Mepolizumab: analysis of use for chronic rhinosinusitis

Drug utilisation sub-committee (DUSC)

February 2026

Abstract

Purpose

To review the utilisation of mepolizumab for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) as requested by DUSC at its October 2025 meeting.

Date of listing on the Pharmaceutical Benefits Scheme (PBS)

Mepolizumab was PBS listed for CRSwNP on 1 April 2023.

Data Source / methodology

Data extracted from the PBS database maintained by Department of Health, Disability and Ageing, processed by Services Australia were used for the analyses.

Key Findings

- Since PBS listing on 1 April 2023, 2,509 patients have been supplied 31,992 prescriptions of mepolizumab for CRSwNP. In 2024, there were 1,717 patients supplied 13,484 prescriptions of mepolizumab for CRSwNP.
- The number of treated patients has increased each quarter, and patients who initiate appear to continue treatment, as approximately 80% of patients who have initiated treatment were identified as continuing treatment at the end of the data collection.
- Publicly available data from the Medicare Benefits Schedule showed a decrease in the number of services related to surgeries for nasal polyps from 2023. However, this decrease was likely due to administrative changes to MBS item codes rather than the PBS listing of mepolizumab.
- The supplied quantity and time between supplies of mepolizumab appear to be in accordance with recommended dosing.
- The majority of patients who initiated mepolizumab for CRSwNP were male (57%).
- The States with the highest use per population were SA, QLD and WA.

Purpose of analysis

To review the utilisation of mepolizumab for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) as requested by DUSC at its October 2025 meeting.

Background

Clinical situation

CRSwNP is a subtype of chronic rhinosinusitis characterised by persistent inflammation of the nasal and sinus mucosa, which can cause symptoms such as blocked nose and loss of smell, and soft jelly-like growths (nasal polyps) to form inside the nose.[1] The first-line treatment for nasal polyps is usually medical therapy in the form of topical or oral corticosteroids. In patients where this treatment has failed to relieve the symptoms, the polyps can be removed surgically. These surgical procedures are often not curative and patients may need to continue medical therapy or undergo further surgeries.[2] The condition is frequently associated with elevated eosinophil levels and may coexist with other eosinophilic disorders such as asthma.[3]

Pharmacology

Mepolizumab is a humanised monoclonal antibody that selectively binds to interleukin-5 (IL-5), a key cytokine involved in the growth and differentiation, recruitment, activation, and survival of eosinophils. By inhibiting IL-5, mepolizumab reduces eosinophil levels in the blood and tissues, thereby mitigating eosinophilic inflammation. This mechanism is particularly relevant in CRSwNP, where eosinophilic infiltration contributes to polyp formation and symptom severity.[4]

Therapeutic Goods Administration (TGA) approved indications

Mepolizumab is registered by the TGA as an add-on treatment for adult patients (18 years and older) with severe CRSwNP who have an inadequate response to intranasal corticosteroids. It is also approved for severe eosinophilic asthma and relapsed or refractory eosinophilic granulomatosis with polyangiitis.[4]

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[1] Nucala (mepolizumab) [Consumer Medicine Information]. GlaxoSmithKline Australia Pty Ltd; Prepared 15 April 2025. Available from: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-CMI-02418-1

[2] Sharma R, Lakhani R, Rimmer J, Hopkins C. Surgical interventions for chronic rhinosinusitis with nasal polyps. Cochrane Database Syst Rev. 2014 Nov 20;2014(11):CD006990. doi: 10.1002/14651858.CD006990.pub2. PMID: 25410644; PMCID: PMC11166467.

[3] Bachert C, Han JK, Desrosiers M, Hellings PW, Amin N, Lee SE, et al. Efficacy and safety of mepolizumab in chronic rhinosinusitis with nasal polyps: a randomized clinical trial. JAMA. 2020;324(4):296–305.

[4] Nucala (mepolizumab). Australian Approved Product Information. GlaxoSmithKline Australia Pty Ltd; Approved 14 Jan 2022. Available from: https://www.tga.gov.au/resources/prescription-medicines-registrations/nucala-glaxosmithkline-australia-pty-ltd-1.

Dosage and administration

Mepolizumab is administered as a 100 mg subcutaneous injection once every 28 days. It is supplied as a single-dose pre-filled pen for self-administration.[4]

The current Product Information (PI) and Consumer Medicine Information (CMI) are available from the TGA (Product Information) and the TGA (Consumer Medicines Information).

PBS listing details (as at December 2025)

Mepolizumab was listed on the PBS for CRSwNP on 1 April 2023 as an Authority Required listing, under the Section 100 Highly Specialised Drugs Program. The listings for S100 HSD Public and S100 HSD Private both include criteria for initial and continuing treatment.

Table 1: PBS listing of mepolizumab for CRSwNP

PBS Item Number	Name, form & strength, pack size	Max qty packs	Max qty units	Rpts	DPMQ	Brand name and manufacturer
13237Q (S100 HSD Public)	Mepolizumab 100 mg/mL injection, 1 mL pen device	1 pack	1 unit	5	$1,556.10	Nucala® GlaxoSmithKline Australia Pty Ltd
13242Y (S100 HSD Private)	Mepolizumab 100 mg/mL injection, 1 mL pen device	1 pack	1 unit	5	$1,604.98	Nucala® GlaxoSmithKline Australia Pty Ltd

Source: the PBS website. Special Pricing Arrangements apply.

