CORLAMM

Expert Position Statement:

Biologics in CRSwNP

College of Otorhinolaryngologists -
Head and Neck Surgeons,
Academy of Medicine of Malaysia

CORLAMM Expert Position Statement: Biologics in CRSwNP

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Statement of intent

This document aims to provide guidance for biologics eligibility tailored to the local context, considering local disease characteristics, resource availability, and healthcare funding.

The content is formulated based on current scientific evidence and/or best clinical practice during its development and publication. Healthcare professionals are encouraged to exercise clinical judgement when applying these information to their clinical practice.

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Address from CORLAMM President

Chronic rhinosinusitis (CRS) represents a significant and multifaceted inflammatory condition that continues to impose a considerable burden on patients, healthcare systems, and society at large. Characterised by persistent sinonasal inflammation lasting beyond 12 weeks, CRS often leads to impaired quality of life, reduced productivity, and frequent healthcare utilisation. Despite advances in medical and surgical management, a subset of patients remains refractory to conventional therapies, highlighting the need for more targeted and effective treatment strategies.

In recent years, the emergence of biologic therapies has marked a transformative shift in the management paradigm of CRS, particularly in cases associated with type 2 inflammation. By selectively targeting key immunological pathways, biologics offer a personalised approach that addresses the underlying disease mechanisms rather than merely alleviating symptoms. This evolution reflects a broader movement towards precision medicine, where treatment decisions are increasingly guided by endotypes, biomarkers, and individual patient profiles.

These guidelines have been developed to provide clinicians with evidence-based recommendations on the appropriate use of biologics in CRS. They aim to clarify indications, patient selection criteria, therapeutic monitoring, and safety considerations, while also addressing practical aspects of implementation in diverse clinical settings. Recognising the rapidly evolving landscape, the guidelines incorporate the latest clinical trial data, real-world evidence, and expert consensus.

It is our hope that this document will serve as a valuable resource for otolaryngologists, allergists, pulmonologists, and other healthcare professionals involved in the care of patients with CRS. By promoting a structured and informed approach to biologic therapy, we strive to improve patient outcomes, optimise resource utilisation, and advance the standard of care in this challenging condition.

Ultimately, the successful integration of biologics into CRS management depends not only on scientific progress but also on multidisciplinary collaboration, patient engagement, and ongoing research. As our understanding continues to grow, these guidelines should be viewed as a living document—one that will evolve alongside emerging evidence and clinical experience.

Prof Dato' Dr Philip Rajan Devesahayam
President
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Address from Chair of Expert Panel

Chronic rhinosinusitis with nasal polyps (CRSwNP) remains a challenging condition associated with substantial disease burden, impaired quality of life, and frequent healthcare utilisation. While the Malaysian Clinical Practice Guidelines (CPG) on the Management of Rhinosinusitis in Adolescents and Adults was last updated in 2016, important advances have since emerged, particularly with the introduction of biologic therapies targeting underlying type 2 inflammation. These developments have expanded the therapeutic landscape for patients with uncontrolled CRSwNP. However, guidance on their appropriate use within the Malaysian context remains limited. In view of evolving evidence and emerging clinical demands, there is a clear need for updated, locally relevant recommendations to support appropriate patient selection and treatment strategies.

This CORLAMM Expert Position Statement represents a crucial step forward in addressing this gap. Developed by a panel of local experts, this document provides practical, evidence-based guidance on the use of biologics in CRSwNP, including patient eligibility, therapeutic monitoring, safety considerations, and referral pathways tailored to Malaysian clinical settings. Importantly, it offers a structured algorithm to inform decision-making for biologics use among otolaryngologists. It is our hope that this position statement will serve as a valuable reference to guide clinicians in delivering more effective treatment for patients with CRSwNP, ultimately improving clinical outcomes and quality of life.

