

Guidelines and Expert Recommendations for the Positioning of Biologics in the Treatment of CRSwNP

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LEARNING OBJECTIVE

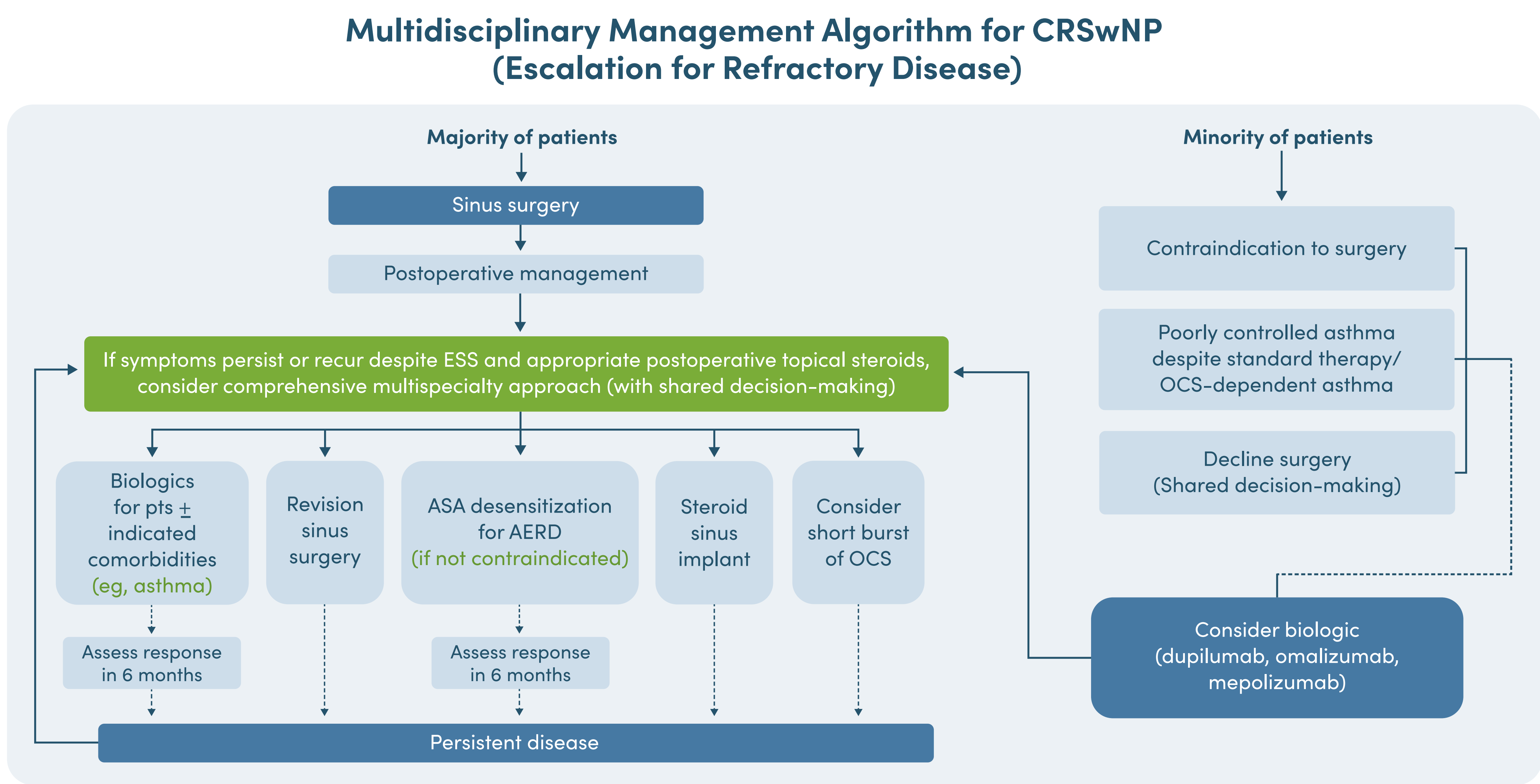
Incorporate current guidelines and expert recommendations into the positioning of biologic therapy, sinus surgery, and OCS for the treatment of patients with CRSwNP

BACKGROUND

Biologics have emerged as a safe and effective new therapeutic strategy for the treatment of CRSwNP

Clinical trial and real-world evidence to inform the positioning of biologic agents in the management of CRSwNP continues to evolve

CURRENT GUIDANCE ON BIOLOGIC THERAPY IN THE TREATMENT OF CRSWNP



INDICATIONS FOR BIOLOGIC THERAPY IN CRSWNP

Biologics are indicated for patients with bilateral polyps who have previously had surgery and satisfy three of the following criteria:

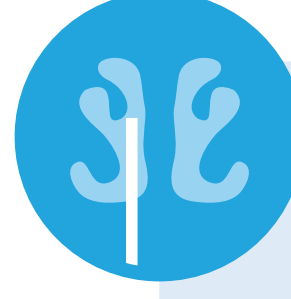
EUFOREA/EPOS 2023

Indication for biological treatment in CRSwNP	
Presence of bilateral polyps in patient who had ESS*	
THREE criteria are required	
Criteria	Cut-off points
Evidence of type 2 inflammation	Tissue eos ≥ 10 /hpf, OR blood eos ≥ 150 OR total IgE ≥ 100
Need for systemic corticosteroids or contraindication to systemic steroids	≥ 2 courses per year OR long term (>3 months) low dose steroids
Significantly impaired quality of life	SNOT-22 ≥ 40
Significant loss of smell	Anosmic on smell test (score depending on test)
Diagnosis of comorbid asthma	In case of asthma: regular need for inhaled corticosteroids

*Exceptional circumstances excluded (eg, not fit for surgery).