MBS listing details (as at December 2025)

Table 2: MBS listing related to surgeries for removal of nasal polyps

MBS Item Number	Name, form & strength, pack size	Fee and Benefit
41662	Nasal polyp or polypi (simple), removal of, other than a service associated with a service to which item 41702, 41703 or 41705 applies on the same side. Intended to cover the removal of simple nasal polyp or polypi. Simple nasal polyp or polypi are those confined to the middle meatus, the equivalent of Grade 0, 1 or 2 in any accepted clinical nasal polyp grading system.	Fee: $96.20 Benefit: 75% = $72.15 85% = $81.80
41668	Nasal polyp or polypi, removal of. Intended to cover the removal of nasal polyp or polypi extending beyond the middle meatus, the equivalent of Grade 3 or beyond in any accepted clinical nasal polyp grading system.	Fee: $256.50 Benefit: 75% = $192.40 85% = $218.05
41710	Antrostomy by any approach, other than a service associated with a service to which item 41702, 41703, 41705 or 41698 applies on the same side.	Fee: $412.75 Benefit: 75% = $309.60
41734	Endoscopic Lothrop procedure or radical external frontal sinusotomy with osteoplastic flap, unilateral, other than a service associated with a service to which item 41698, 41703, 41705 or 41764 applies on the same side.	Fee: $1,182.90 Benefit: 75% = $887.20
41752	Sphenoidal sinus, unilateral, intranasal operation on, other than a service associated with a service to which item 41703 or 41705 applies on the same side.	Fee: $344.95 Benefit: 75% = $258.75
41737	Frontal sinus, unilateral, intranasal operation on, including complete dissection of frontal recess and exposure of frontal sinus ostium (excludes simple probing, dilatation or irrigation of frontal sinus), other than a service associated with a service to which item 41698, 41703, 41705 or 41764 applies on the same side.	Fee: $563.75 Benefit: 75% = $422.85
41702	Functional sinus surgery of the ostiomeatal unit, including ethmoid, unilateral, other than a service associated with a service to which item 41662, 41698, 41703, 41705, 41710 or 41764 applies on the same side.	Fee: $796.05 Benefit: 75% = $597.05
41703	Functional sinus surgery, complete dissection of all 5 sinuses and creation of single sinus cavity, unilateral, other than a service associated with a service to which item 41662, 41698, 41702, 41705, 41710, 41734, 41737, 41752 or 41764 applies on the same side.	Fee: $1,176.85 Benefit: 75% = $882.65
41705	Functional sinus surgery, complete dissection of all 5 sinuses to create a single sinus cavity, with extended drilling of frontal sinuses, unilateral, other than a service associated with a service to which item 41662, 41698, 41702, 41703, 41710, 41734, 41737, 41752 or 41764 applies on the same side.	Fee: $1,914.90 Benefit: 75% = $1,436.20

Restriction

The PBS treatment criteria for initial treatment with mepolizumab states that the patient must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

There are seven clinical criteria for the initial treatment of mepolizumab, including that the patient must have undergone surgery for the removal of nasal polyps; or the patient must have the written advice from at least two physicians of the above-mentioned prescriber types demonstrating inappropriateness for surgery.

The PBS population criteria states that the patient must be at least 18 years of age.

For details of the current PBS listing refer to the PBS website.

Date of listing on PBS

Mepolizumab was PBS listed for CRSwNP on 1 April 2023.

Changes to listing

Mepolizumab was first listed on the PBS for severe eosinophilic asthma on 1 January 2017. The PBS listing for severe eosinophilic asthma was altered to refer to the condition as uncontrolled severe asthma on 1 July 2021. Mepolizumab was PBS listed for CRSwNP on 1 April 2023.

Current PBS listing details are available from the PBS website.

Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

November 2021

The PBAC did not recommend mepolizumab for treatment of CRSwNP for patients who have received at least one previous surgery for the removal of nasal polyps (NP). Overall, the PBAC considered the clinical claim of superior effectiveness compared SoC was reasonable in patients with CRSwNP. The PBAC considered the revised base case proposed by ESC was appropriate and that the resulting revised ICER high and uncertain at the proposed price. The PBAC considered the financial estimates were highly uncertain and advised that a risk sharing arrangement (RSA) would be required if patients unsuitable for surgery were to be included.

The PBAC agreed with DUSC that overall, the estimates presented in the submission were likely overestimated primarily due to the prevalence rates of chronic rhinosinusitis and CRSwNP used in the submission along with the inclusion of a proportion of CRSwNP patients already prescribed a PBS-listed biologic for severe asthma. The PBAC considered the initial and continuing uptake rates were underestimated and agreed with DUSC that that this was particularly evident for patients unsuitable for surgery.

For further details refer to the Public Summary Document from the November 2021 PBAC meeting.

November 2022

The PBAC recommended the Authority Required listing of mepolizumab for the treatment of CRSwNP, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program).

The resubmission used an epidemiological approach to estimate the utilisation and financial impact of listing mepolizumab on the PBS for CRSwNP. A summary of the key assumptions used to calculate the financial estimates is presented in Table 3.

The PBAC considered the resubmission financial estimates addressed November 2021 PBAC meeting concerns raised by DUSC regarding prevalence rates of chronic rhinosinusitis and CRSwNP used in the submission along with the inclusion of a proportion of CRSwNP patients already prescribed a PBS-listed biologic for severe asthma (paragraph 7.8, mepolizumab PSD, November 2021 PBAC meeting). The PBAC considered the approach taken by the resubmission to estimate the total number of eligible patients was appropriate. However, the PBAC expressed concern regarding the approach taken to determining the total number of patients electing treatment and subsequent estimates. Noting the estimated total eligible patients to be appropriate, the PBAC advised that the financial estimates be revised to include a 48% uptake rate applied across Year 1 to Year 6 with an average of 9.6 prescriptions per patient treated. The PBAC noted that grandfathered patients were accounted for in the prevalence based approach used to determine the financial estimates.

For further details refer to the Public Summary Document from the November 2022 PBAC meeting.

Approach taken to estimate utilisation

The November 2022 submission used an epidemiological model to estimate the use of mepolizumab for CRSwNP.

