Fluticasone furoate with umeclidinium and vilanterol for severe asthma: 24 month predicted versus actual analysis

Drug utilisation sub-committee (DUSC)

April 2025

Abstract

Purpose

To review the utilisation of single inhaler triple therapies for severe asthma to consider if reversion to Authority Required (telephone /online) may be required if use beyond the intent of the restriction is evident.

The single inhaler therapies of interest are:

- Trelegy Ellipta - Fluticasone furoate + umeclidinium + vilanterol henceforth referred to as FF/VI/UMEC.
- Trimbow – beclomethasone + formoterol + glycopyrronium henceforth referred to as BEC/FOR/GLY.
- Enerzair Breezhaler – mometasone + indacaterol + glycopyrronium henceforth referred to as MF/IND/GLY.

Other inhaler therapies referred to in the report are as follows:

- Inhaled corticosteroids (ICS)
- Short/long-acting muscarinic antagonists (SAMA/LAMA)
- Short/long-acting beta agonists (SABA/LABA)

Date of listing on the Pharmaceutical Benefits Scheme (PBS)

MF/IND/GLY was first listed on the PBS for severe asthma on 1st April 2021.

FF/VI/UMEC was first listed on the PBS for severe asthma on 1st April 2022.

BEC/FOR/GLY was first listed on the PBS for severe asthma on 1st January 2023.

Data Source / methodology

PBS dispensing data was extracted from the PBS data maintained by the Department of Health and Aged Care, processed by Services Australia.

Key Findings

- In year 1 of listing there were 24,910 prevalent patients utilising FF/VI/UMEC for severe asthma followed by 45,108 and 53,224 in subsequent listing years noting that the third listing year is incomplete.
- In year 1 of listing there were 97,287 prescriptions dispensed for FF/VI/UMEC at a cost to government of $7.7 million increasing to $19.6 million and $21.6 in subsequent listing years noting that the third listing year is incomplete.
- The number of prescriptions and cost to government for FF/VI/UMEC was [redacted] than predicted in the first year of listing and [redacted] in the second year. Current utilisation in the third year of listing suggests a similar percentage change to the second year.
- The number of new patients initiating single inhaler triple therapies for severe asthma is greater than the number of patients who initiated treatment with tiotropium (item code 11043F) which was used as the basis for a market share approach in each of the PBAC submissions.
- The number of patients initiating on to a single inhaler triple therapy that had a PBS treatment history that was identified as potentially outside of the restriction for severe asthma was 14,625 or 14% of the initial patient numbers up to 30th November 2024.
- 29,090 patients or 28% of patients initiating a single inhaler triple therapy for severe asthma had evidence of more than six COPD restricted prescriptions in their PBS history.
- The total cost to government of inhaler therapies (excluding nebulised products) has remained steady at approximately $600 million per year since 2018. ICS/LABA preparations reduced by $6.5 million dollars per year to $168 million in 2024 from $207 million in 2018. LAMA products reduced by $22.5 million dollars per year from $250 million to $115 million in 2024. SABA products increased by $5.5 million per year up to $110 million in 2024. ICS/LABA/LAMA products had grown by $18.1 million growth rate per year up to $116 million in 2024.
- The proportion of the ICS/LABA market attributable to COPD prescriptions has remained steady at approximately 15% per year with $25 million in 2024 while the remaining 85% was from asthma prescriptions at $143 million in 2024. With the listing of ICS/LABA/LAMA for severe asthma, the proportion of cost attributable to COPD has been reducing. In 2024 the cost attributable to COPD prescriptions was 65% of the total $116 million at $75.4 million and for asthma this was 35% of the total at $40.6 million.

Purpose of analysis

To review the utilisation of single inhaler triple therapies for severe asthma to consider if reversion to Authority Required (telephone /online) may be required if use beyond the intent of the restriction is evident.

Background

Clinical situation

Asthma is a long term condition that affects 1 in 9 Australians with over 400 deaths due to asthma each year.[1] Asthma is the inflammation and airway muscle tightening in response to a trigger which can vary between people. Asthma cannot be cured but symptoms may be controlled through the use of medications.

Severe asthma represents a sub-type of asthma that is difficult to control and typically requires multiple medications administered at higher doses. Fixed-dose combination inhalers which include an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and a long-acting muscarinic antagonist (LAMA) are frequently used for the management of severe asthma to reduce the burden of needing to use multiple inhalers.

Pharmacology

Corticosteroid component:
Binds to glucocorticoid receptors resulting in the increased transcription of genes related to anti-inflammatory proteins.

Beta agonist component:
Binds to and activates beta receptors of the bronchial smooth muscle promoting relaxation and dilation.

Muscarinic antagonist component:
Binds to and deactivates muscarinic receptors on bronchial smooth muscle promoting dilation of the airways.

Therapeutic Goods Administration (TGA) approved indications

FF/VI/UMEC is indicated for the maintenance treatment of asthma in adult patients who are not adequately controlled with a combination of ICS and LABA.

FF/VI/UMEC is also indicated for the maintenance treatment of adults with moderate to severe COPD who require treatment with a LAMA+LABA+ICS. It is not indicated for initiation of therapy in COPD.

[1] *What is asthma?* (2024, March 10). Asthma Australia. https://asthma.org.au/what-is-asthma/

BEC/FOR/GLY is indicated for the maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a LABA and medium dose ICS, and who experienced one or more asthma exacerbations in the previous year.

BEC/FOR/GLY in the lower dosage form (100/6/10) is indicated for maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an ICS and a LABA or a combination of a LABA and a LAMA.

MF/IND/GLY is indicated for the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a LABA and an ICS who experienced one or more asthma exacerbations in the previous year.

Dosage and administration

Table 1: Dosage and administration of single inhaler triple therapy products for severe asthma

Brand name and sponsor	Dose	Frequency of administration
Trelegy Ellipta GlaxoSmithKline Australia Pty Ltd	fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, vilanterol 25 mcg/dose fluticasone furoate 200 mcg, umeclidinium 62.5 mcg, vilanterol 25 mcg/dose	Once daily
Trimbow Chiesi Australia Pty Ltd	beclometasone 100 mcg, formoterol 6 mcg, glycopyrronium 10 mcg/dose beclometasone 200 mcg, formoterol 6 mcg, glycopyrronium 10 mcg/dose	Two inhalations of either strength twice daily
Enerzair Novartis Pharmaceuticals Australia Pty Limited	indacaterol 114 mcg, glycopyrronium 46 mcg, mometasone furoate 68 mcg (cap) indacaterol 114 mcg, glycopyrronium 46 mcg, mometasone furoate 136 mcg (cap)	One capsule of either strength inhaled once daily

Source: Australian Medicines Handbook[2]

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

[2] *Drugs for asthma and chronic obstructive pulmonary disease*. (n.d.). Australian Medicines Handbook. https://amhonline.amh.net.au/chapters/respiratory-drugs/drugs-asthma-chronic-obstructive-pulmonary-disease

PBS listing details (as at 30 November 2024)

Table 2: PBS listing of single inhaler triple therapies for severe asthma.

Item	Name, form & strength, pack size	Max. quant.	Rpts	DPMQ	Brand name and manufacturer
12917W	fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations	1	5	$93.04	Trelegy Ellipta GlaxoSmithKline Australia Pty Ltd
14382Y		2		$175.57	
13200R	beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations	1	5	$79.93	Trimbow Chiesi Australia Pty Ltd
14606R	beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations			$74.80	
12295D	indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules	1	5	$89.05	Enerzair Novartis Pharmaceuticals Australia Pty Limited
14399W		2		$167.19	
12298G	indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules	1		$73.22	
14471P		2		$133.95	

Source: the PBS website.

Restriction

The restriction for FF/VI/UMEC, BEC/FOR/GLY, and MF/IND/GLY for severe asthma are similar:

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

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

Date of listing on PBS

MF/IND/GLY was first listed on the PBS for severe asthma on 1st April 2021.

FF/VI/UMEC was first listed on the PBS for severe asthma on 1st April 2022.

BEC/FOR/GLY was first listed on the PBS for severe asthma on 1st January 2023.