Dr Harvinder Singh
Chairman of Subspecialty Committee for Rhinology
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Treatment Algorithm

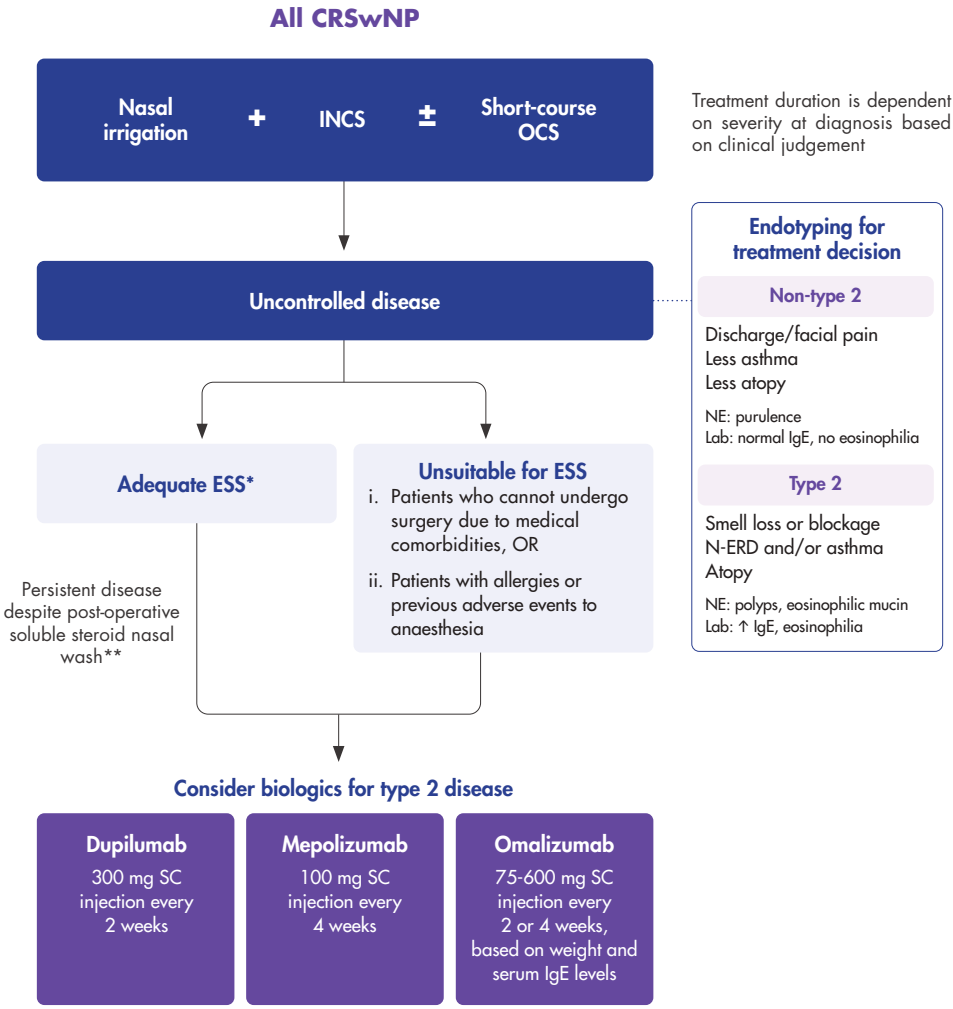

Figure 1: Treatment algorithm for CRSwNP

*Bilateral anterior and posterior ethmoidectomy, middle meatal antrostomy, sphenoidotomy, and frontal sinusotomy.

**Standard soluble nasal wash is 500 µg of budesonide in 240 mL saline irrigation per nostril twice a day (total 1000 µg/day).

Refer to Appendix 1 for definition of disease severity and control for CRSwNP.

CRSwNP: chronic rhinosinusitis with nasal polyps; ESS: endoscopic sinus surgery; INCS: intranasal corticosteroid; NE: nasal endoscopy; N-ERD: NSAID-exacerbated respiratory disease; OCS: oral corticosteroid.

Adapted from Karpischenko S, et al. Asia Pac Allergy. 2024; Abdullah B, et al. World Journal of Otorhinolaryngology-Head and Neck Surgery. 2025; Fokkens WJ, et al. Rhinology. 2020; Malaysian prescribing information for dupilumab, mepolizumab, and omalizumab.

Introduction

Prevalence and definition of CRSwNP

Chronic rhinosinusitis (CRS) affects around 5–15% of people, while doctor-diagnosed CRS accounts for about 2–4%.[1] To date, evidence remains insufficient to estimate the prevalence of chronic rhinosinusitis with nasal polyps (CRSwNP) in the ASEAN region and Malaysia.[2]

The definition of CRSwNP is outlined in Box 1; disease severity and control are defined in Appendix 1, including definitions of severe and uncontrolled CRSwNP, as well as criteria to assess current clinical control of CRS.