Table 3: Key inputs for financial estimates

Assumption	November 2021	November 2022
Prevalence of CRSwNP	3%	0.51%
Proportion with baseline blood eosinophil count (BEC)	91% (baseline BEC ≥150 cells/µL)	68.3% (baseline BEC ≥300 cells/µL)
Proportion who see a specialist	35%	
Proportion requiring (first) NP surgery	61%	47%
Proportion suitable for surgery	93%	93%
Proportion who experiences NP regrowth post-surgical removal	61%	21%
Proportion with prior surgery who have a high level of symptoms	45%	-

Assumption	November 2021	November 2022
Proportion of CRSwNP patients who are already prescribed another PBS-listed biologic for severe asthma		10.78%
Grandfathered patients	90 additional patients per year	Included in the calculation of the prevalent population
Uptake rate for initial patients	Year 1: 5% to Year 6: 3.5%	Year 1: 48% to Year 6: 68%[a]
Uptake rate for continuing patients	Year 1: 3.5% to Year 6: 2.45%	Year 1: 34.85% to Year 6: 49.37%

Source: Table 16, mepolizumab PSD, November 2021 PBAC meeting; Table 17, mepolizumab PSD, November 2022 PBAC meeting

a: The PBAC advised that the financial estimates be revised to include a 48% uptake rate applied across Year 1 to Year 6

Methods

Data extracted from the PBS claims database maintained by the Department of Health, Disability and Ageing and processed by Services Australia were used for the analyses. Prescription data were extracted from 1 April 2023 up to and including 30 September 2025. Authority approvals data were extracted from 1 April 2021 up to and including 30 September 2025. Data were extracted on 2 December 2025.

As this analysis uses date of supply prescription data, there may be small differences compared with publicly available Services Australia Medicare date of processing data.[5]

Data of the number of services for the item numbers 41662, 41668, 41702, 41703, 41705, 41710, 41734, 41752 and 41737 (surgeries related to nasal polyps) was downloaded from Services Australia[6] from January 2016 to October 2025 on 15 December 2025. Where statistics are requested for an old item number, services for the old number are mapped to the current item number and presented as this in the report.

Patient level analysis

The number of incident patients, prevalent patients, and prescriptions supplied was determined by counting the number of people supplied at least one PBS prescription using person specific numbers (non-identifying) in the data for the specified time periods. Patient initiation was defined as the date of supply of the first PBS or RPBS prescription. PBS prescription data also contains age and gender information. Patient age was derived as the age at first supply. This information was used to perform a breakdown of incident patients by age and gender.

[5] PBS statistics. Australian Government Services Australia. Canberra. Available from http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp.

[6] MBS statistics. Australian Government Services Australia. Canberra. Available from https://medicarestatistics.humanservices.gov.au/statistics/mbs_item.html.

The State or Territory of the patient was determined from the patient's residential postcode, and these data were standardised using the estimated Australian population on 31 March 2025.[7]

Treatment duration analysis

Kaplan-Meier analysis was undertaken to analyse the time on treatment of mepolizumab, however the data were too immature to fully analyse the length of treatment, with the median time on therapy not being reached at analysis end date.

Predicted versus actual analysis

Predicted versus actual analysis of the number of patients treated, and prescriptions dispensed. The differences in actual compared to predicted utilisation was determined using the following calculation: Difference (%) = ((Actual – Predicted)/Predicted) × 100.

Results

Data Quality

Table 4: Comparison of PBS item and Authority codes

PBS item restriction	Authority code restriction	Count	Percent
Asthma	CRSwNP	3,352	3%
Asthma	Uncontrolled severe asthma	78,662	69%
Asthma	Not available	359	0.3%
CRSwNP	CRSwNP	28,275	25%
CRSwNP	Uncontrolled severe asthma	3,820	3%
CRSwNP	Not available	318	0.3%

Table 5: Indication sequence using Authority codes

Indication sequence using Authority code	Patient count	Percentage
NA	60	1%
Asthma	4,581	64%
Asthma>CRSwNP	<5	0%
CRSwNP	2,470	35%
CRSwNP>Asthma	6	0%
CRSwNP>Asthma>CRSwNP	<5	0%
Total number of patients	7,122	

[7] Australian Bureau of Statistics. National, state and territory population [Internet]. Canberra: ABS; 2025 June [cited 2025 December 18]. Available from: https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/latest-release.

Table 6: Indication sequence using PBS item codes

Indication sequence using PBS item code	Patient counts	Percentage
Asthma	3,958	56%
Asthma>CRSwNP	245	3%
Asthma>CRSwNP>Asthma	384	5%
Asthma>CRSwNP>Asthma>CRSwNP	60	1%
Asthma with four or more changes	107	2%
CRSwNP	1,929	27%
CRSwNP>Asthma	211	3%
CRSwNP>Asthma>CRSwNP	164	2%
CRSwNP>Asthma>CRSwNP>Asthma	34	0%
CRSwNP with four or more changes	30	0%
Total number of patients	7,122	

Table 4 shows that 93% of prescriptions had matching PBS item codes and Authority codes. Tables 5 and 6 show that using Authority codes 99% of patients were only supplied under one restriction, and using PBS item codes 83% of patients were only supplied under one restriction. In 2024 there were 354 more prescriptions supplied for CRSwNP under PBS item codes than Authority codes, however in 2025 (January to September) there were 310 fewer prescriptions supplied for CRSwNP under PBS item codes than Authority codes. For the analyses presented in this report, prescriptions with an Authority code for CRSwNP, or where a prescription was supplied using a PBS item code for CRSwNP without a matching Authority code, were used.