Changes to listing

Each listing was aligned by clinical criteria and 60 day dispensing was introduced for FF/VI/UMEC and MF/IND/GLY on 1st September 2024.

With the listing of FF/VI/UMEC on 1st April 2022 the restriction authority level for all severe asthma triple therapies were reduced from Authority Required (telephone/online) to Authority Required (STREAMLINED).

Current PBS listing details are available from the PBS website.

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

The PBAC considered MF/IND/GLY in the July 2020 PBAC meeting. The PBAC noted the financial estimates were sensitive to substitution rates and the assumption that medium and high dose MF/IND/GLY will only substitute for high dose ICS/LABA plus LAMA. The PBAC considered that these concerns would be addressed by listing on a cost-minimisation basis against the least costly combination of ICS/LABA plus LAMA. The PBAC remained

concerned about the risk of inappropriate use in patients with less severe asthma otherwise managed on ICS or ICS/LABA and patients aged under 18 years of age who would be outside of the trial population. The PBAC considered a higher restriction level (Authority Required – Telephone/Electronic /Emergency) would be appropriate to minimise this risk.

For further details refer to the Public Summary Document from the July 2020 PBAC meeting.

The PBAC considered FF/VI/UMEC for severe asthma at the November 2021 meeting. The PBAC noted the same concerns related to the inappropriate use of FF/VI/UMEC in children and adolescents. The PBAC considered that the listing of FF/VI/UMEC should be at the Authority Required (STREAMLINED) level to maintain consistencies between single inhaler triple therapies across COPD and asthma indications. The PBAC noted that this recommendation should then flow on to the MF/IND/GLY listing. The PBAC noted that a DUSC review should be undertaken after sufficient time has elapsed with a view to reverting the restriction levels to Authority Required (telephone/online) if use is beyond the intent of the restriction.

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

The PBAC considered BEC/FOR/GLY at the March 2022 meeting. The PBAC noted the estimated use and financial implications of BEC/FOR/GLY on a cost-minimised basis and considered it appropriate.

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

Approach taken to estimate utilisation

The MF/IND/GLY submission considered by PBAC in July 2020 used a market share approach based on the yearly prescriptions of tiotropium (item code 11043F) which is restricted to severe asthma in adults in combination with an ICS and LABA unless contraindicated. Growth, substitution and uptake rates were then applied to estimate utilisation.

The FF/VI/UMEC submission considered by PBAC in November 2021 utilised a similar market share approach given the limited data available for MF/IND/GLY having only been listed for seven months at the time of the committee meeting.

The BEC/FOR/GLY submission considered by the PBAC in March 2022 was able to use a market share approach using MF/IND/GLY prescription numbers to estimate utilisation.

Methods

Data from 1 Jan 2014 to 31 December 2024 were extracted from the PBS data maintained by Department of Health and Aged Care, processed by Services Australia on or before 6th December 2024 for the PBS item codes corresponding to Anatomical Therapeutic

Chemical (ATC) classification codes R03A and R03B. PBS prescription data were used to determine the number of prescriptions supplied and the PBS expenditure based on the published list prices. These data were also used to count the number of patients, both incident (new to treatment) and prevalent (number treated in each time period, i.e. year). PBS prescription data also contains age and gender information. This information was used to perform a breakdown of patients by age and gender at initiation of single inhaler triple therapy.

The Sankey diagrams have been noted to contain data up to 30th November 2024. These diagrams were produced by first establishing an initiator pool of patients who started single inhaler triple therapy and extracting the previous PBS history of inhaler use for these patients. Item codes from this history were matched to inhaler type, i.e. fluticasone with salmeterol was matched to 'ICS/LABA'. Stepwise analysis of a patient's history as they moved through their asthma treatment journey became cumbersome with increasingly fragmented and individualised possibilities. It was decided to instead note the presence of each class of medicine in a patient's journey and therefore one prescription of a SABA and one prescription of an ICS would mark that patient as having had a SABA + ICS in their treatment history. Prescriptions utilising item codes with a streamlined authority code for COPD were summed for each patient. As most inhalers are given as six month supplies then a sum of more than six in a patient's history implies more than one original prescription from a prescriber was marked specifically for COPD. This was then used to estimate the potential COPD population. These pathways were all collated and the 'networkD3' R package was used to create the Sankey diagram.

Results

Analysis of drug utilisation

Overall utilisation

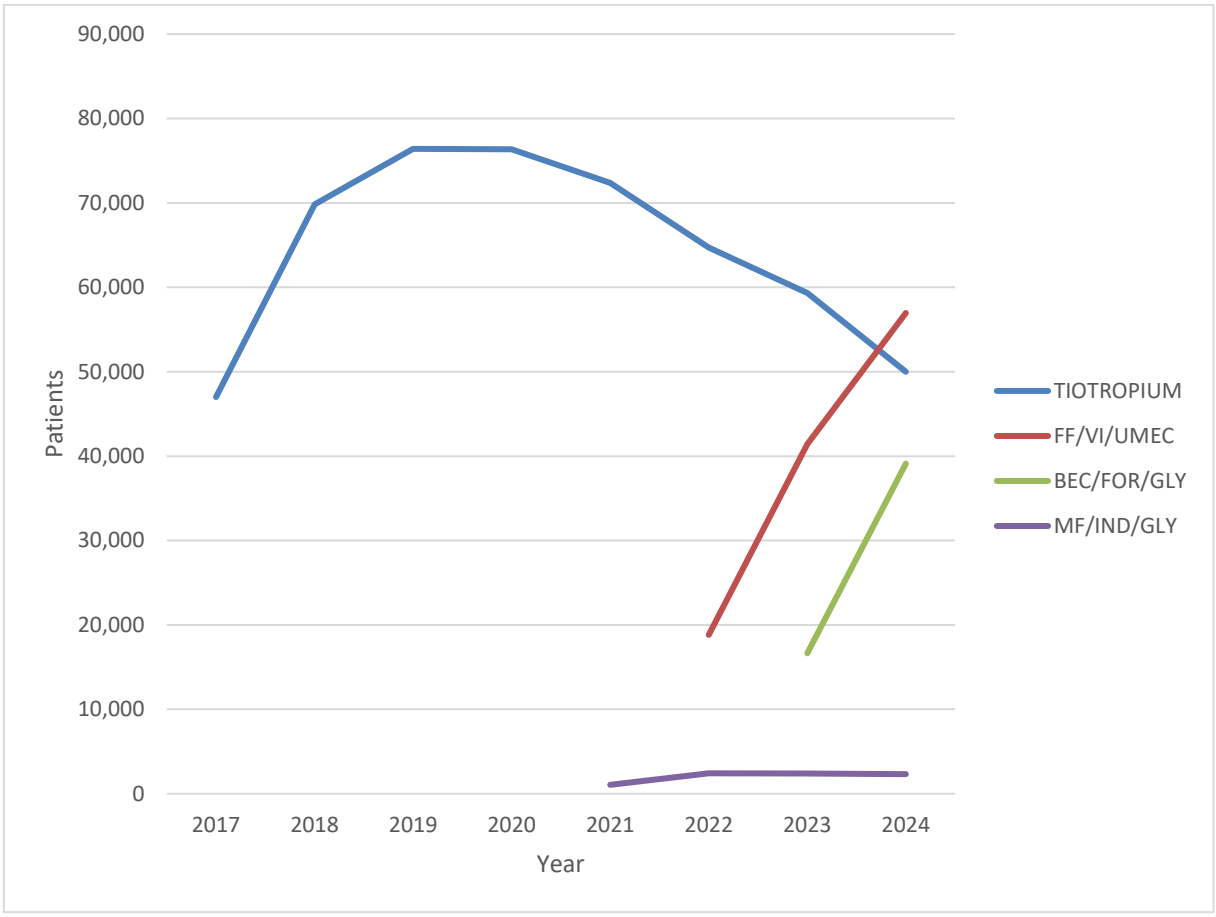

Figure 1: Number of prevalent patients utilising single inhaler triple therapies and tiotropium for severe asthma.