Box 1: Definition of CRSwNP from ICAR-RS 2021[3]

Sinonasal inflammation persisting for more than 12 weeks, with a combination of at least 2 of the following symptoms and confirmed by endoscopic or radiographic findings:

- Nasal obstruction/congestion/blockage
- Anterior or posterior (mucopurulent) nasal drainage
- Loss or decreased sense of smell
- Facial pressure/pain/fullness

AND

presence of polyps

ICAR-RS: International Consensus Statement on Allergy and Rhinology: Rhinosinusitis

Endotyping in CRSwNP

While CRS has traditionally been classified by the presence or absence of nasal polyps, the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) 2020 further distinguishes CRS into primary and secondary disease, with additional classification by anatomical location and underlying endotype or aetiology (Figure 2).[4]

Endotyping differentiates type 2 from non-type 2 CRSwNP to inform prognosis, treatment response, and long-term management strategies.[5] Patients with evidence of underlying type 2 inflammation, confirmed by tissue or blood eosinophils levels, are eligible for type 2 biologic therapy (refer to Resource for blood eosinophil conversion calculator).[2,5] As recent corticosteroid use may affect eosinophil counts, corticosteroids should be temporarily withheld prior to endotyping.[2]

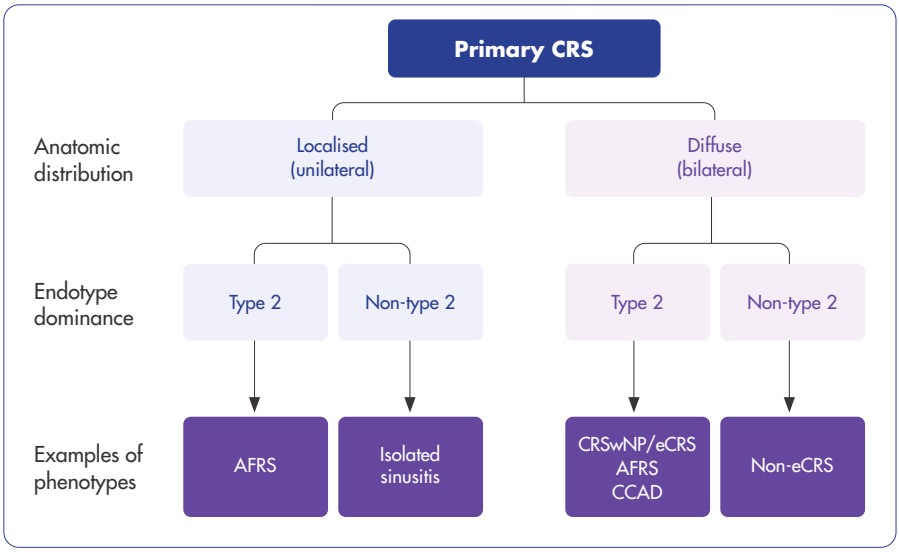

Figure 2: EPOS 2020 classification of primary CRS

AFRS: allergic fungal rhinosinusitis; CCAD: central compartment atopic disease; CRS: chronic rhinosinusitis; CRSwNP: chronic rhinosinusitis with nasal polyps; eCRS: eosinophilic chronic rhinosinusitis; EPOS: European Position Paper on Rhinosinusitis and Nasal Polyps.

Reproduced with permission from Fokkens WJ, et al. Rhinology. 2020;58(Suppl S29):1-464.

Standard of care for CRSwNP

Appropriate medical therapy for CRSwNP typically involves nasal irrigation and intranasal corticosteroid (INCS).[4,6-8] Oral corticosteroid (OCS) may be added to INCS in patients with partially or uncontrolled disease,[4] usually at 25–50 mg equivalent of prednisone (Appendix 2) for short courses of 2–3 weeks, not exceeding a cumulative dose of 500 mg per year.[7]

The role of antibiotic for CRSwNP remains uncertain; long-term antibiotic (> 4 weeks) is generally limited to macrolides in non-type 2 disease due to their anti-interleukin (IL)-8 effects, with careful consideration of the risk of prolonged QT interval.[4,7]

