Asthma Control Test (ACT)

Question	Score
1. During the last 4 weeks, how much of the time has your asthma kept you from getting as much done at work, school or home?	
All of the time: 1 · Most of the time: 2 · Some of the time: 3 · A little of the time: 4 · None of the time: 5	
2. During the past 4 weeks, how often have you had shortness of breath?	
More than once a day: 1 · once a day: 2 · 3-6 times a week: 3 · Once or twice a week: 4 · Not at all: 5	
3. During the last 4 weeks, how often have your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) woken you up at night or earlier than usual in the morning?	
≥4 nights a week: 1 · 2-3 nights a week: 2 · Once a week: 3 · Once or twice: 4 · Not at all: 5	
4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?	
≥3 times per day: 1 · 1-2 times per day: 2 · 2-3 times per week: 3 · ≤1 per week: 4 · Not at all: 5	
5. How would you rate your asthma control during the past 4 weeks?	
Not controlled at all: 1 · Poorly controlled: 2 · Somewhat controlled: 3 · Well-controlled: 4 · Completely controlled: 5	
	Total

20-25: well-controlled; 16-19: not well-controlled; 5-15: very poorly controlled.
The minimum clinically important difference is 3 points.

Zerafil®
Omalizumab

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References:
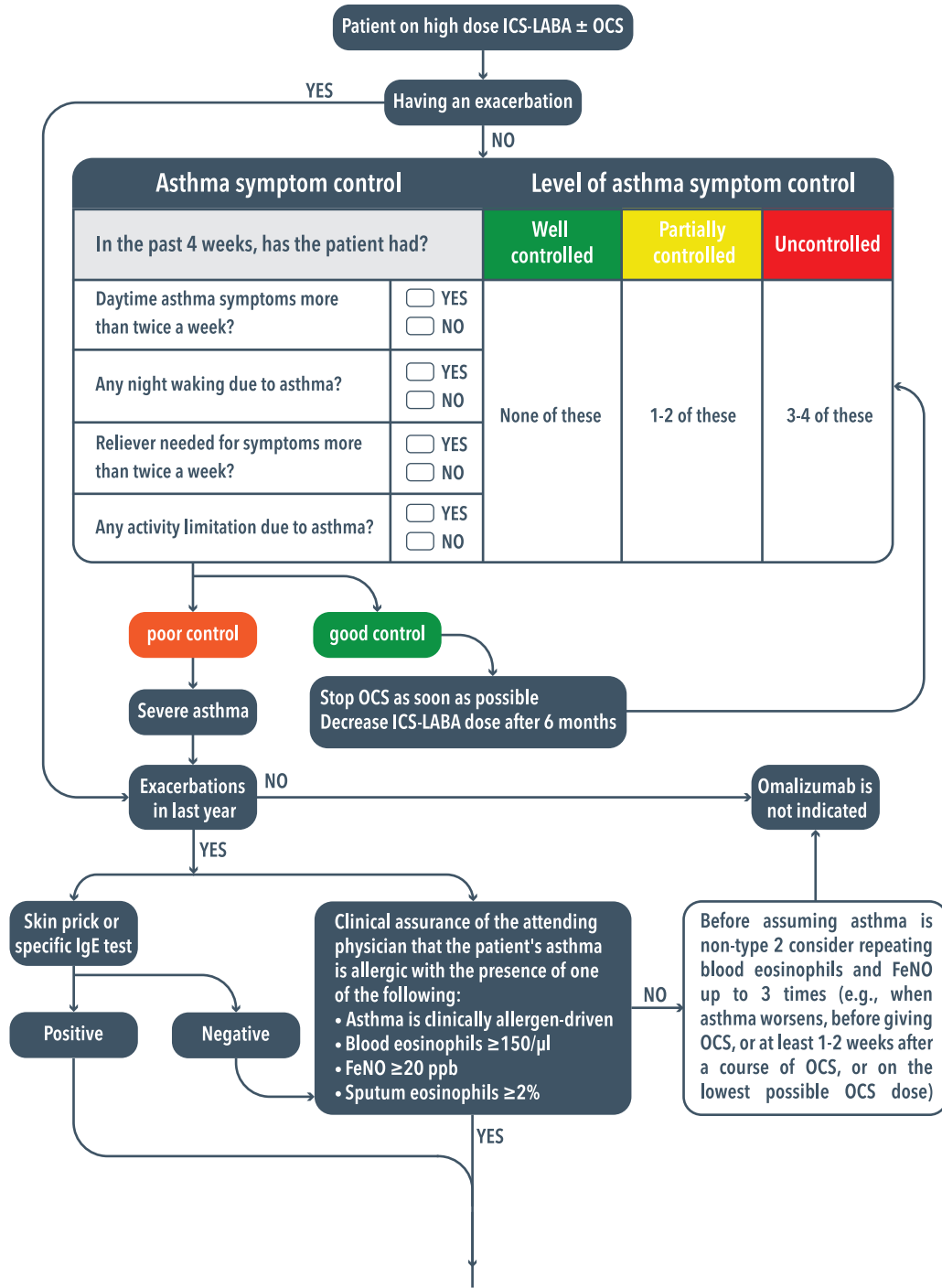1-2023 GINA report for asthma
2-Milger K, Korn S, Feder C, et al. Criteria for evaluation of response to biologics in severe asthma - the Biologics Asthma Response Score (BARS). *Pneumologie*. 2023;10.1055/a-2102-8128. doi:10.1055/a-2102-8128