Tiotropium (item code 11043F) was listed on the PBS in 2017 for the treatment of severe asthma and its utilisation was used in establishing the financial estimates for all single inhaler triple therapies which were listed from 2021 onwards. Figure 1 shows that tiotropium utilisation for severe asthma peaked in 2020 prior to the listing of any single inhaler triple therapies. However the number of prevalent patients declined substantially upon the listing of FF/VI/UMEC. Both FF/VI/UMEC and BEC/FOR/GLY have increased substantially since listing reaching 56,956 and 39,104 prevalent patients in 2024 respectively, while MF/IND/GLY has maintained a number of ~2,400 per year in 2022-2024.

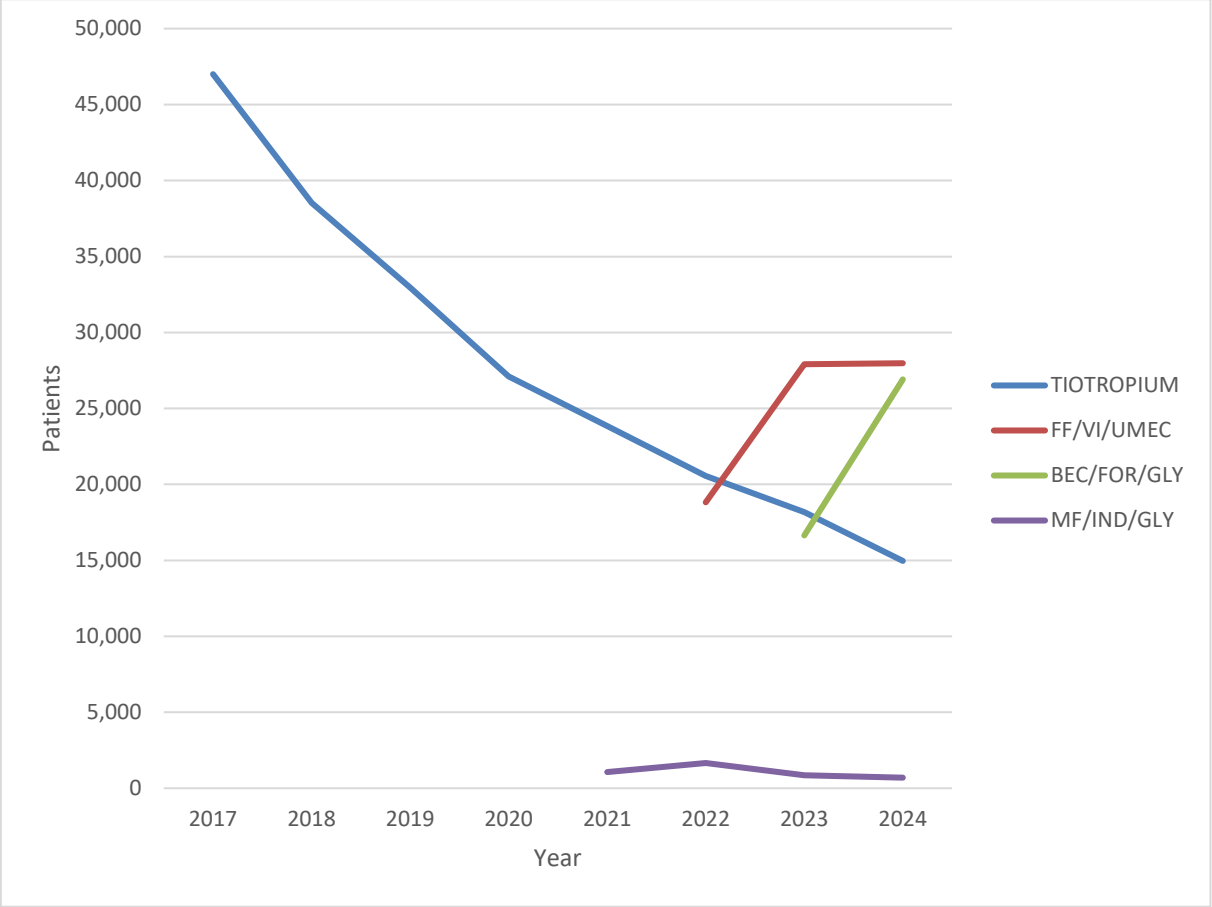

Figure 2: Number of initiating patients utilising single inhaler triple therapies and tiotropium for severe asthma.

Figure 2 shows the declining number of initiating patients on tiotropium since listing in 2017 with 14,964 new patients in 2024. The number of initiators on FF/VI/UMEC appears steady with 27,918 and 27,975 in 2023 and 2024 respectively and appears to have plateaued upon the listing of BEC/FOR/GLY in 2023 which had 26,911 new patients in 2024. MF/IND/GLY had 697 new patients in 2024.

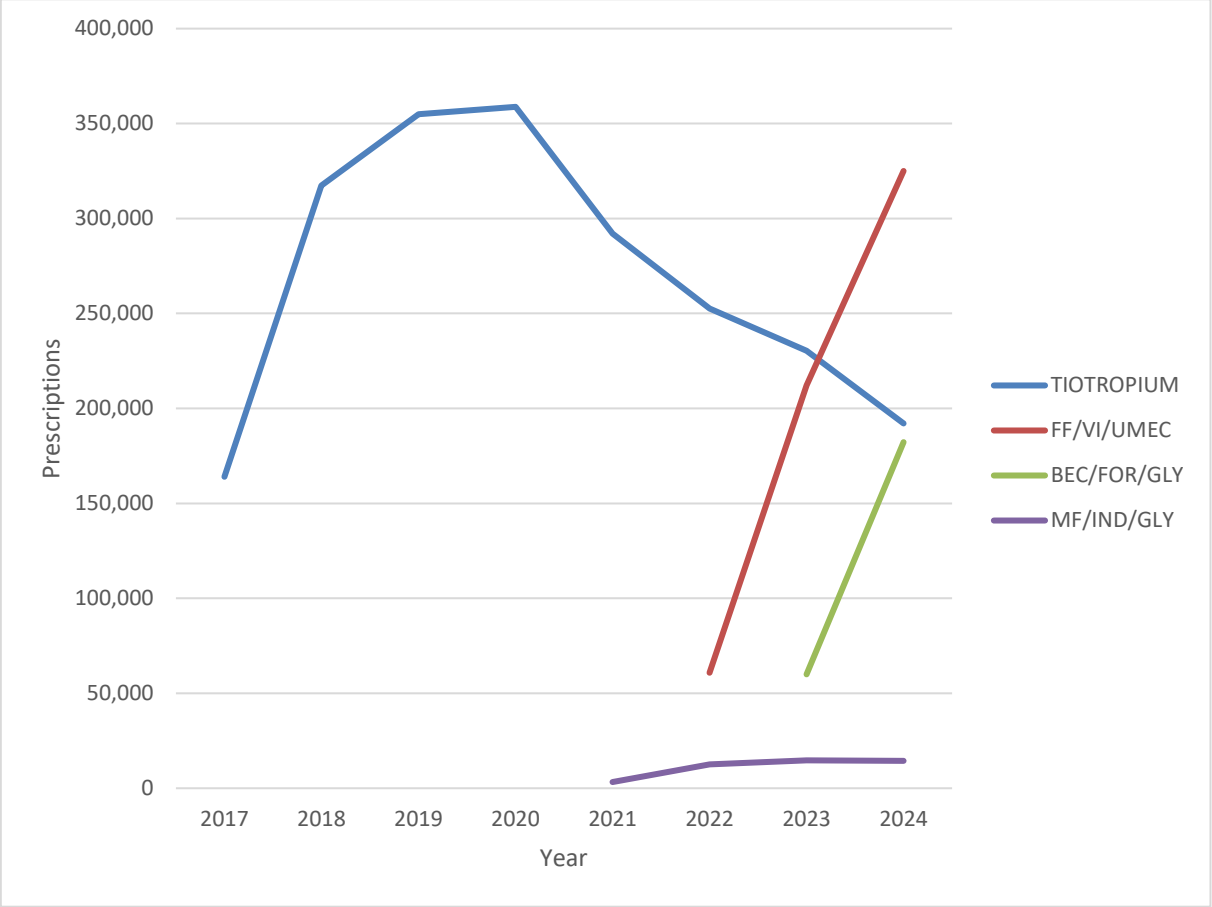

Figure 3: Number of prescriptions of single inhaler triple therapies and tiotropium for severe asthma.