In patients with uncontrolled disease regardless of appropriate medical therapy, endoscopic sinus surgery (ESS) may be considered to remove diseased tissue and improve anatomical function to optimise delivery of topical therapy.[2,6] However, biologics may be considered at this stage for patients who are unsuitable for ESS,[6,7] or where disease persists with previous ESS.[4]

In patients with uncontrolled disease, OCS can provide short-term symptom relief and reduce polyp size, but their prolonged use is associated with adverse effects.[9] Meanwhile, inadequate surgery may lead to repeated procedures, scarring, and mucosal damage; however, polyp recurrence may still occur in some patients despite adequate sinus surgery.[8] Given these limitations, biologics offer a novel treatment approach by targeting cytokines involved in type 2 inflammation that contribute to CRSwNP.[5]

Biologics for CRSwNP

In certain predisposed individuals, there appears to be high rates of residual symptoms and polyp recurrence despite appropriate medical therapy and adequate sinus surgery, highlighting the need for targeted therapies in CRSwNP.[10] With prevalent type 2 inflammation, biologics targeting IL-4, IL-5, IL-13 and immunoglobulin E (IgE) pathways play a key role in transforming CRSwNP management.[11]

Randomised controlled trials and real-world evidence show robust efficacy and good safety, alongside reduced polyp size, improved symptoms, and better quality of life.[9,12-14] To date, biologics approved for CRSwNP in Malaysia include dupilumab, mepolizumab and omalizumab (Table 1).

Table 1: Biologics approved for CRSwNP in Malaysia[15-17]

Biologics (MOA)	CRSwNP indication	Dosing regimen	Other indications as per NPRA approval
Dupilumab (anti-IL-4/IL-13)	As an add-on therapy with INCS for the treatment of adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.	300 mg every other week	Severe asthma, atopic dermatitis, prurigo nodularis
Mepolizumab (anti-IL-5)		100 mg every 4 weeks	Severe eosinophilic asthma, EGPA
Omalizumab (anti-IgE)	As an add-on therapy with INCS for the treatment of adults (≥ 18 years) with CRSwNP for whom therapy with INCS does not provide adequate disease control.	Depends on IgE and body weight	Allergic asthma, chronic spontaneous urticaria

CRSwNP: chronic rhinosinusitis with nasal polyps; EGPA: eosinophilic granulomatosis with polyangiitis; IgE: immunoglobulin E; INCS: intranasal corticosteroid; MOA: mechanism of action; NPRA: National Pharmaceutical Regulatory Agency.

Refer to Appendix 3 for adverse events of biologics.

Recommendations for Biologics in CRSwNP

Patient selection criteria for biologics

Biologics are indicated for:

1. Patients with uncontrolled CRSwNP despite adequate sinus surgery and appropriate medical therapy who meet at least 3 of 5 criteria from Figure 3.[2,18]
2. ESS-naïve patients with medical or surgical contraindications, including medical comorbidities and a history of allergies or previous adverse events to anaesthesia.[2,18]

Indication for biologics 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 eosinophils ≥ 10/hpf OR Blood eosinophils ≥ 150 cells/µL OR Total IgE ≥ 100 IU/mL
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

Figure 3: EPOS/EUFOREA 2023 patient selection criteria for biologics

These criteria aim to identify patients with type 2 inflammation and significant impairment in quality of life due to CRSwNP.

*If SNOT-22 reporting is not feasible in your setting, use a VAS score.

**If smell test is not available, use clinical judgement.

Refer to Appendix 4 for details on SNOT-22 and VAS score.

ESS: endoscopic sinus surgery; EPOS: European Position Paper on Rhinosinusitis and Nasal Polyps; EUFOREA: European Forum for Research and Education in Allergy and Airway Diseases; IgE: immunoglobulin E; SNOT-22: Sinonasal Outcome Test-22; VAS: visual analogue scale.