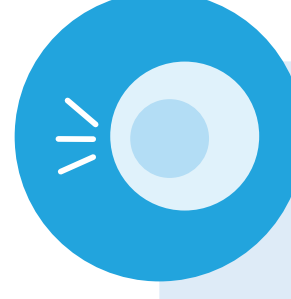
INDICATIONS FOR BIOLOGIC THERAPY IN CRSWNP

EUFOREA/EPOS 2023: Key Points



Sinus surgery remains a prerequisite

- Results in a positive impact in most patients
- Cost of biologics can be a challenge for patients
- Required duration and risk profiles of biologic treatment are not yet fully characterized



Type 2 inflammation is not mandatory

- Definition of type 2 inflammation in CRSwNP is not yet established
- Extent to which biologics might be helpful in mixed inflammation is unclear



BEC cut-off lowered from ≥ 250 to ≥ 150 cells/mL

- Alignment with pulmonological literature

Individualized treatment is based on shared decision-making

Hypothetical scenario	Treatment options for which SDM can be used to arrive at a plan
Patient has contraindication to corticosteroids	ESS, biologics
Patient does not have short-term cash available for medical expenses and does not have insurance	Corticosteroids (multiple formats of delivery)
Patient has contraindications to anesthesia	Corticosteroids, biologics
Patient has symptomatic recurrence of nasal polyps after revision ESS	Revision ESS, biologics (with or without sinus implants/corticosteroids)
Patient has transportation issues and cannot make scheduled appointments regularly	Corticosteroids, ESS, biologics
Patient prefers not to take medication multiple times a day	Biologics, ESS, sinus implant
Patient is afraid of needles and does not want surgery	Corticosteroids (multiple formats of delivery)
Patient's primary goal is reduction or elimination of nasal polyps	ESS, corticosteroids, biologics
Patient's primary goal is improvement of smell	Biologics, corticosteroids, ESS

Of note: treatment options available may also be combined

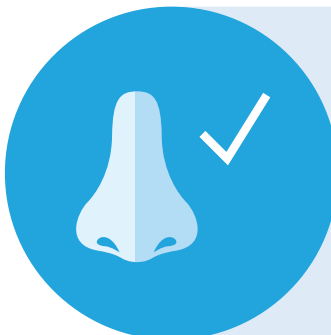
ACHIEVING A GOOD TREATMENT RESPONSE

When evaluating biologic response, patient- and physician-reported outcomes are not always aligned. Both are needed to establish overall disease control

A good response to biologic treatment includes:



Reduction in nasal polyp size



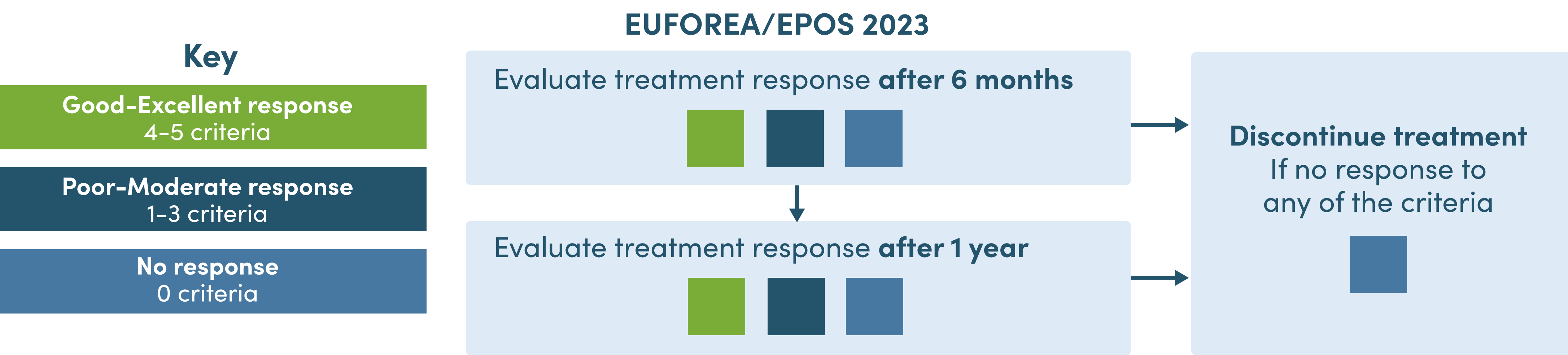
Improvement of QOL and/or sense of smell



Decreased need for systemic corticosteroids



Impact on comorbidities



Guidance on monitoring and adjusting treatment



Switching Biologic

Evidence points to significant differences in the treatment effect of biologics targeting different points in the type 2 inflammatory cascade. Thus, inadequate response to one biologic should not preclude trial of another.