Figure 3 shows the number of prescriptions of single inhaler triple therapies as well as tiotropium for severe asthma. The number of prescriptions for tiotropium has decreased steadily since the listing of the single inhaler triple therapies while the number of prescriptions for FF/VI/UMEC and BEC/FOR/GLY mirrors the trend of prevalent patients and is increasing substantially each year since listing.

Utilisation by relevant sub-populations and patient level analysis

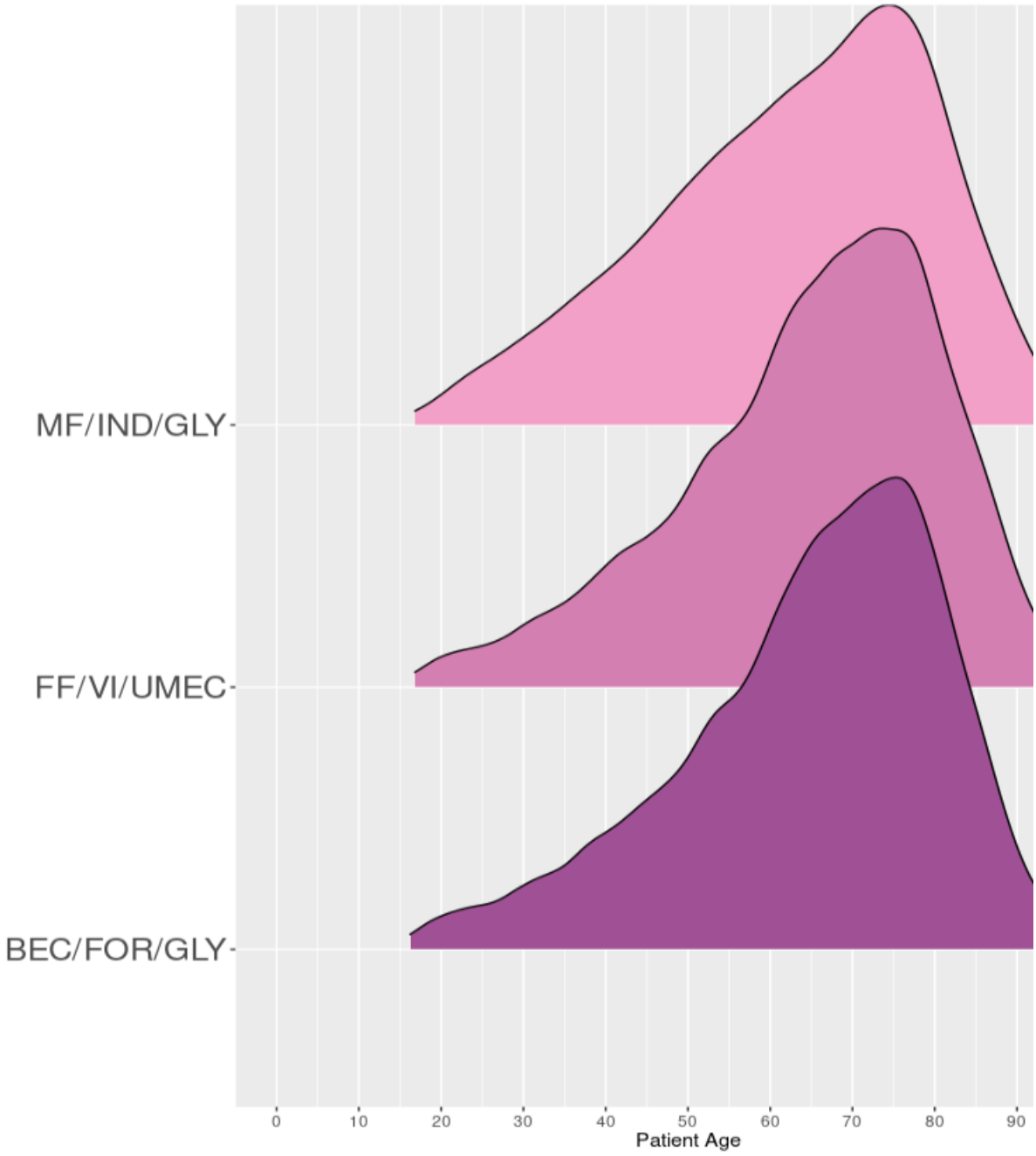

Figure 4: Age range of patients initiating on single inhaler triple therapies for severe asthma.

Figure 4 shows the initiating ages of patients starting single inhaler triple therapy. The majority of patients starting single inhaler triple therapies were aged between 60-80 years of age with a peak generally seen at 75 years of age for all three therapies. Of the ~100,00 people who have initiated a single inhaler triple therapy up to 2024, only 295 were under the age of 18 with the majority of these patients aged between 16-17. There were no significant differences in distributions when categorised based on gender.

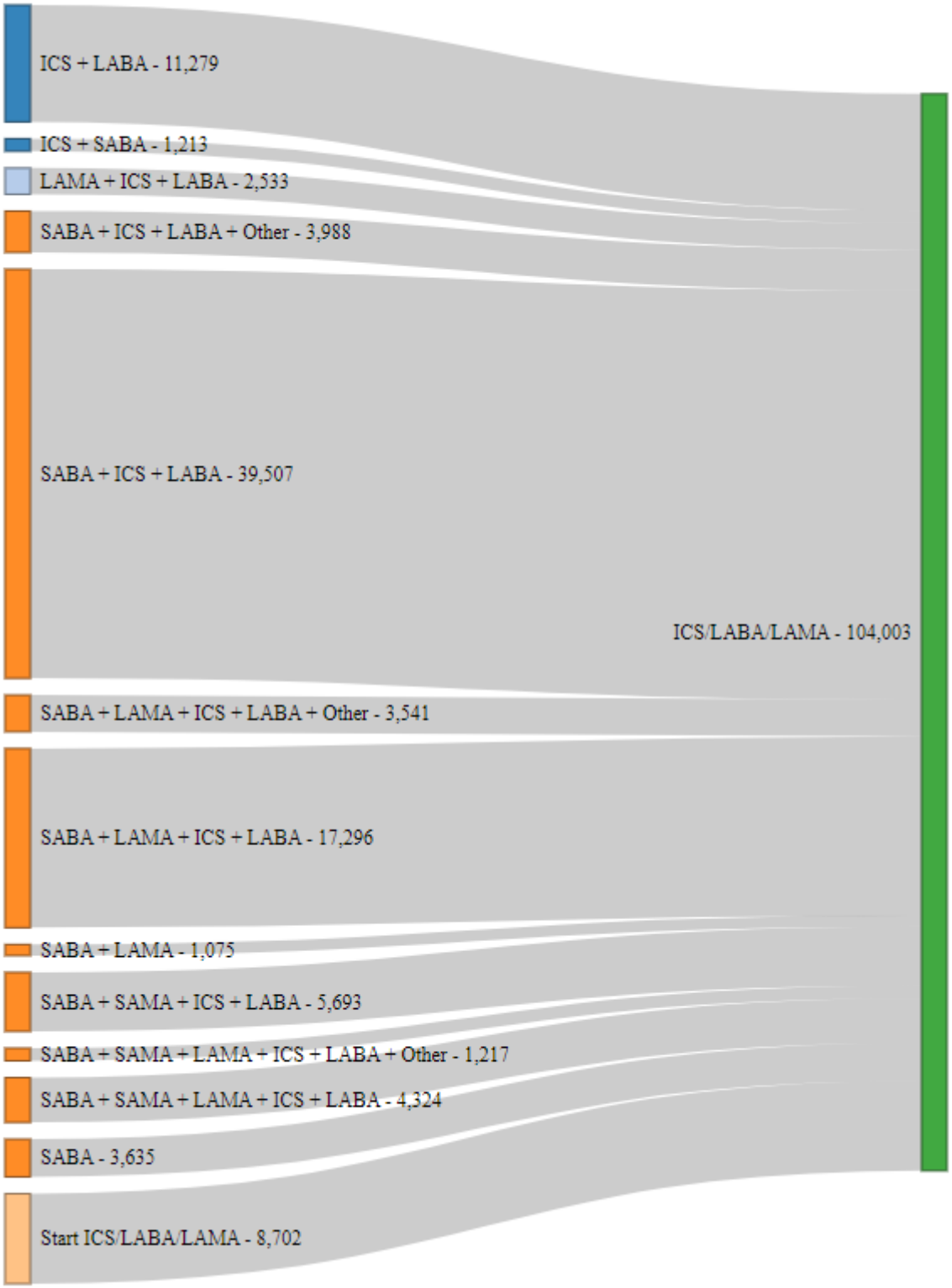

Figure 5: Previous inhaler therapies used by patients initiating on to a single inhaler triple therapy for severe asthma.