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Monitoring responses to biologics

An initial evaluation to determine response to biologic therapy is recommended at 4 months,[2] followed by assessments at 6 months and re-evaluation at 12 months according to EPOS/EUFOREA 2023 criteria (Figure 4).[2,18]

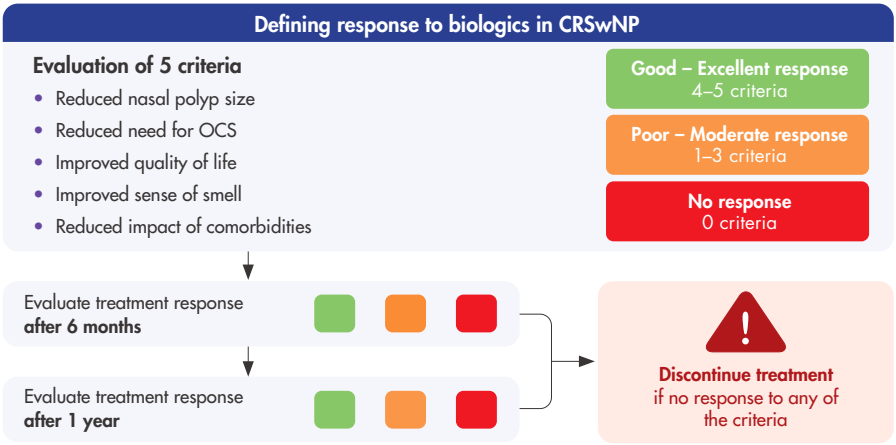

Figure 4: EPOS/EUFOREA 2023 patient response criteria for biologics

CRSwNP: chronic rhinosinusitis with nasal polyps; EPOS: European Position Paper on Rhinosinusitis and Nasal Polyps; EUFOREA: European Forum for Research and Education in Allergy and Airway Diseases; OCS: oral corticosteroid.
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The ASEAN CRSwNP 2025 consensus specify response criteria in more detail, including tests and thresholds for improvements in nasal polyp size, OCS use, quality-of-life measures, and olfactory function 6 and 12 months after biologics initiation, as summarised in Table 3.[2]

Table 3: ASEAN CRSwNP 2025 consensus response criteria for biologics

Patient response criteria as per EPOS/EUFOREA 2023[18]	Type of test	Threshold[2]	
		After 6 months	After 12 months
Reduced nasal polyp size	NPS	≥ 1-point improvement	Target score < 4 on both sides
Reduced need for OCS	Need for OCS	No need for OCS	
Improved quality of life	NCS	≥ 0.5-point improvement	Target score < 2
	VAS	≥ 2-point improvement	Target score < 5
	SNOT-22	≥ 8.9-point improvement	Target score < 30
Improved sense of smell	Smell test	Improvement from anosmia to hyposmia/normosmia If smell testing is unavailable, a ≥ 3-point improvement in VAS smell change can be used	

Quality-of-life measure can be assessed by either NCS, VAS, or SNOT-22.
Refer to Appendix 4 for details on NPS, NCS, VAS, and SNOT-22.
EPOS: European Position Paper on Rhinosinusitis and Nasal Polyps; EUFOREA: European Forum for Research and Education in Allergy and Airway Diseases; NCS: nasal congestion score; NPS: nasal polyp score; OCS: oral corticosteroid; SNOT-22: Sinonasal Outcome Test-22; VAS: visual analogue scale.

Monitoring safety with biologics

Although biologics are generally considered safe, transient hypereosinophilia may occur with anti-IL-4/IL-13 therapy, usually within 2–6 months of treatment initiation.[18] In view of potential for organ damage, clinicians are advised to assess the patient at every visit with blood eosinophil measurements as appropriate (Table 4).[18]

Table 4: Frequency of blood eosinophil monitoring after initiation of anti-IL-4/IL-13 biologics[18]

Time point	Frequency of monitoring
At biologic initiation	At 1 and 3 months, with frequent measurement in patients with high blood eosinophil level (> 500 cells/μL) and on chronic systemic corticosteroids before biologic
After 3 months	Frequency adjusted according to blood eosinophil level • 1500 cells/μL: Every 2–4 weeks • 3000 cells/μL: Temporisation of the dose (to every 4 weeks) or treatment with a short course of systemic corticosteroid

Consult an immunologist if persistent high blood eosinophils or vasculitis symptoms.