Analysis of drug utilisation

Overall utilisation

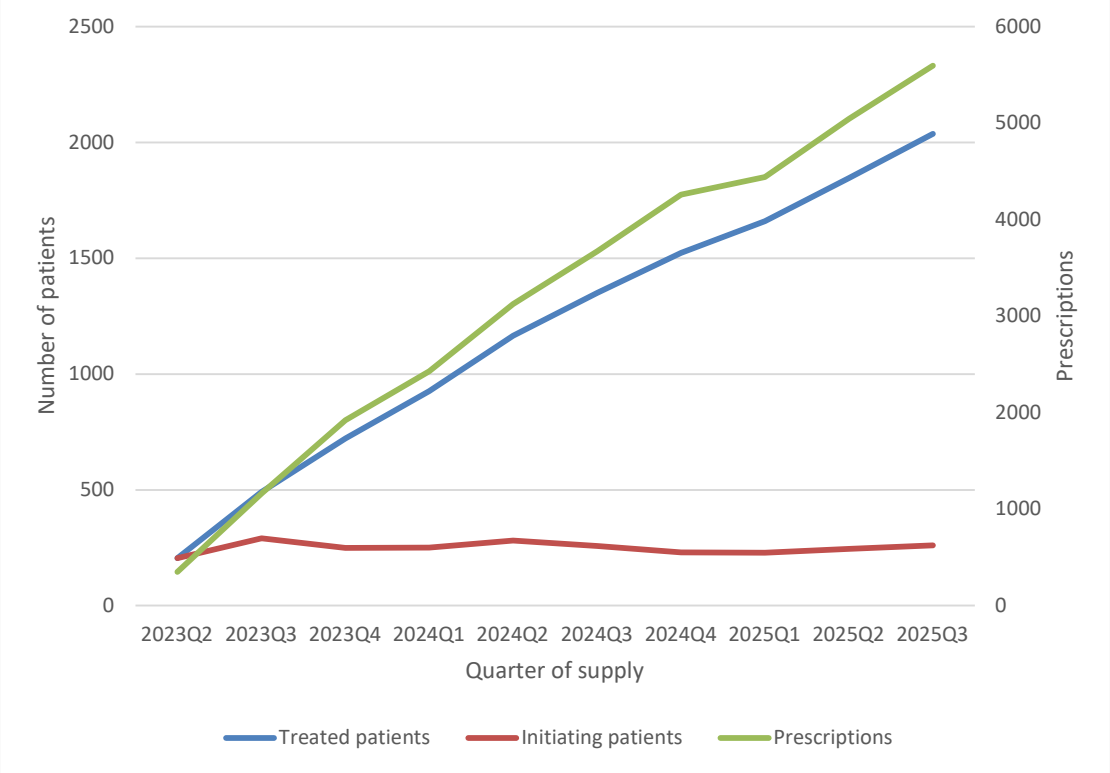

Figure 1: Patients and prescriptions for mepolizumab for CRSwNP

The number of initiating patients has been fairly stable, between 200 to 300 each quarter, since listing. It does not appear that there was a large group of patients waiting for the PBS listing of mepolizumab for CRSwNP. The number of treated patients and supplied prescriptions have not stabilised. This suggests patients are remaining on treatment after initiation.

An analysis of the length of treatment was attempted, however the data were too immature to fully analyse the length of treatment of mepolizumab, with the median time on therapy not being reached at analysis end date. Of the 2,509 patients who have initiated treatment with mepolizumab, 2,025 (80.71%) were identified as continuing treatment at the end of the data collection.

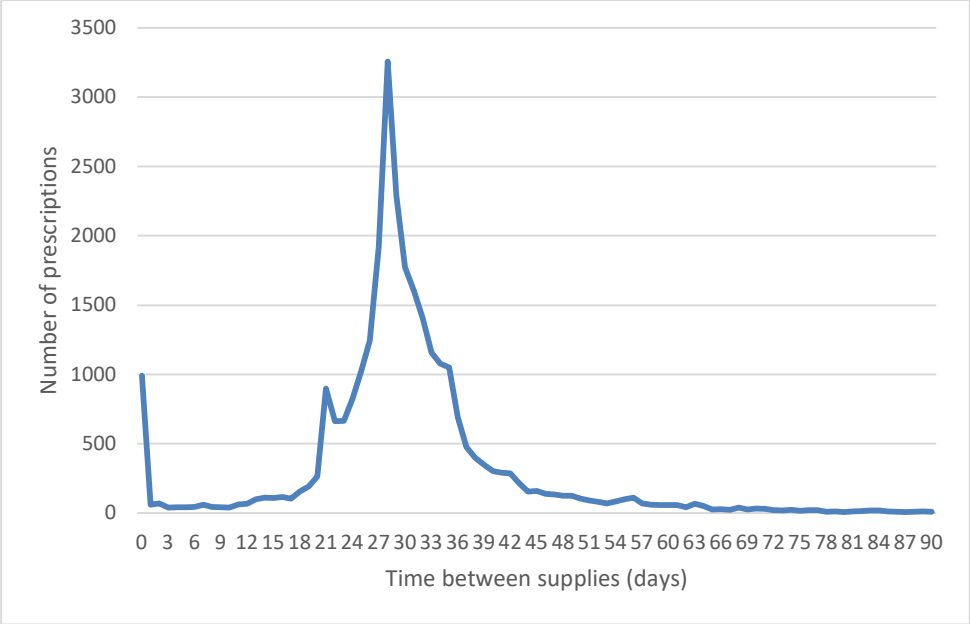

Figure 2: Time between supplies of mepolizumab for CRSwNP

The recommended dosage of mepolizumab is one 100 mg subcutaneous injection once every 28 days. An analysis of the time between supplies of mepolizumab (Figure 2) shows that the majority of prescriptions were supplied at approximately 28 days, although there was a slight increment at 21 days. The mean and median time between supplies of mepolizumab for CRSwNP were 31.7 and 29.0 days respectively. Additionally, all prescriptions were supplied with a quantity of one. This suggests the supply of mepolizumab appears to be in accordance with the recommended dosage of mepolizumab for CRSwNP.