Figure 5 shows the pathway through previous inhaler therapies that patients have gone through before initiating a single inhaler triple therapy. The majority of the ~100,000 patients who have initiated single inhaler triple therapy have come from a stream which shows the utilisation of both an ICS and LABA therapy which is in line with the restrictions for severe asthma. There is a group of approximately 5,900 patients who have no PBS history of a LABA or ICS and would fall outside of the current restriction. There is also a group of 8,702 patients who have no previous history of prior therapy and have initiated straight onto triple therapy. It should be noted that pathways with less than 1,000 patients were excluded from Figure 5 to reduce clutter.

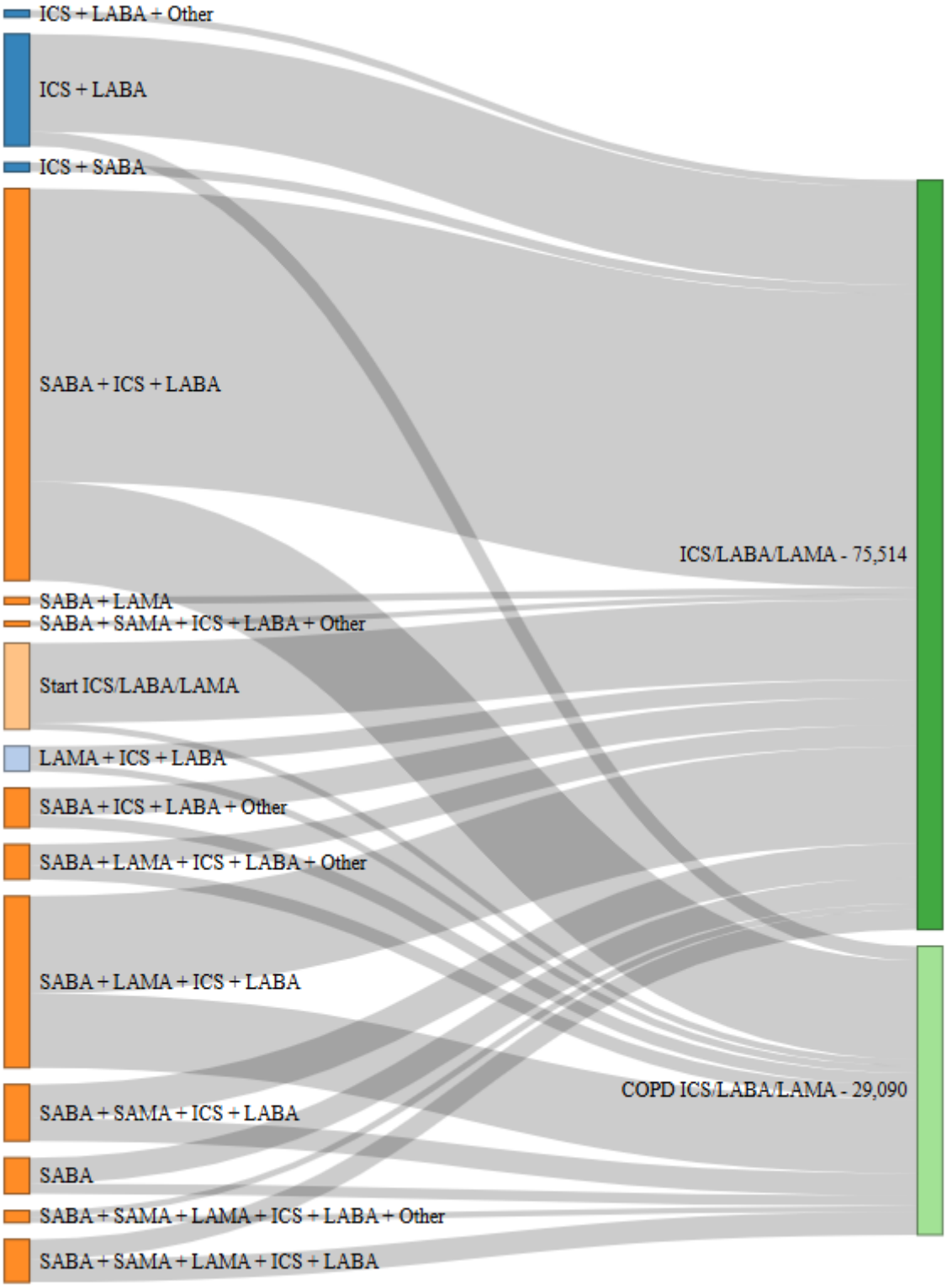

Figure 6: Previous inhaler therapies used by patients initiating on to a single inhaler triple therapy for severe asthma and including a marker for possible COPD patients.

Figure 6 is similar to Figure 5 in showing patient pathways to initiating single inhaler triple therapy, however it differs to show those patients who may have COPD rather than severe asthma. This estimate shows that 29,090 or 28% of initiators have had more than six authority prescriptions specifically using a COPD streamlined authority code in their history. It should be noted that pathways with less than 500 patients were excluded from Figure 6 and is the reason that there is a slightly higher number of patients in total compared to Figure 5.

