned to tezepelumab
- Titrated off prednisone over 8 weeks
- Only 1 acute exacerbation in last 12 months
- Outside working in garden and taking nightly walks with his wife

Choose the Right Biologic?

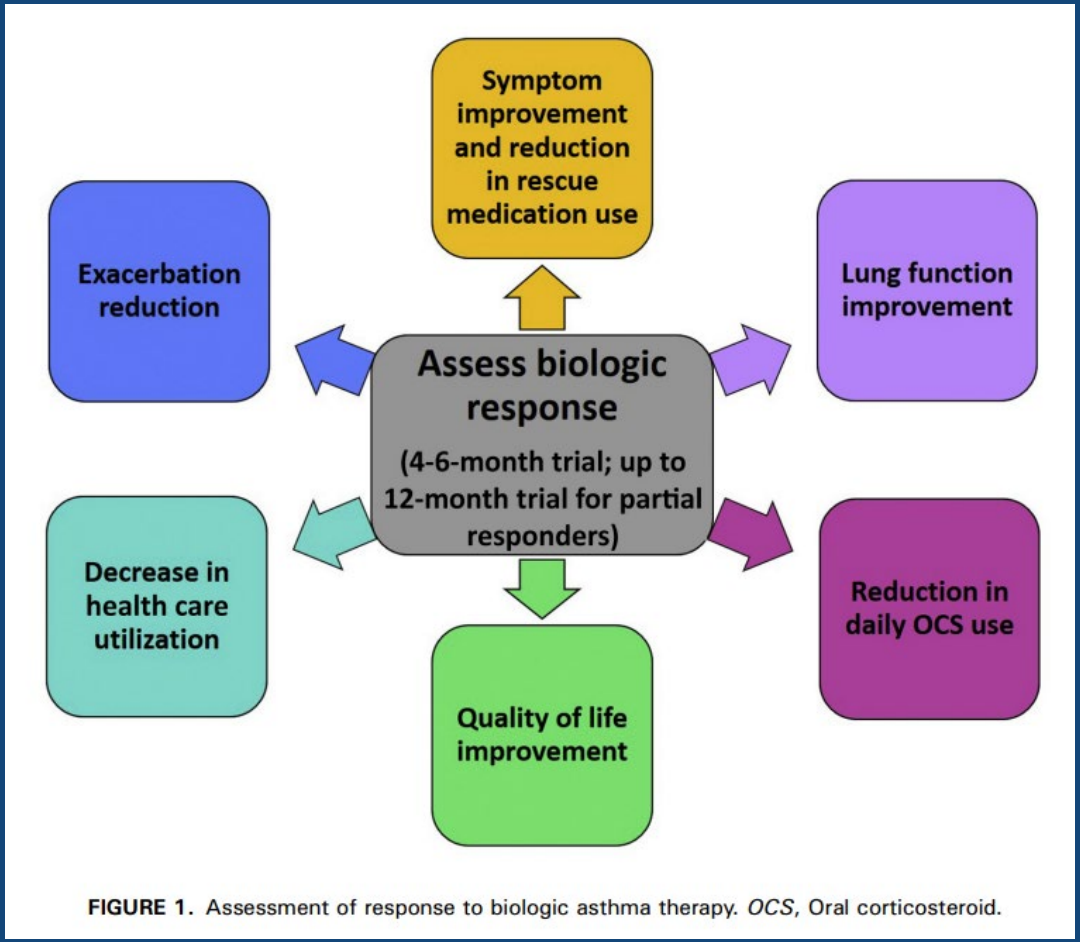

FIGURE 1. Assessment of response to biologic asthma therapy. *OCS*, Oral corticosteroid.

Pepper et al. How to Assess Effectiveness of Biologics for Asthma and What Steps to Take When There Is Not Benefit. J Allergy Clin Immunol Pract 2021; 9:1081-8.

Conclusions

- Severe asthma remains a considerable clinical challenge and public health issue
- Evaluation and management of people with severe asthma involves evaluation of medication adherence and technique, complicating comorbidities, clinical phenotypes, and inflammatory endotypes
- Precision medicine guides selection of biologic therapeutics along with shared decision-making

Thank You!!

Questions?