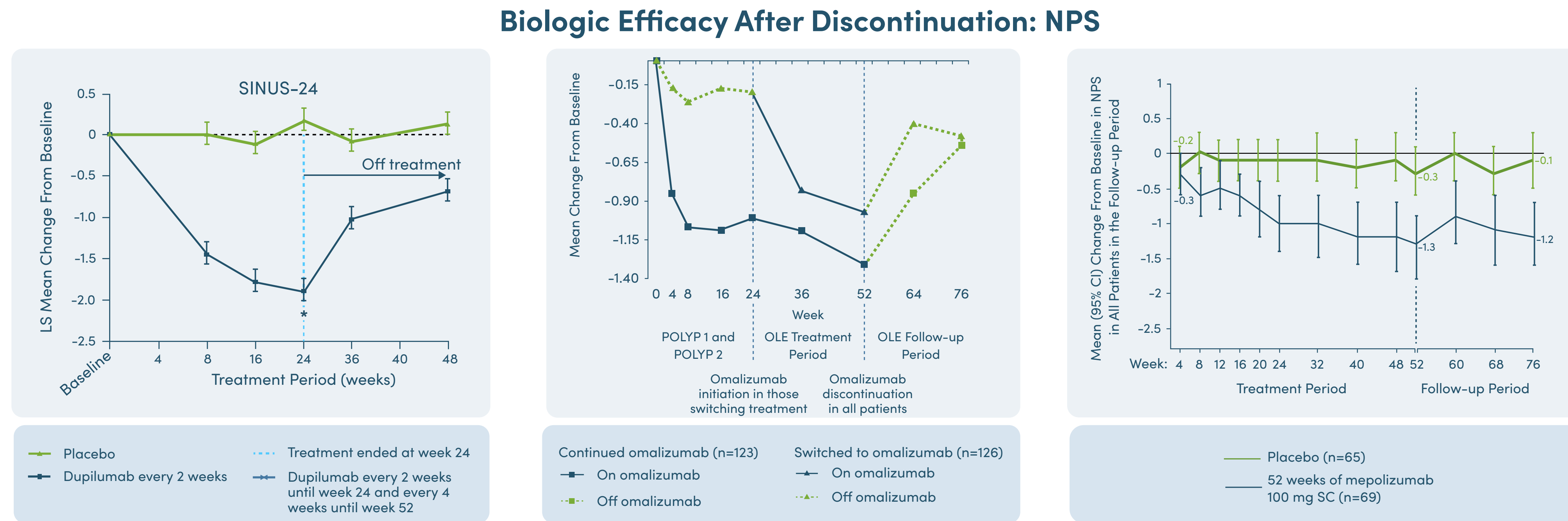


Biologic Discontinuation

Side effects are seldom a reason for discontinuation. Transient hypereosinophilia is a known phenomenon of treatment with anti-IL4R alpha (usually 2-6 m), but can cause organ damage if persistent.

WHEN TO END BIOLOGIC THERAPY

It remains unclear whether discontinuation may be appropriate for patients once disease control is achieved



References

Bachert C, et al. *Lancet*. 2019;394(10209):1638-1650.; Desrosiers M, et al. *Int Forum Allergy Rhinol*. 2023.; Fokkens WJ, et al. *Rhinology*. 2023;61(3):194-202.; Gevaert P, et al. *J Allergy Clin Immunol*. 2022;149(3):957-965.e953.; Han JK, et al. *Lancet Respir Med*. 2021;9(10):1141-1153.; Ledford D, et al. *J Allergy Clin Immunol*. 2017;140(1):162-169.e162. Moore WC, et al. *Eur Res J*. 2021;6;59(1):2100396.; Ramkumar SP, et al. *Front Allergy*. 2023;10;4:1137907.; Vennera MDC, et al. *Thorax*. 2018;73(8):782-784.

Glossary

AERD, aspirin-exacerbated respiratory disease; ASA, acetylsalicylic acid; BEC, blood eosinophil count; CRSwNP, chronic rhinosinusitis with nasal polyps; eos, eosinophils; EPOS, European Position Paper on Rhinosinusitis; ESS, endoscopic sinus surgery; EUFOREA, European Forum for Research and Education in Allergy and Airways Disease; HES, hypereosinophilic syndrome; hpf, high-power field; Ig, immunoglobulin; IL, interleukin; LS, least squares; OCS, oral corticosteroids; OLE, open-label extension; N-ERD, nonsteroidal anti-inflammatory drug-exacerbated respiratory disease; pts, patients; Q2W, every 2 weeks; Q4W, every 4 weeks; QOL, quality of life; RDBPC, randomized double-blind placebo-controlled; SC, subcutaneous; SDM, shared decision-making; SNOT-22, 22-item sinonasal outcome test