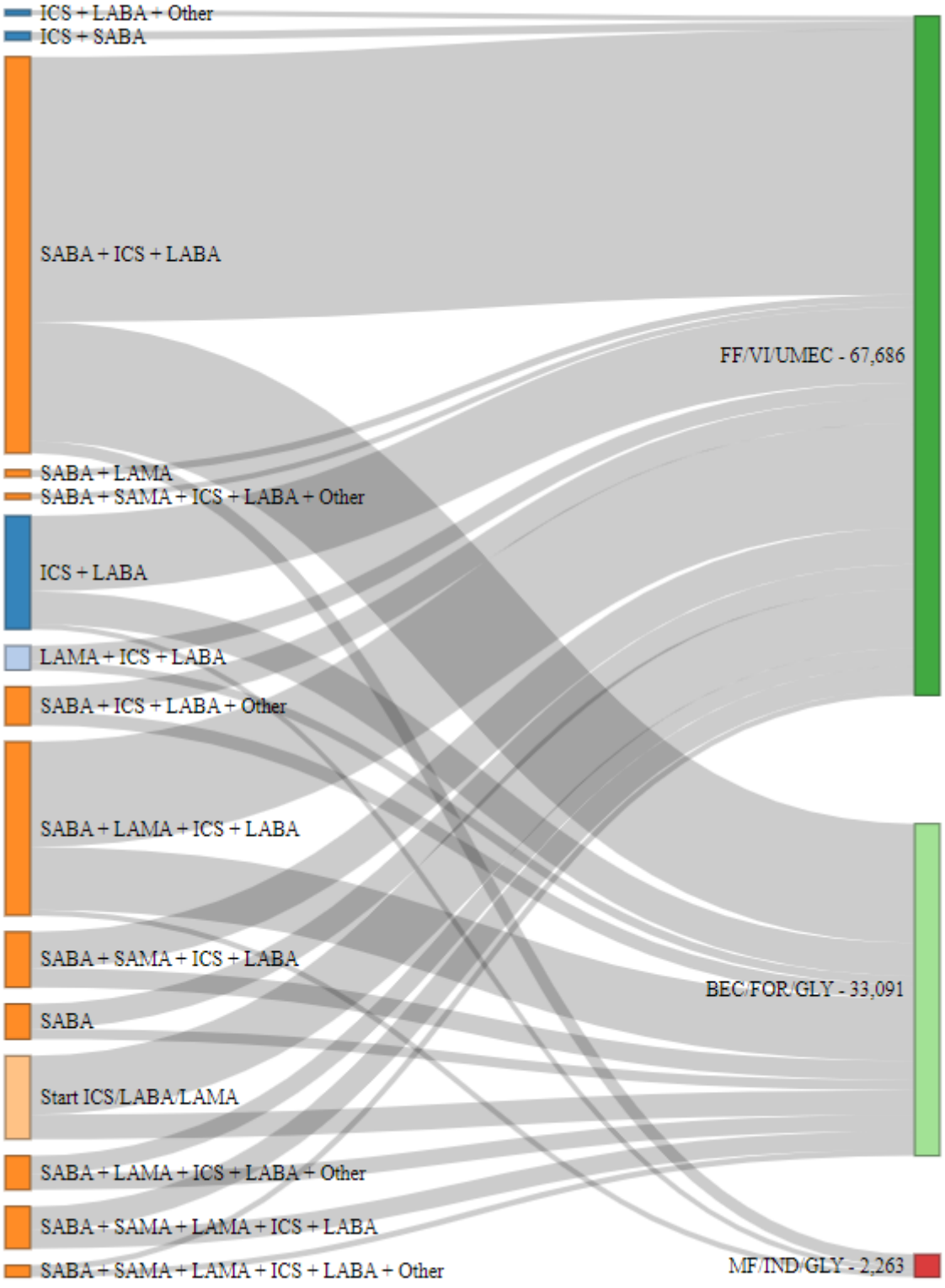

Figure 7: Previous inhaler therapies used by patients initiating on to a single inhaler triple therapy for severe asthma by single inhaler type.

Figure 7 shows the patient pathways of patients beginning single inhaler triple therapy by therapy type. The majority of patients who started straight onto an single inhaler triple therapy without any history of previous inhaler use were started on FF/VI/UMEC or BEC/FOR/GLY.

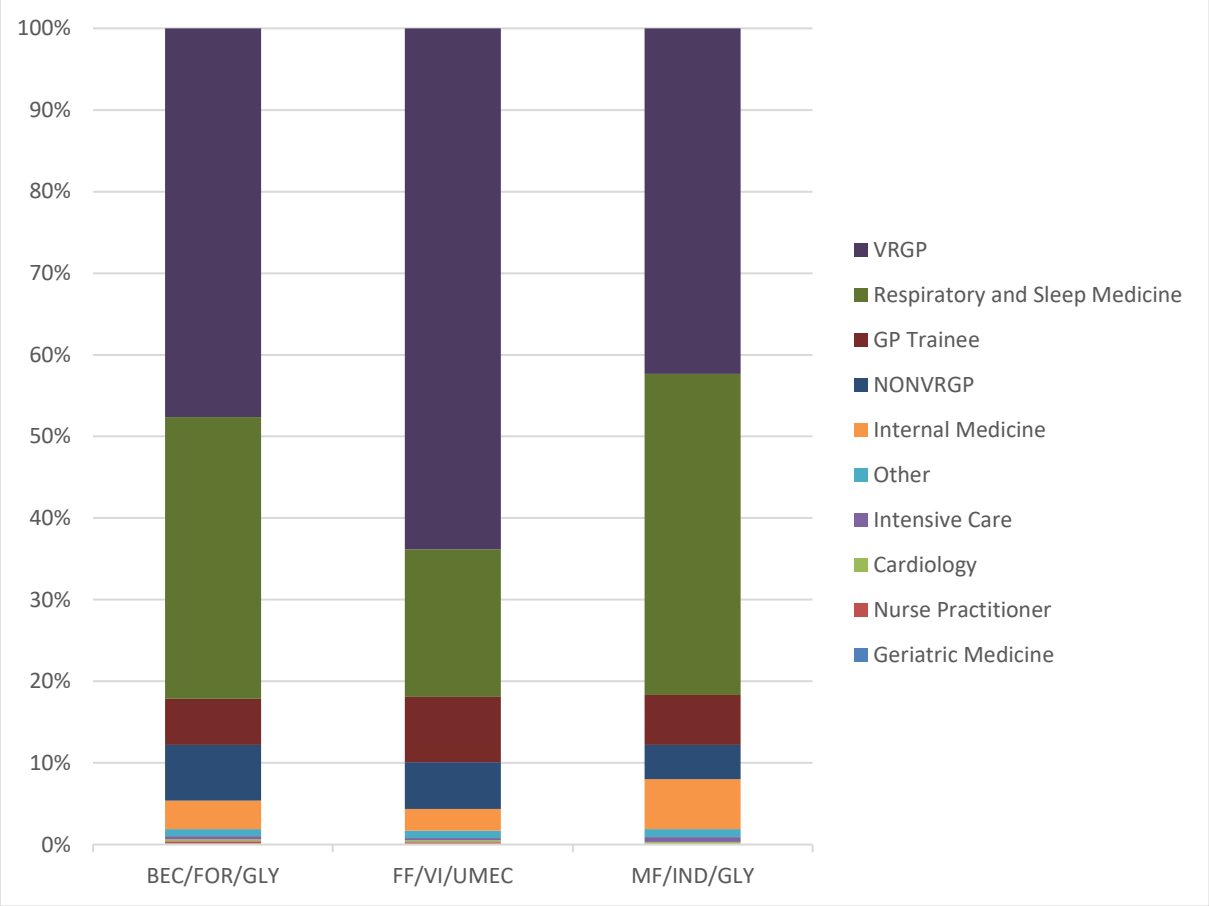

Figure 8: Prescriber type of first prescription for a single inhaler triple therapy.
Note: VRGP – Vocationally Registered General Practitioner, NONVRGP – Non-Vocationally Registered General Practitioner.

Figure 8 shows the prescriber type of the first prescription for patients starting a single inhaler triple therapy. The trend between all three medicines is similar with the primary prescribers being general practitioners (non/vocationally registered and trainees) and respiratory physicians. FF/VI/UMEC had a higher proportion of VRGPs prescribing initial prescriptions compared to the other therapies.