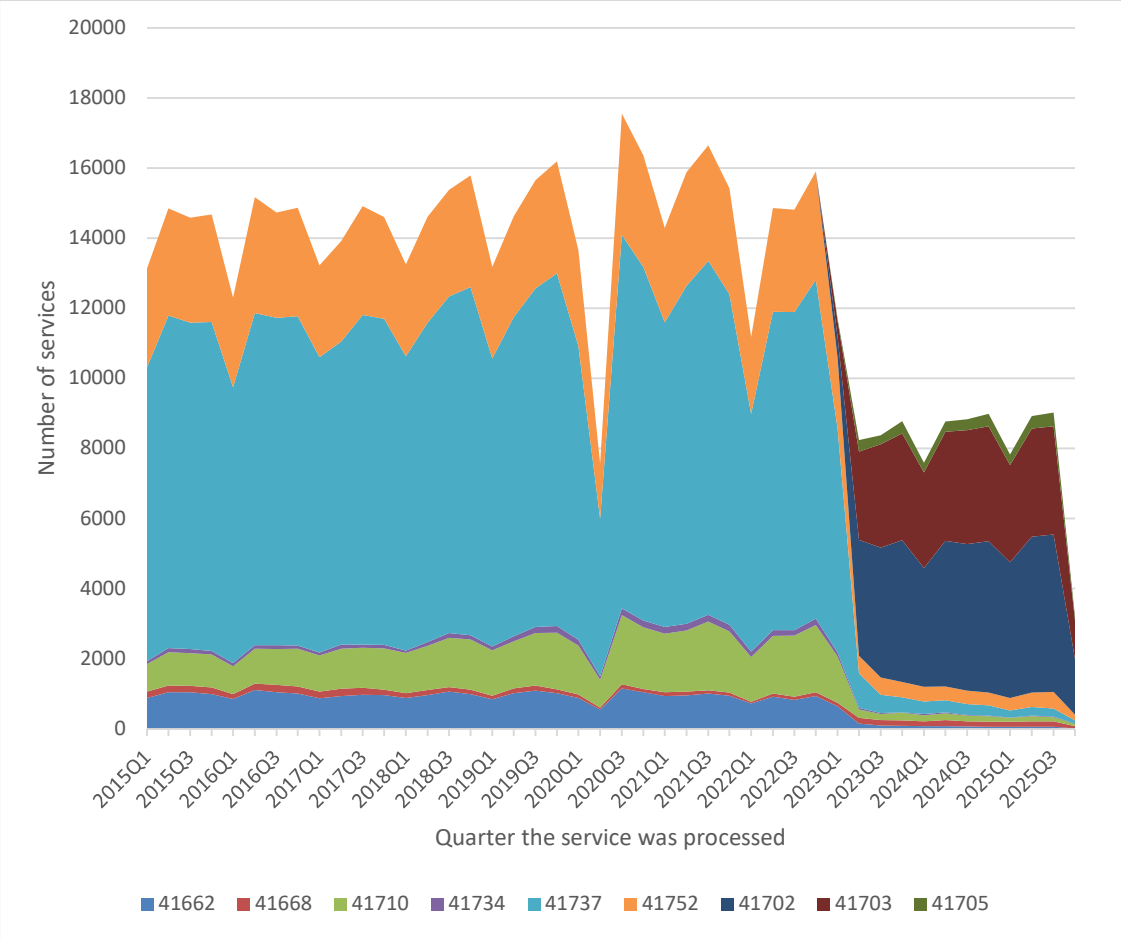

Figure 3: Number of services related to surgeries for nasal polyps

The MBS data of the number of services related to surgeries for nasal polyps (Figure 3) shows a decrease in the number of services processed in the second quarter of 2020, there were 7,559 services processed in the second quarter of 2020 compared to 13,665 in the first quarter. This was likely due to a temporary reduction in the number of surgeries due to the COVID-19 pandemic.

The reduction in the number of services related to surgeries for nasal polyps from 2023 was likely due to administrative changes related to new item codes (41702, 71703 and 41705) being listed on the MBS in the first quarter of 2023. The administrative changes were made to address several issues, including inappropriate claiming of multiple similar or identical items.