Considerations for biologic discontinuation

Biologics should be discontinued in patients who do not achieve any of the EPOS/EUFOEA 2023 response criteria (Figure 4) after 6 months of biologics treatment.[18] A switch to an alternative biologic or other treatment modalities may be considered in these patients.[2,5]

Patients should be reevaluated 6 months after switching biologics. Biologic therapy should be discontinued in patients who fail to achieve any of the EPOS/EUFOREA 2023 response criteria.[2,5,18]

Long-term biologic use in patients with good response

While Phase III clinical trials of biologics for CRSwNP were limited to 1 year of treatment, real-world experiences may offer valuable insights to guide treatment beyond the first year:

- In severe asthma and atopic dermatitis, biologic therapy may be continued long-term in responders after 1 year, usually without modification to the initial dosing regimen.
- In CRSwNP, patients with good response after 1 year of treatment may continue long-term biologic therapy, with adequate symptom control supporting consideration of extending dosing intervals beyond the initial recommended regimen.

Referral pathway for CRSwNP

Early referral from primary care to an otorhinolaryngology specialist, ideally within 6–12 weeks, is recommended to facilitate timely confirmation of CRSwNP by endoscopy and/or computed tomography.[6]

When asthma or atopic dermatitis coexist with CRSwNP, a multidisciplinary approach led by the otorhinolaryngology specialist involving allergists, immunologists, pulmonologists, and dermatologists will support comprehensive evaluation and optimisation of both medical and surgical therapies for the CRSwNP patient.[6,19]

Resource: Blood Eosinophil Unit Conversion Calculator

A blood eosinophil unit conversion calculator can be used to obtain absolute eosinophil count in **cells/µL**, following the steps below (Figure 5):

1. Access the blood eosinophil calculator via the QR code.
2. Enter the reported eosinophil count and its respective unit. Test results may be entered as a gross figure or a percentage of white blood cell count.
3. Click "Calculate" to show absolute eosinophil count in cells/µL.

1 Blood EOS Calculator

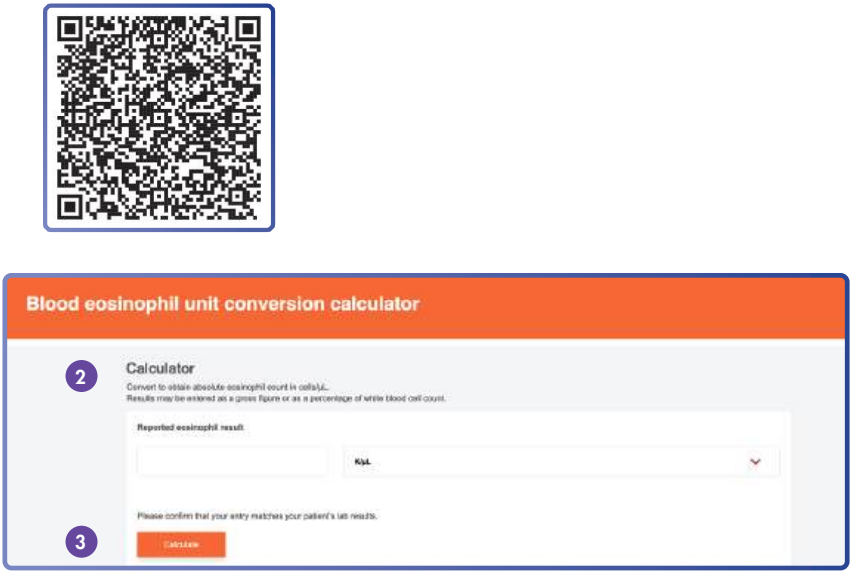

Figure 5: Blood eosinophil unit conversion calculator

Appendices

Appendix 1: Definition of disease severity and control for CRSwNP

Appendix Table 1: Definition of severe and uncontrolled CRSwNP[5]

Severe CRSwNP

Bilateral CRSwNP (confirmed by nasal endoscopy) with a NPS of ≥ 4, and persistent symptoms despite long-term INCS with the need for add-on treatment.

Persistent symptoms assessed by:

- Loss of smell score (0–3) ≥ 2 points
- NCS (0–3) ≥ 2 points
- SNOT-22 ≥ 35 points
- Total symptom VAS ≥ 5 out of 10 cm

Uncontrolled CRSwNP

Persistent or recurring CRSwNP despite long-term INCS, and having received ≥ 1 course of systemic corticosteroids* in the preceding 2 years and/or previous sinonasal surgery*

- Long-term low dose systemic corticosteroid is not recommended
- 1 course of systemic corticosteroids refers to minimum 5 days of systemic corticosteroids at a dose of 0.5–1 mg/kg/day or more
- Previous sinonasal surgery refers to any surgical procedure from the resection of polyps to conventional ESS or extended approaches

*Unless having a medical contraindication or rejected by the patient.