Analysis of expenditure

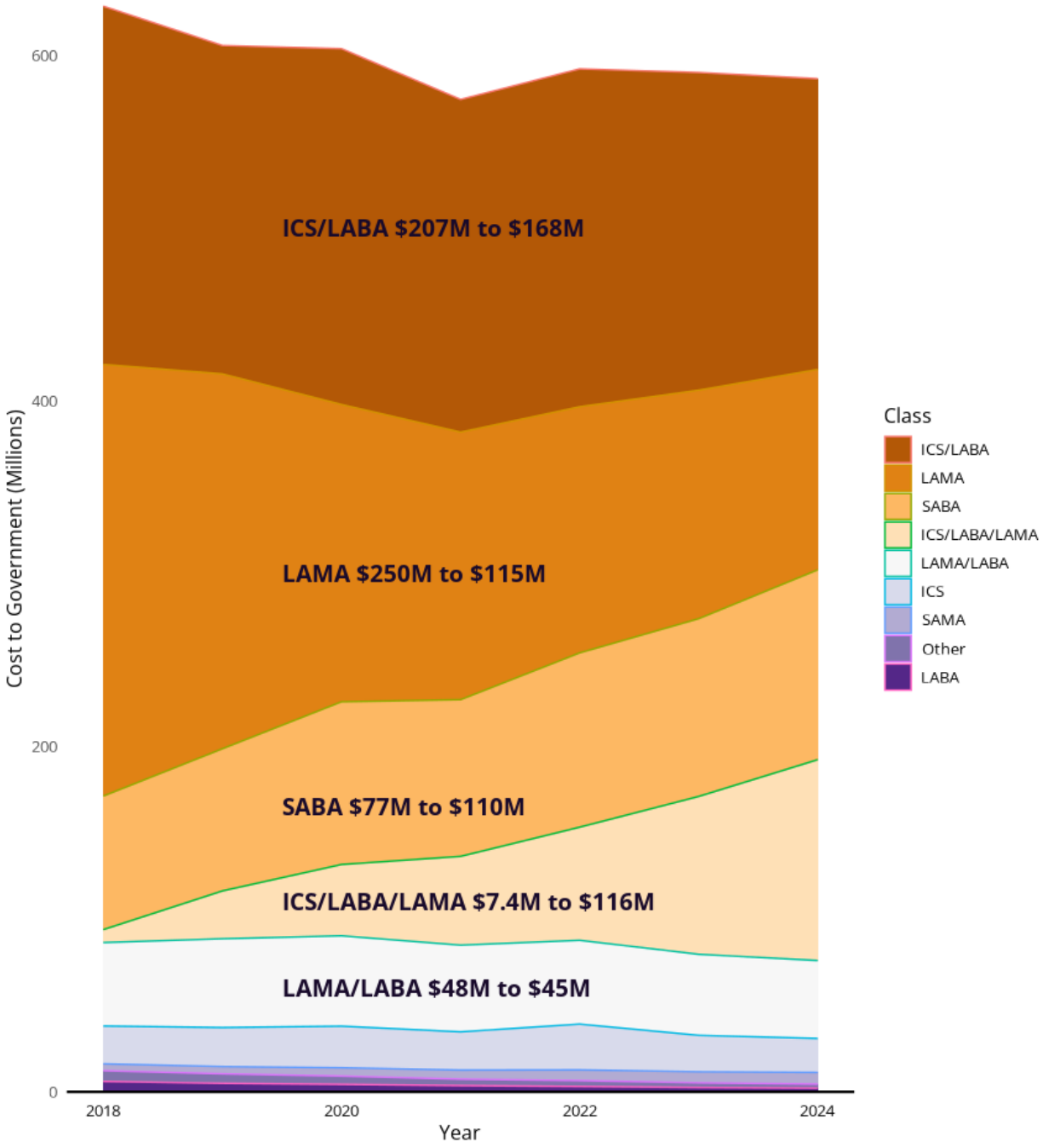

Figure 9: Cost to government for all inhaler therapies (Anatomical Therapeutic Chemical classification code R03A and R03B) excluding nebulised preparations.

Figure 9 shows that the cost to government of all inhaler therapies has remained steady over the last six years at around $600 million per year. There has been substantial changes within the different classes of medications that make up the market despite the steady overall cost to government. Over the last six years there has been a significant reduction in the costs of ICS/LABA preparations which have reduced by $6.5 million dollars per year to $168 million from $207 million. A larger reduction has been seen in the LAMA market with

a $22.5 million dollar reduction per year from $250 million to $115 million. The increase in the SABA market accounts for a small proportion of the decreases in the other markets with a $5.5 million per year growth rate while the ICS/LABA/LAMA market accounts for a larger proportion with a $18.1 million growth rate per year.

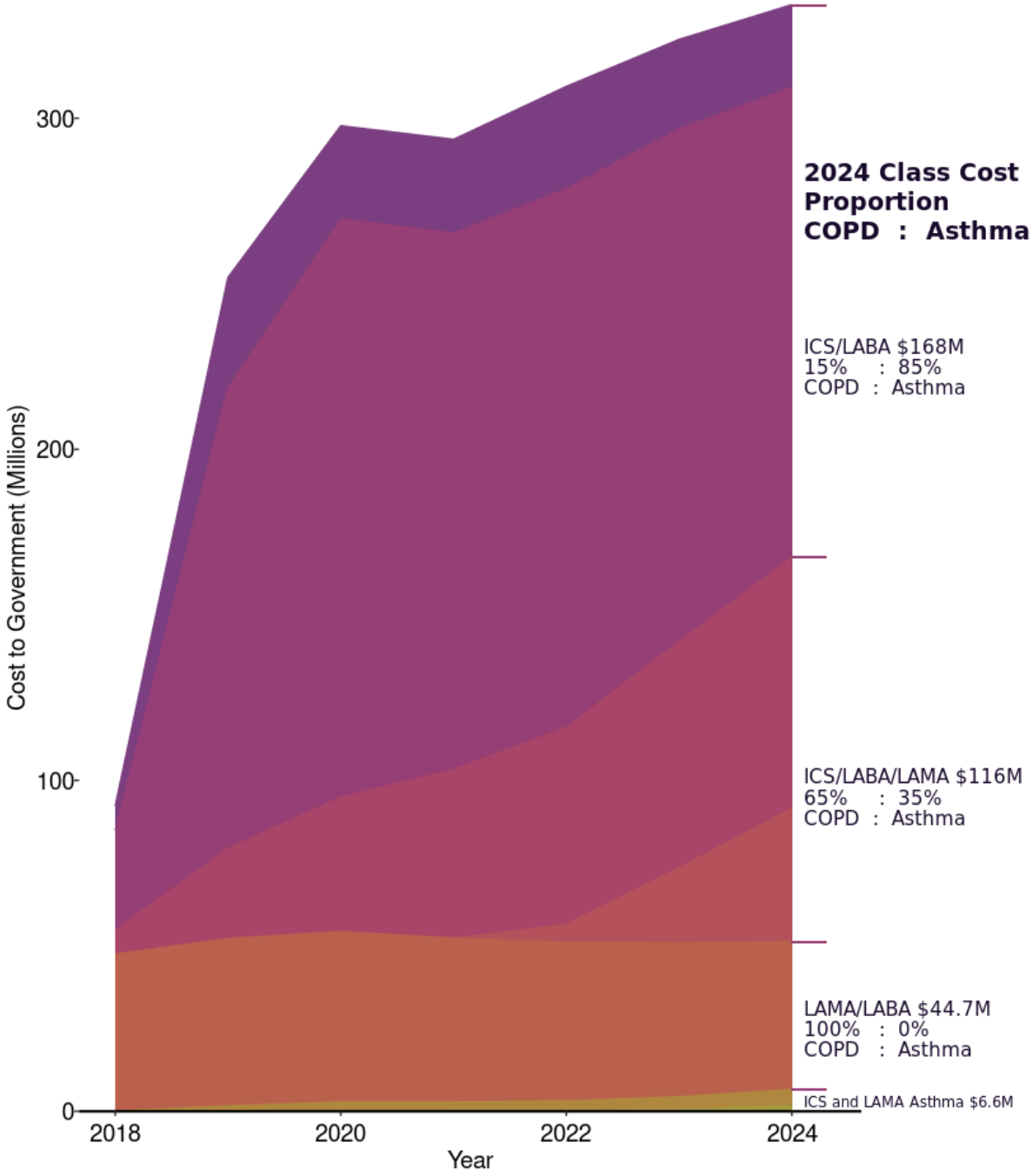

Figure 10: Cost to government for all inhaler therapies (Anatomical Therapeutic Chemical classification code R03A and R03B) excluding nebulised preparations for Authority Required (STREAMLINED) PBS restrictions. Total cost to government in 2024 are given on the right and categorised based on therapy type with each shade in a given section representing the cost estimated to be attributed to either COPD or asthma restriction codes.

Note: The data for this graph was extracted based on matching Item codes and Streamlined authority codes with prescription data, it therefore consists primarily of Authority Required (STREAMLINED) prescriptions and should be considered less accurate when compared to Figure 9.

Figure 10 shows the cost to government for all inhaler therapies (excluding nebulised medications) which are currently listed on the PBS and have an Authority Required (STREAMLINED) restriction. The proportion of the ICS/LABA market attributable to COPD prescriptions has remained steady at approximately 15% per year with $25 million in 2024 while the remaining 85% is from asthma prescriptions at $143 million in 2024. With the listing of ICS/LABA/LAMA for severe asthma the proportion of cost attributable to COPD has been reducing. In 2024 the cost attributable to COPD prescriptions was 65% of the total $116 million at $75.4 million and for asthma this was 35% of the total at $40.6 million.