Utilisation by relevant sub-populations/regions or patient level analysis

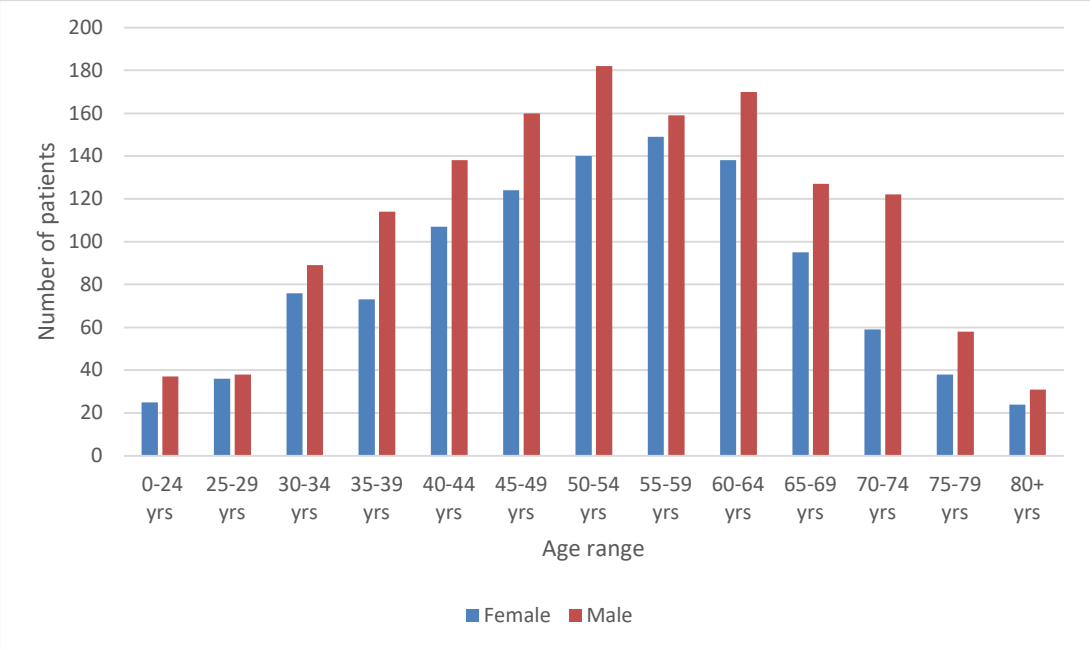

Figure 4: Age and gender of initiating patients for mepolizumab for CRSwNP

Of the patients who initiated mepolizumab for CRSwNP (Figure 4), 57% were male and 43% were female. The mean and median age of initiating patients were 52.8 and 53.0 respectively. The mean age of female initiating patients was 52.4, and the mean age of male initiating patients was 53.1. There was a small number of patients (<5) who were under the age of 18 at initiation.

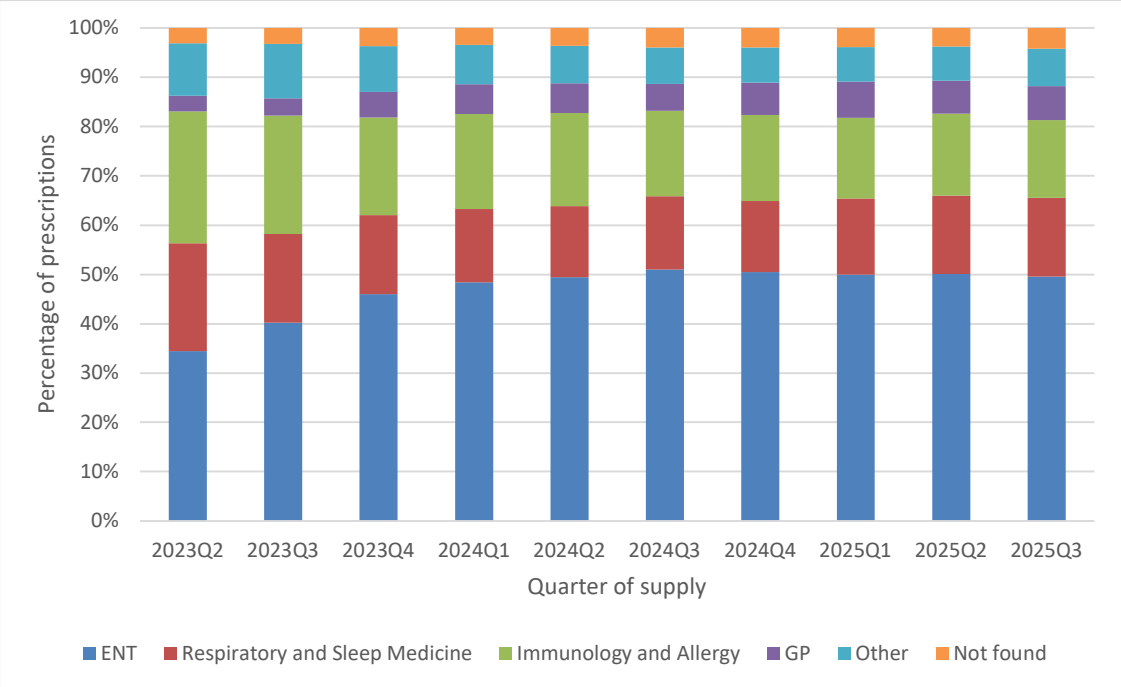

Figure 5: Prescriptions over time by prescriber type

Specialties of prescribers included in the 'Other' category included Internal Medicine, Paediatric Medicine, Pathology and Intensive Care. It appears that over time the number of supplied prescriptions which were prescribed by 'Other' or 'Not found' prescribers has remained fairly low at approximately 10-15%. The amount of GP prescribing appears to have slightly increased over time, which was reasonable as the list of medical practitioners allowed to prescribe mepolizumab for CRSwNP under the PBS restriction includes 'general physician experienced in the management of patients with CRSwNP'.