CRSwNP: chronic rhinosinusitis with nasal polyps; ESS: endoscopic sinus surgery; INCS: intranasal corticosteroid; NCS: nasal congestion score; NPS: nasal polyp score; SNOT-22: Sinonasal Outcome Test-22; VAS: visual analogue scale.

Appendix Table 2: EPOS 2020 assessment criteria for current clinical control of CRS[4]

Assessment criteria	Clinical control of CRS in the last month		
	Controlled (all present)	Partly controlled (≥ 1 present)	Uncontrolled (≥ 3 present)
Nasal blockage	Not present or not bothersome	Present on most days of the week	Present on most days of the week
Rhinorrhoea/ post-nasal drip	Little and mucous	Mucopurulent on most days of the week	Mucopurulent on most days of the week
Facial pain/pressure	Not present or not bothersome	Present on most days of the week	Present on most days of the week
Smell	Normal or only slightly impaired	Impaired	Impaired
Sleep disturbance or fatigue	Not present	Present	Present
Nasal endoscopy (if available)	Healthy or almost healthy mucosa	Diseased mucosa#	Diseased mucosa#
Rescue treatment (in the last 6 months)	Not needed	Need 1 course of rescue treatment	Symptoms (as above) persist despite rescue treatment(s)

#Showing nasal polyps, mucopurulent secretions, or inflamed mucosa.
CRS: chronic rhinosinusitis; EPOS: European Position Paper on Rhinosinusitis and Nasal Polyps.
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Appendix 2: Corticosteroid dose equivalents

Appendix Table 3: Corticosteroid dose equivalents[4]

Equivalent dose (mg)	Steroid	Duration of action
1.2	Betamethasone	Long-acting
1.5	Dexamethasone	Long-acting
8	Methylprednisolone	Intermediate-acting
8	Triamcinolone	Intermediate-acting
10	Prednisone	Intermediate-acting
10	Prednisolone	Intermediate-acting
40	Hydrocortisone	Short-acting
50	Cortisone	Short-acting

E.g., Dexamethasone dose equivalent of prednisone 50 mg would be 7.5mg.
Prednisone 10 mg = Dexamethasone 1.5 mg
Prednisone 50 mg = Dexamethasone 7.5 mg
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Appendix 3: Adverse events of biologics

Appendix Table 4: Common and very common adverse events[15-17]

Biologics	Steroid
Dupilumab	Arthralgia, conjunctivitis†, diarrhoea, dizziness, eosinophilia, eye pruritus, gastritis, injection site reactions†, insomnia, myalgia, nasopharyngitis, herpes infections, oropharyngeal pain, toothache
Mepolizumab	Abdominal pain (upper), back pain, eczema, headache†, hypersensitivity, injection site reaction, lower respiratory tract infection, nasal congestion, pharyngitis, pyrexia, urinary tract infection
Omalizumab	Abdominal pain (upper), arthralgia, dizziness, headache†, injection site reactions, nasopharyngitis, pyrexia†, sinusitis, viral upper respiratory tract infection

Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10).
Adverse events are listed in alphabetical order; the table includes common adverse events unless otherwise indicated as very common adverse events (denoted by †).

Appendix 4: Clinical outcome measures in CRSwNP

22-item Sinonasal Outcome Test (SNOT-22)

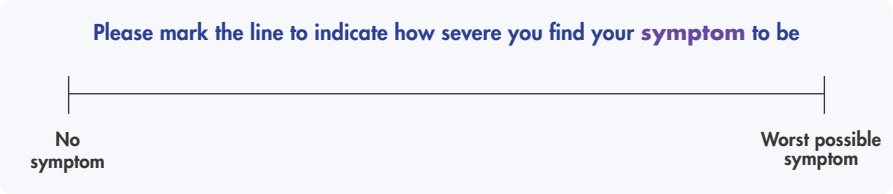
The SNOT-22 is a validated, disease-specific, patient-rated questionnaire comprising 22 items that assess health-related quality of life in rhinosinusitis across 5 domains: rhinologic, extranasal rhinologic, ear/facial, psychosocial, and sleep.[20,21]