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Algorithm for Asthma Treatment with Zerafil® Omalizumab

Patient on high dose ICS-LABA ± OCS

↓

Having an exacerbation — YES → / NO ↓

Asthma symptom control	Level of asthma symptom control		
In the past 4 weeks, has the patient had?	**Well controlled**	**Partially controlled**	**Uncontrolled**
Daytime asthma symptoms more than twice a week? ☐ YES ☐ NO	None of these	1-2 of these	3-4 of these
Any night waking due to asthma? ☐ YES ☐ NO			
Reliever needed for symptoms more than twice a week? ☐ YES ☐ NO			
Any activity limitation due to asthma? ☐ YES ☐ NO			

poor control → **Severe asthma**

good control → **Stop OCS as soon as possible. Decrease ICS-LABA dose after 6 months**

Exacerbations in last year — NO → **Omalizumab is not indicated**

YES ↓

Skin prick or specific IgE test → Positive / Negative

Clinical assurance of the attending physician that the patient's asthma is allergic with the presence of one of the following:
• Asthma is clinically allergen-driven
• Blood eosinophils ≥150/µl
• FeNO ≥20 ppb
• Sputum eosinophils ≥2%

— NO → **Before assuming asthma is non-type 2 consider repeating blood eosinophils and FeNO up to 3 times (e.g., when asthma worsens, before giving OCS, or at least 1-2 weeks after a course of OCS, or on the lowest possible OCS dose)**

YES ↓

Zerafil® Omalizumab can be prescribed

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Assess response after 4-6 months

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Criterion	Parameter	Good response 2 points	Intermediate response 1 point	Insufficient response 0 points
Reduction of exacerbation	Annual exacerbations	0 exacerbations or reduction ≥75%	Reduction of exacerbations 50-74%	Reduction of exacerbations ≤50%
Reduction of OSC	Daily dosage of OCS	Stopping OCS or reduction ≥75%	Reduction 50-74%	Reduction ≤50%
Improvement of asthma control	Asthma Control test (ACT)	Improvement >3 and score ≥20	Improvement 3-5 and score <20	Improvement <3
Score = Sum of points/3				
		≥1.5	0.5-1.33	<0.5

Also consider:
• Response of other type 2 comorbidities like nasal polyposis and chronic spontaneous urticaria, if present.
• Patient satisfaction

good response →
• Assess patient's condition every 3 to 6 months
• Consider decreasing/stopping OCS first, then stopping other add-on medications
• Consider ICS-LABA dose reduction after 3-6 months, continue at least moderate dose

Intermediate response → **Extend trial to 6-12 months**

Insufficient response →
• Stop omalizumab
• Re-assess phenotype and treatment options
• Do not stop ICS
• Consider add-on low dose OCS
• Consider add-on low dose azithromycin