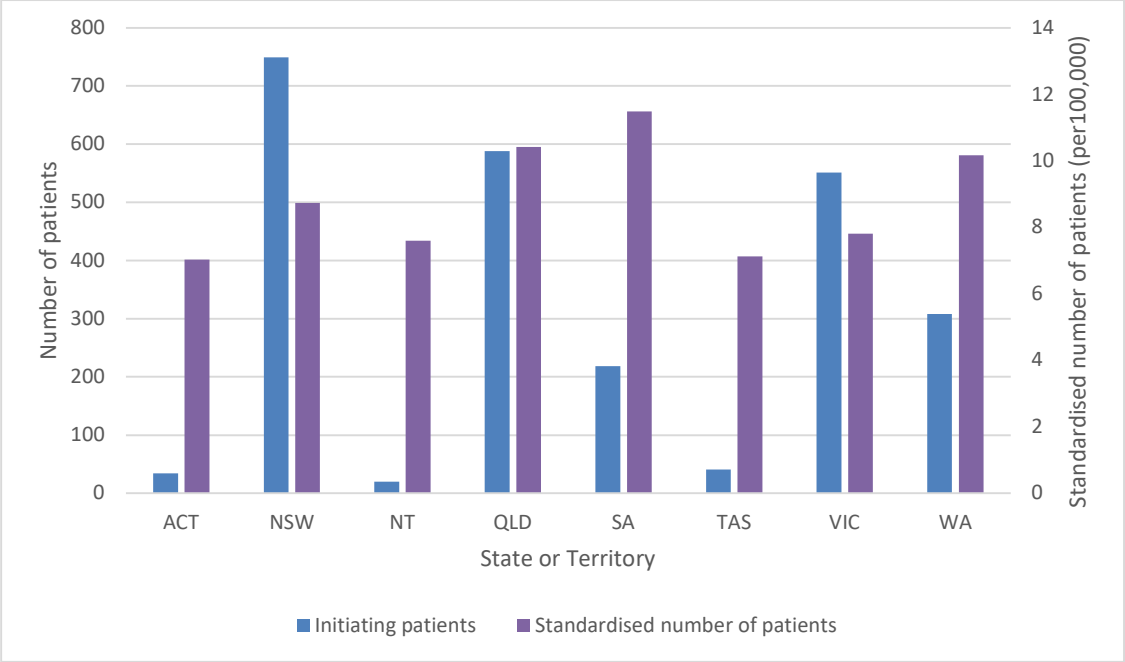

Figure 6: Number of initiating patients by State or Territory of residence

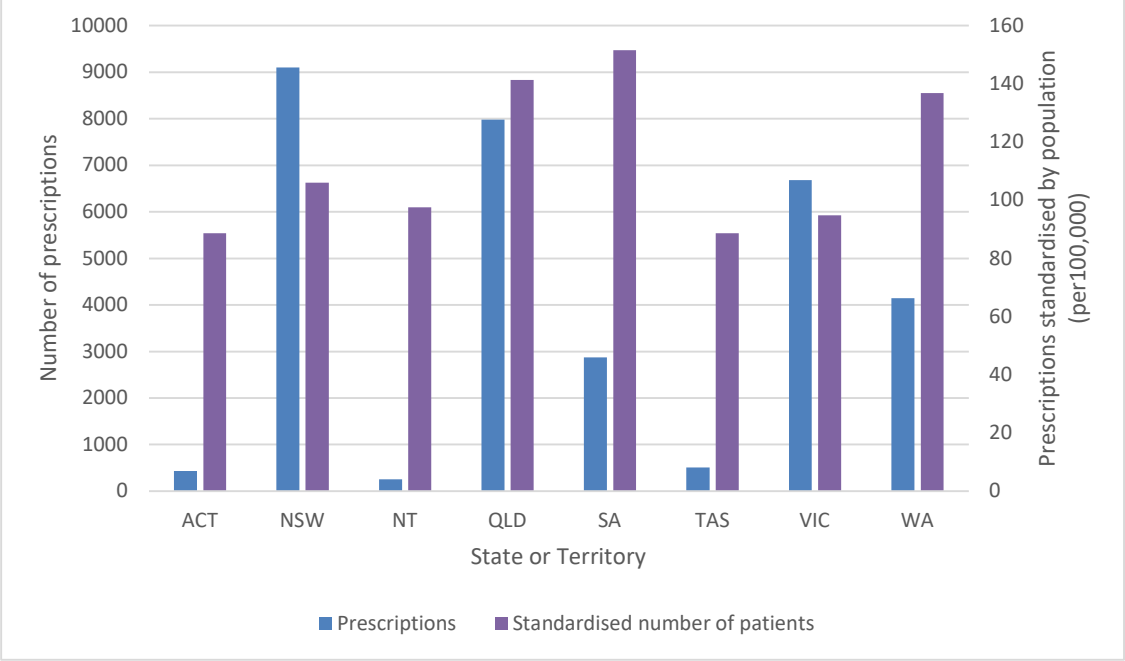

Figure 7: Prescriptions by State or Territory of residence

The number of initiating patients and the number of supplied prescriptions were both highest in NSW, however the State with the highest use per population was SA, followed by QLD and WA.

Analysis of actual versus predicted utilisation

Table 7: Analysis of actual versus predicted utilisation of mepolizumab for CRSwNP

		Year 1 (Apr 2023-Mar 2024)	Year 2 (Apr 2024-Mar 2025)	Year 3* (Apr 2025 -Mar 2026)
Patients	Predicted	[redacted][1]	[redacted][1]	[redacted][1]
	Actual	997	1,906	2,149
	Difference	[redacted]	[redacted]	[redacted]
Prescriptions	Predicted	[redacted][2]	[redacted][2]	[redacted][2]
	Actual	5,858	15,496	10,638
	Difference	[redacted]	[redacted]	[redacted]
Prescriptions per patient[a]	Predicted	9.6	9.6	9.6
	Actual	5.9	8.1	5
	Difference	-39%	-16%	-48%

Note: Year 3 actual figures include seven months of data, from April 2025 to September 2025 inclusive.
a: The PBAC (Nov 2022) advised an average of 9.6 prescriptions per patient treated should be applied in the estimates.
1: 500 to <5,000
2: 30,000 to < 40,000

The number of treated patients and supplied prescriptions were both overestimated in each year of listing, which may be due to an overestimate of the number of eligible patients, the uptake rates, or a combination of both.

DUSC considered that overall, the estimates presented in the first submission were overestimated (paragraph 6.2, mepolizumab PSD, November 2021 PBAC meeting). The use of mepolizumab for CRSwNP in the second submission was estimated to be higher than the first submission. The main changes between the first and second submission were that the prevalence in the second submission was changed to 0.51% (from 3% in the first submission) and the uptake rates were increased in the second submission. For initiators they were increased from between 3.5% to 5% in the first submission to 48% to 68% in the second submission. However, the PBAC advised that the financial estimates should include a 48% uptake rate applied across Year 1 to Year 6 with an average of 9.6 prescriptions per patient treated (paragraph 7.9, mepolizumab PSD, November 2022 PBAC meeting).