Each of the 22 items is scored on a 0–5 scale, yielding a total score of 0–110, with higher score reflecting greater rhinosinusitis-related health burden.[22] An absolute difference of 8.9 or more between assessments represents a clinically meaningful difference.[20]

Visual analogue scale (VAS)

Patients rate the symptom severity using a 10-cm VAS, with 0 indicating total absence of symptom(s) and 10 denoting the worst thinkable severity (Appendix Figure 1).[4] This tool is particularly useful for assessing nasal obstruction and discharge, facial pain or pressure, headache, loss of smell, and overall symptoms.[23]

VAS scores may be used to categorise CRS as mild (0–3), moderate (> 3–7), or severe (> 7–10), with scores 5 and above typically reflecting impaired quality of life.[24]

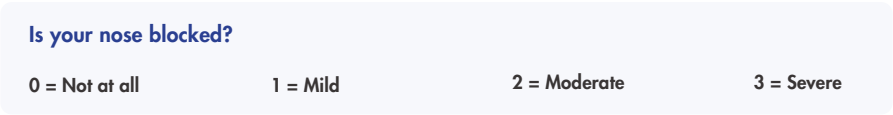


Appendix Figure 1: VAS to assess symptom severity
Adapted from Krouse J, et al. Int J Gen Med. 2010.

Nasal congestion score (NCS)

Patients evaluate the severity of nasal congestion on a scale of 0–3 (Appendix Figure 2), where:[23]

- 0 indicates no awareness of airflow obstruction
- 3 indicates almost complete or complete bilateral nasal blockage that is highly bothersome and requires mouth breathing most or all the time



Appendix Figure 2: NCS to rate nasal congestion
Adapted from Bachert C, et al. Lancet. 2019; Gevaert P, et al. J Allergy Clin Immunol. 2020.

Nasal polyp score (NPS)

The NPS is an endoscopic scoring system that assesses polyp size and the extent of anatomical disease.[25,26] Each nostril is scored from 0–4 (Appendix Table 5, Appendix Figure 3). The NPS is calculated by summing the scores from both nostril (range 0–8), with a score of ≥ 5 indicating severe CRSwNP.[25]

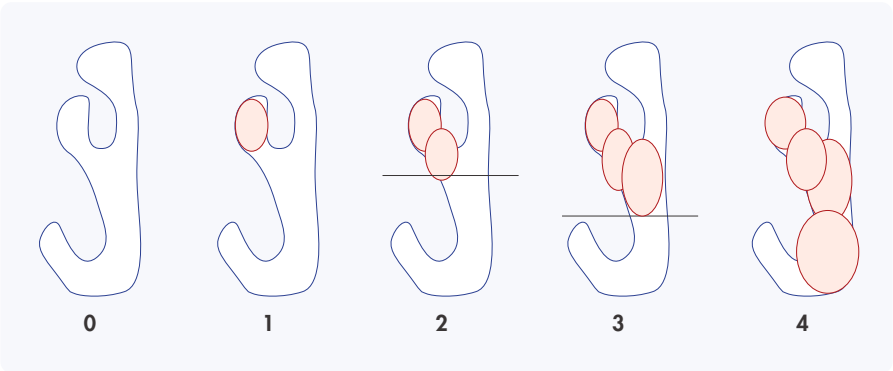
Appendix Table 5: NPS scoring system[13,25,26]

NPS	Description
0	No nasal polyps
1	Small nasal polyps in the middle meatus not reaching below the inferior border of the middle turbinate
2	Nasal polyps reaching below the lower border of the middle turbinate‡
3	Large nasal polyps reaching the lower border of the inferior turbinate or polyps medial to the middle turbinate
4	Nasal polyps reaching below the lower border of the middle turbinate‡

‡The scoring is modified to accommodate patients who have had a middle turbinectomy, such that the polyp must reach the top of the inferior turbinate to be graded as score 2.

Total NPS is the sum of unilateral polyp scores for each nasal passage.

NPS: nasal polyp score.



Appendix Figure 3: Polyp grading system (right nasal cavity)

Adapted from Meltzer EO, et al. J Allergy Clin Immunol. 2006.

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Notes

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