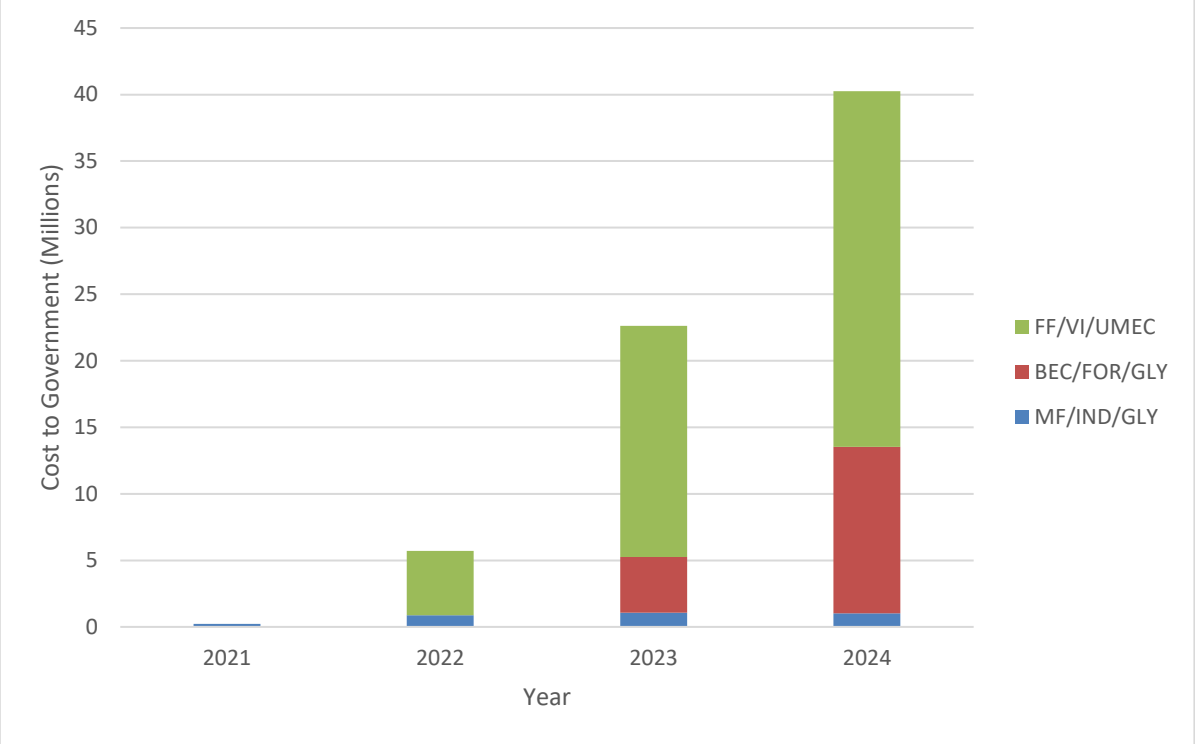

Figure 11: Cost to government for all single inhaler triple therapies for severe asthma.

Figure 11 shows the cost to government for all single inhaler triple therapies for severe asthma and shows the growth of the market from $5 million in 2022 to $40 million in 2024. The majority of the cost in 2024 is associated with FF/VI/UMEC at $26.7 million while BEC/FOR/GLY made up $12.5 million and the remaining $1 million was MF/IND/GLY.

Analysis of actual versus predicted utilisation

Table 3: Actual versus predicted utilisation and cost to the PBS/RPBS of FF/VI/UMEC for severe asthma.

		Year 1	Year 2	Year 3
		1st April 2022 to 31th March 2023	1st April 2023 to 31th March 2024	1st April 2024 to 31th March 2025*
Patients	**Actual**	24,910	45,108	53,224
Prescriptions	**Predicted**	[redacted]	[redacted]	[redacted]
	Actual	97,287	241,271	259,547
	Difference	[redacted]	[redacted]	NA
Net Cost PBS/RPBS	**Predicted**	[redacted]	[redacted]	[redacted]
	Actual	$7,701,770	$19,624,566	$21,587,385
	Difference	[redacted]	[redacted]	NA

* Year 3 contains data up to December 2024 and is not representative of a full listing year.

The first year of listing of FF/VI/UMEC resulted in 24,910 prevalent patients followed by an increase of 80% to 45,108 in year 2. In the 9 months of available data for listing year three there were 53,224 prevalent patients and is indicative of slowing growth. The submission for FF/VI/UMEC used a market share approach in estimating the financial implications and consequently there were no predicted patient values. The actual numbers of prescriptions and cost to government were [redacted] than predicted. In the first year of listing the change between actual and predicted prescriptions was an [redacted] and in year 2 of listing there was an [redacted]. The listing year to date of year 3 also suggests a similar increase in year 3. These [redacted] are mirrored in the net cost to government.

Committee-in-confidence

[redacted]

End Committee-in-confidence

Discussion and DUSC Consideration

The PBAC (July 2020) noted concerns regarding the use of single inhaler triple therapies in children and adolescents in the MF/IND/GLY submission consideration in July 2020 as well as the submission for FF/VI/UMEC. DUSC noted that use in this population was minimal with only 295 patients aged less than 18 years and the majority of them aged 16-17 years.

All three submissions for single inhaler triple therapy used market share approaches based on the number of prescriptions of tiotropium (item code 11043F). Figure 1 shows that in 2022 there were 64,704 prevalent patients on tiotropium (item code 11043F) a decrease of 11,600 from 2020. This appeared to correspond closely to the rise of single inhaler triple therapies with FF/VI/UMEC having 18,821 prevalent patients in 2022 since listing in April of that year. The number of patients using tiotropium further decreased in the years following 2022 however the increase in patient counts of FF/VI/UMEC and BEC/FOR/GLY indicated a growth in the market with counts far exceeding the decrease in tiotropium utilisation. DUSC acknowledged and agreed with the sponsor comments that current utilisation of single inhaler triple therapies are still below the estimated annual prevalence of severe asthma in Australia.

There were a substantial number of patients utilising COPD prescriptions prior to initiating on a single inhaler triple therapy. These patients can be seen in Figure 6 where 29,090 patients had evidence of more than six COPD restricted prescriptions in their PBS history. This number is likely an overestimate given that Streamlined codes can be applied to prescriptions incorrectly. However there is still strong evidence to suggest that up to 28% of patients initiated on the severe asthma restriction for single inhaler triple therapies had COPD. DUSC acknowledged responses from sponsors and consumers and noted the overlapping nature of the two diseases and considered that further investigation may be required.

The total cost to government of inhaler therapies had remained steady at approximately $600 million per year since 2018 despite the introduction of single inhaler triple therapies. This was likely due to a decrease in utilisation of the constituent medicines within the triple therapy products. The reduction in the use of these products and the subsequent rise in the use of single inhaler triple therapies restricted to severe lung diseases represented a potential quality use of medicines issue. The convenience of a single inhaler product trumping traditional step-wised approaches to treatment may be resulting in overexposure to higher concentrations of ingredients than necessary for symptom management. DUSC noted the comments from the Centre of Excellence in Severe Asthma which acknowledged concerns of potential overutilisation. The Centre of Excellence suggested a compromise that the PBAC may wish to consider altering the current restriction to ‘include evidence of impaired lung function OR persistent airflow limitation OR suboptimal response to current medication after a suitable period’. DUSC considered that these additions to the restriction may help to ensure appropriate use of single inhaler therapies while ensuring equal access for all Australians.

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

GSK is dedicated to the quality use of medicines and educating best practice in asthma management to achieve best patient outcomes. Data presented in the report only reflects trends in the number of prescriptions claimed through the PBS and is not necessarily indicative of specific treatment pathways for asthma patients. GSK remains dedicated to collaborating with stakeholders to improve patient care and health outcomes through evidence-based practices and education.

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.

To the fullest extent permitted by law, neither the Department of Health, Disability and Ageing nor any Department of Health, Disability and Ageing employee is liable for any liability, loss, claim, damage, expense, injury or personal injury (including death), whether direct or indirect (including consequential loss and loss of profits) and however incurred (including in tort), caused or contributed to by any person's use or misuse of the information available from this report or contained on any third party website referred to in this report.

References

1. *What is asthma?* (2024, March 10). Asthma Australia. https://asthma.org.au/what-is-asthma/
2. *Drugs for asthma and chronic obstructive pulmonary disease*. (n.d.). Australian Medicines Handbook. https://amhonline.amh.net.au/chapters/respiratory-drugs/drugs-asthma-chronic-obstructive-pulmonary-disease