The average of 9.6 prescriptions per patient treated was slightly overestimated, as the average number of prescriptions per patient was 8.1 in year 2 of listing. It is understandable that the average number of prescriptions per patient was lower in year 1 of listing, and year 3 only includes seven months of data.

Discussion

The use of mepolizumab for CRSwNP has increased steadily since it was PBS listed on 1 April 2023. Between 200 and 300 patients have initiated each quarter, and approximately 80% of patients who initiated were identified as continuing treatment at the end of the data collection (30 September 2025). It is likely that use will continue to increase in the future.

At its September 2025 meeting, DUSC requested linkage between PBS and MBS data to determine whether the PBS listing of mepolizumab had reduced the number of surgeries for nasal polyps. However, the patient level data could not be obtained in time for analysis. From the publicly available MBS data, it appears that the number of surgeries for nasal polyps has substantially decreased since 2023, due to administrative changes.

It appears that mepolizumab has been supplied in accordance with recommended dosing of one 100 mg subcutaneous injection once every 28 days, as quantities higher than one were not supplied and the time between supplies of mepolizumab peaked around 28 days.

Under the PBS restriction, the medical practitioners allowed to prescribe mepolizumab for initiating or continuing treatment of CRSwNP are (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP. Some prescribing by 'Other' prescribers may be clinicians with multiple specialties. It appears prescribers are adhering to the list of medical practitioners in the PBS restriction.

The PBS restriction states patients must be at least 18 years of age, and this has also been adhered to by prescribers, with less than five initiating patients (less than 2% of 2,509 patients total) aged under the age of 18.

DUSC Consideration

DUSC noted that the number of initiating patients was fairly stable, at approximately 200 to 300 patients per quarter, and the number of treated patients and supplied prescriptions have increased steadily each quarter. DUSC noted that approximately 80% of patients who initiated treatment were identified as continuing at the end of the data collection period and commented that many patients are remaining on treatment. DUSC noted that CRSwNP is a chronic disease and prevalence estimates for CRSwNP vary across the literature, and that definitions of remission, treatment duration, and stopping criteria remain unclear. DUSC considered that the continuation rate was aligned with the chronic nature of CRSwNP.

DUSC noted that mepolizumab is administered as a 100 mg subcutaneous injection, once every four weeks. DUSC commented that the time between supplies shows that most patients were supplied mepolizumab every 28 days, which was consistent with the recommended dosing. DUSC considered the slight increase of supply at 21 days was likely due to the early supply rule.

DUSC noted that the PBS restriction for initiating and continuing treatment states that the patient must be treated by a medical practitioner who is a respiratory physician, clinical immunologist, allergist, ear nose and throat specialist or a general physician experienced in the management of patients with CRSwNP. DUSC noted that the prescribing for mepolizumab for CSRwNP was concentrated among allergists and respiratory physicians when it was first PBS listed. DUSC commented that prescribing by general practitioners has increased over time but considered that prescribing by general practitioners now appears to have stabilised.

DUSC noted that the report found that 57% of patients who initiated mepolizumab for CRSwNP were male. DUSC commented that this was consistent with the epidemiology of the disease[8], and commented that while chronic rhinosinusitis is more common in women, polyps are more common in men. DUSC considered that the median age of initiating patients, of approximately 50 years old, was also consistent with the epidemiology of the disease.[8]

DUSC noted that the Pre-Sub-Committee Response (PSCR, p1) stated that the initiation and continuation rates are consistent with ongoing clinical benefit and appropriate clinical decision-making. The PSCR (p2) stated that long term adherence is consistent with ongoing clinical benefit, implying effective disease control and improvements in patients' health-related quality of life. DUSC commented that benefits cannot be implied from the PBS supply data and considered that the data do not specifically demonstrate these claims.

The PSCR (p3) noted that in recommending mepolizumab for CRSwNP in November 2022, the PBAC requested an RSA to address the uncertainty associated with including patients unsuitable for surgery in the proposed PBS population (paragraph 7.10, mepolizumab, PSD, November 2022, paragraph 7.10). The PSCR (p3) stated that the Australian Mepolizumab Registry for CRSwNP (AMR) captured data [redacted] there was limited published information from the AMR. Consequently, DUSC considered that the results were unverifiable.

The PSCR (p1) noted that use of mepolizumab was lower than predicted, [redacted] The PSCR (pp1, 3) requested removal of the RSA for mepolizumab in CRSwNP. DUSC commented that although use has been below the

[8] Silver, J., Packnett, E., Park, J. *et al.* Biologic use and treatment patterns in patients with chronic rhinosinusitis with nasal polyps: a US real-world study. *Allergy Asthma Clin Immunol* **19**, 104 (2023). https://doi.org/10.1186/s13223-023-00855-7

estimated use, the number of patients and supplied prescriptions are growing, and persistence is likely to be long. DUSC considered that the RSA should not be removed.

DUSC noted the graph of MBS services related to nasal polyp surgery, and that the report had suggested the number of surgeries may have decreased. DUSC noted that the listing of mepolizumab occurred at the same time as administrative changes to the MBS item codes, which were made to address several issues, including inappropriate use of multiple similar or identical items. DUSC commented that if the listing of mepolizumab had resulted in a decrease of the number of surgeries, the number of MBS services should be decreasing over time. However, the graph included in the report showed a sharp decrease in services, followed by a stabilisation. DUSC considered that there was no evidence to suggest the decrease in MBS services related to nasal polyps could be attributed to mepolizumab being PBS listed.

DUSC Actions

DUSC requested that the report be provided to the PBAC for consideration.

Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

Sponsors' comments

GlaxoSmithKline Australia Pty Ltd: The sponsor has no comment.

Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health, Disability and Ageing has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

To the extent provided by law, the Department of Health, Disability and Ageing makes no warranties or representations as to accuracy or completeness of information contained in this report.

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